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Special Issue

Ethnomedicine

POTENTIAL OF ETHNOMEDICINES TO BE DEVELOPED AS NUTRACEUTICALS ... 13

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From the Editor's Desk...

There is the need for scientific evidence - based validation of bioactivity and use of the ethno- and folk medicines, so as to inspire greater confidence in the healthcare scientists and facilitate development of these herbs that have been in use since ages, as safe and efficacious medicines, in compliance with all regulatory specifications and guidelines.

Dear Readers,

With travel restrictions being eased the world over, the European Union's digital COVID certificate programme has been in the midst of some controversy. The Digital certificate programme or EU's 'Green Pass', as its known colloquially has been created to restore freedom of travel for the public and remove the barriers on entry placed due to the pandemic, and is a digital proof that a person has either been vaccinated against Covid-19, or received a negative test result, or recovered from the viral infection.Thus, while the AstraZeneca vaccine produced and authorized in Europe (Vaxzervria) is included in the list of vaccines recognized by the EU 'Green Pass', the same formation of the vaccine (Covishield) produced under license by the Serum Institute of India (SII), is excluded. The EU move is expected to elicit world-wide outcry since many Low & Middle Income Countries (LMIC) including India, China and Russia have used vaccines that haven't received EMA authorisation and so not recognized by the 'Green Pass' though these vaccines have been part of the WHO – led COVAX facility and being supplied to nations as part of the initiative to ensure equitable access to COVID-19 vaccines. Though Covishield is being granted approval by individual EU countries, its inclusion in the 'Green Pass' list, is still to come!

We are here with the much – awaited special on ***Ethnopharmacology.*** The pandemic has once again brought to the fore, the tremendous but as yet untapped potential that ethno- and folk medicines present. In situations like the present pandemic, when health care scientists are stumped as to what could be effective prophylactic & / or therapeutic options for the raging infection, the general public as well as medicos have shown increasing propensity to bank on traditional and folk medicines as 'add-ons' to the prescribed treatment. A case in point being, the phytopharmaceutical AQCH that is being developed by Sun Pharma as an anti-dengue agent but was later granted approval by DCGI for clinical trials, as potential treatment of COVID-19, based on promising preliminary *in vitro* efficacy studies. AQCH incidentally, is a phytopharmaceutical, is derived from tropical, climbing shrub *Cocculushirsutus,* which is extensively used in Asia in various traditional systems of medicine, for a wide range of medicinal uses, including as diuretic, laxative, skin diseases and urinary disorders. There is the need for scientific evidence - based validation of bioactivity and use of the ethno- and folk medicines, so as to inspire greater confidence in the healthcare scientists and facilitate development of these herbs that have been in use since ages, as safe and efficacious medicines, in compliance with all regulatory specifications and guidelines. All of this and more, is discussed by experts in this special issue and we are certain you will find the issue very interesting and informative. I place on record our gratitude to Prof. Pulok Mukherjee, Director, Institute of Bioresources and Sustainable Development (IBSD), Imphal and Secretary of the Society for Ethnopharmacology, India (SFE-India) and President, International Society for Ethnopharmacology (ISE), Switzerland, for officiating as Guest Editor for the special. I also take this opportunity to thank Dr. Santanu Bhadra, for all his support during the making of the issue.

Alka Mukne

Editorial Calendar for 2021 - 22

Theme Based Special Issues	Month & Year
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Our Mission

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of Pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and other on vital professional issues and support pharmaceuticals education and sciences in all aspects.

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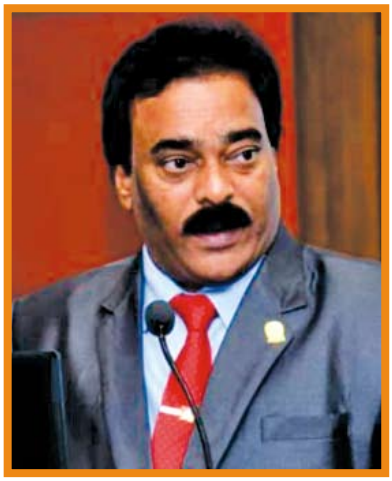
President Speak...



It is imperative to bring science, practice and workforce & education together into one transformative framework and wider profession to clearly set out the goals for development for the next decade.

Dear IPA Members,

The second wave of COVID gave the biggest impact with its fast spread and increase in mortality compared with the earlier wave. Public health precautions for containing person-to-person transmission are relevant, essential and valuable before, besides and beyond vaccines. Wearing masks and avoiding crowds are the mantras of personal protection that have to stay with us for several months more. In urban India, vaccine hesitancy noted since January 2021 was replaced by vaccine urgency in April and vaccine anxiety in May. Non-availability of vaccines to several vaccination centres led to their temporary closures. The opening up of vaccination to the entire adult population above 18 years led to a further mismatch between demand and supply. Smaller towns and villages are yet to display a swelling demand, due to both vaccine hesitancy and the barriers posed by the technology gateway mandated for registration. We, being health care professionals need to educate the people about Covid vaccination and have to clarify myths and facts in the public mind. WHO mentions that the vaccine would not cause positive test results for PCR or Antigen tests. This is because the tests check for active diseases and not whether the individual is immune or not. If a person takes a vaccine in the incubation period of Covid disease, the test may become positive after some days because of the disease and not because of the vaccine. Also, if by any chance, the person had got the virus during the vaccination process or just right after it, they might test positive. Few people may experience side effects like headache, mild fever, body aches, pain or swelling, or redness at the site of injection of the vaccine. These symptoms subside in a day or two and may need analgesics like paracetamol. On the other hand, symptoms of Covid progress slowly over a period of 5-6 days. Cough, nasal discharge, throat pain, loss of taste or smell, fever, general weakness, and later, in some cases, breathing difficulty, depending on the severity of the disease.

On behalf of IPA, a member organisation of FIP, I welcome the move of FIP launching the Development Goals (21 FIP Development Goals), set to transform global pharmacy working in partnership and collaboration with its members and member organisations. It is imperative to bring science, practice and workforce & education together into one transformative framework and wider profession to clearly set out the goals for development for the next decade. The FIP Development Goals are a key resource for transforming the pharmacy profession over the next decade globally, regionally and nationally. Each of the FIP DGs is composed of 3 Elements for Practice, Science and Workforce that all form fundamental categories of the Goals. Alongside each Element is a set of mechanisms which form tools and structures to facilitate and support the process of transformation. FIP has launched the 21 development goals and requested the member organisations to identify three suitable goals to work together.IPA has identified three top priority goals and working for the road map with FIP. I am of the opinion that IPA should gather Pharmacy intelligence data about the actual deployment of registered pharmacists in India. It was proposed to collect information in selected regions with the help of IPA State and Local branches, Institutions and Placement cells about the employment details of recent graduates and post graduates. How many are employed in practice-related jobs and how many in teaching, how many in industry-related services and how many are continuing further studies and how many of them are actually registered with pharmacy councils.. This information collected can be collated so that the basic information gathered shows recognizable patterns that can be used to generate information about what is required and what is actually available. I believe this is one way to generate reliable pharmacy intelligence, which is basically lacking from India.

The IPA Annual Convention 2021 was held during 16-17, July 2021 by virtual mode and IPA Anantpur local branch in Andhra Pradesh organised the event. It was one of the biggest online events in recent times of any professional organisation.

The construction of long awaited IPA building has been completed and interior work is going on. If everything goes well, the inauguration of the IPA Building will be done during the last week of August 2021. I extend my deep sense of gratitude to Pharma institutions, Pharma industries for their voluntary contribution and sponsorship. My sincere appeal to all the IPA members, IPA state and local branches, donors to come forward and contribute towards the fixtures and furniture of the IPA office and building.

Dr. T. V. Narayana

GUEST EDITORIAL

Prof. Pulok K Mukherjee, FRSC, FNAAS, FNASc
Director, IBSD, Imphal

Ethnopharmacology is a multidisciplinary field investigating the anthropological rationale and the pharmacological basis of the medicinal use of natural products derived from plants, animals, fungi, microorganisms, and minerals through different cultures. “Ethnomedicine” is the important branch of natural science and its potential as alternative medicine. This system has evolved by several indigenous people on the basis of their religious beliefs and practices to manage their health. Medicinal plants are used in diverse traditional systems of Medicine. Evidence based validation of the ethnopharmacological claims on traditional medicine is the need of the hour for its globalization and promotion. The integration of hyphenated analytical techniques is required for addressing quality related safety aspects to develop safe and efficacious products from medicinal plants. The development of ethno-medicine and ethno-pharmacology with the integration of multidisciplinary research approach will definitely help to extend the use of traditional medicine derived from plant origin globally with proper evidence based validation. The systematic data mining of the existing effective traditional formulations with robust scientific evidence should be developed as a standardized, synergistic, safe and more economical alternatives, which can certainly help the drug discovery processes to identify safe candidates and healthcare through natural resources.

This special issue is developed through the initiatives of the Society for Ethnopharmacology, India, (SFE-India), affiliated to the International Society for Ethnopharmacology. With great inspiration for Dr. APJ Abdul Kalam, Respected Former President of India, the Society for Ethnopharmacology, India (SFE – India) was constituted in 2013 by the eminent academicians, researchers, industrialists with the vision of providing an environment for knowledge sharing among researchers, healthcare-practitioners and decision-makers interested in promotion of Ethnopharmacology and medicinal plant. The society serves as a bridge between the academic and industry together scientific and academic professional in Ethnopharmacology and also other professionals interested in the area for developing cost effective natural remedies as well as herbal product. Every year the society organizes International conferences and national convention for discussion and sharing knowledge on different issues on cultivation, production, quality evaluation, safety, clinical studies, biological screening and several other issues of natural product research. For further details please visit www.ethnopharmacology.in.

This special issue highlights on several crucial and contemporary aspects on Ethnomedicine, traditional Indian system of medicine and Ethnopharmacology. We express our special gratitude to all the authors for their valuable contribution and to the reviewers for their esteemed support for this issue. We would like to express our special gratitude to Dr. AlkaMukne, Editor, Pharma Times and Coordinator SFE India Mumbai Chapter and Dr. SantanuBhadraSFE for taking the lead in publishing this special issue.

We are thankful to Mr. Birendra Kumar Sarkar, President; Mr. Indraneel Das, Vice-president; Dr. C K Katiyar, Vice-president, Dr. S. C. Mandal, executive secretary and all other executive committee members of the Society for Ethnopharmacology, India, and all the contributors for their time and support. Special thanks extended to all the coordinators of Local chapters of SFE-India for their cooperation and support for the dissemination of Knowledge for the development of Ethnopharmacology and medicinal plant research at large. The Society for Ethnopharmacology, India (SFE-India) even though so young has made several outreach activities for the development of different aspects on promotion of traditional knowledge for their validation and evaluation in all context, for a healthier tomorrow, capitalizing the very rich heritage and cultural resources, which is so ethnic, so ancient and so Indian.

METABOLOMICS IN STANDARDIZATION AND AUTHENTICATION OF ETHNOMEDICINES

Sayeed Ahmad
Bioactive Natural Product Laboratory, Department of Pharmacognosy and Phytochemistry, School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi

Abstract

Metabolomics is one of the powerful tools for quality based assessment, standardization or even authentication of natural products derived medicine or herbal formulation. Due to increasing commercial utility and mesh-up of natural medicine with the spurious/ adulterated drugs, particularly with those belonging to the same species, consideration of authenticity is being more concerned to validate the ethnomedicine, based on their quality, safety and efficacy for their regulatory prospectus. As we are aware of the complexity of phytoconstituents, quality based standardization and authentication of ethnomedicine is still a challenging endeavor for the researcher to generate scientific data in this prospectus. Modern analytical techniques such as LC-MS, GC-MS and NMR are the most specific techniques to validate the ethnomedicine concerning their standardization and authenticity by evaluating the multiplicity of phytochemicals in the form of metabolomes. Quality and quantity based evaluation of phytochemicals not only formalized us with the comparative and correlative evaluation but also robust the validation symmetry in the authentication of ethnomedicine. Although due to the large symmetry of phytochemicals among different variables, multivariate statistical analysis summarizes a large number of variables in the form of a single principal component which makes it easy in comprehensive data evaluation. In this review, an attempt has been made to point out the metabolomic approach and summarize previous studies conducted with the consideration of quality based standardization and authentication of ethnomedicine or formulations.

Keywords: Ethnomedicine, metabolomics, standardization, authentication

Introduction

Ethnomedicines have a long history and are still being used as primary health care especially in indigenous population. It is gaining more acceptance all over the world for improving human health[1]. Ethnopharmacology is an interdisciplinary science which combines pharmacognosy and pharmacology to investigate biologically active materials that have been used to improve human health in the past. It employs field observations, utilization and therapeutic efficacy of folklore medicines, together with the authentication of the material as well as phytochemical and pharmacological research[2]. The development of current therapeutic systems relies heavily on ethnopharmacology-inspired drug discovery from natural sources. Majority of drugs originating from natural sources have been found to have broad ethnomedical use[3].

Ethnomedicines' safety and efficacy data are insufficient to meet the requirements to support their usage globally. The reason behind its lack of research facts is due to a lack of suitable or accepted method for standardizing ethnomedicines, as well as a lack of suitable or acceptable health care practices[4].

Within the 'omics' science, metabolomics is a new and rapidly emerging field which is a powerful technique that directly represents the fundamental biochemical activity and state of cells/tissues, unlike other omics[5]. It is the study of metabolites present in cells, tissues and biofluids or in organisms under a given set of conditions. Qualitative and quantitative analysis of metabolic products is known as the metabolome of a biological system at a definite point in time. Metabolites are the end product of interaction of either genomic and/or proteomic systems within or outside its environment. It has its own origin in the profiling of metabolites and is now fast growing in the area of scientific research[6]. For quality evaluation of natural products, metabolomics employs low-molecular-weight compounds with the goal of correlating phenotypic and genotypic differences in biological systems. The chemically diverse metabolites found in natural products are the potential source for development of the leads to treat and manage a variety of diseases[7].

With the high throughput comprehensive identification technique, metabolomics has emerged as a very effective hyphenated technique in profiling of targeted and untargeted metabolites for scientific validation and development of ethnomedicines. One of the difficulties with natural product based drug development is the possibility of redundancy, or working on multiple samples with the same active metabolites. Various 'dereplication' processes have been implemented to address this issue. The combination of a metabolomic approach and appropriate bio-statistical method has the potential to provide quick analysis of

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Dr Sayeed Ahmad, (Associate Professor) Department of Pharmacognosy and Phytochemistry, School of Pharmaceutical Education and Research, Jamia Hamdard, New Delhi, has been associated in teaching and research in the field of herbal drugs and natural products, since 2005 after completion of his Doctorate in Pharmacognosy and Phytochemistry. He did his postdoc from Albert Einstien College of Medicine New York, USA and also worked as visiting scientist in many countries. He has been honoured with many awards such as CST-UP young scientist award (2008-09), DST BOYSCAST (2009-10), AICTE Career award (2009-10) as well as UGC research award 2016 and SFE Young Ethnopharmacologist Award 2017, SFE Special Recognition award 2020, in addition to many best publication awards. He has to his credit >300 publications in several peer-reviewed refereed journals (Total Impact factor >600, h-index 34, i10 index 100, Citations >4300) and also authored books in Pharmacognosy. Dr Ahmad has delivered >60 invited talks and chaired many scientific sessions at different forums on herbal drugs and chromatography. He has instituted above a dozen of MOUs including NCNPR, USA and University of Khartoum Sudan and many Industries. He has supervised 30 M Pharm and 27 PhD scholars-

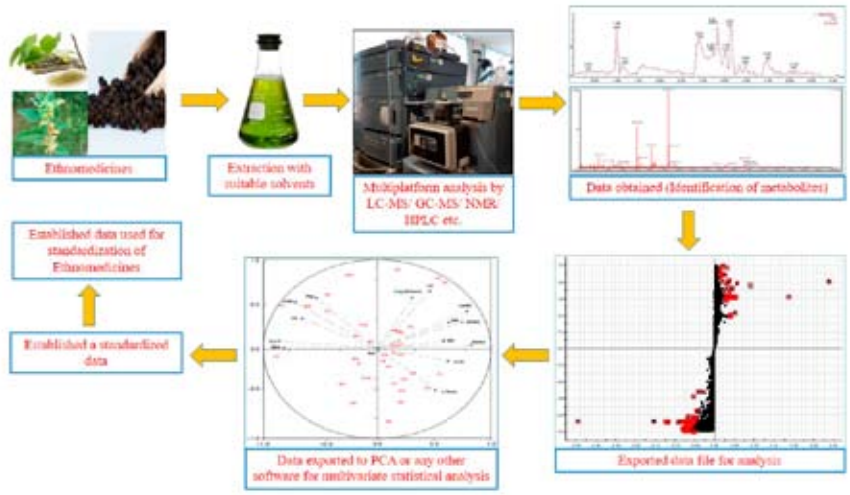

Figure 1: *Strategy for the Standardization of Ethno-medicinally used Natural Products.*

composite data produced from high throughput screening. Strategy for the standardization of ethno-medicinally used natural products has been presented in Figure 1.

Metabolomics in standardization of crude drugs of ethnomedicines

Ethnomedicines, particularly, have been employed for a variety of therapeutic purposes. Earlier, quality was measured as per traditional method which has been mentioned in different pharmacopoeias and traditional textbooks[8]. Quality of the formulation or materials was evaluated by microscopic/macroscopic characters, physical characters (extractive values, ash values) and sensory evaluation of primary and secondary metabolites by qualitative or quantitative analysis through TLC in various systems of medicine such as traditional Chinese medicine (TCM), Ayurveda, Unani, Siddha and traditional Japanese medicine (TJM)[9]. These traditional procedures do not correlate to modern medicine. In modern medicine, active pharmaceutical ingredients (API) are defined, but in ethnomedicines, there are no such ingredients because, if we consider a single material to include many compounds, a polyherbal formulation must have dozens to hundreds of distinct compounds[10]. Thus, it is not possible to evaluate the quality by checking only one or few compounds. Metabolomics has emerged as a representation for quality control analysis in the last few decades to meet an unmet demand. Metabolomics, both targeted and untargeted, are required. Variations may be due to a variety of reasons, including distinct species, geographical variances, collection time and adulterants in case of plant materials. As a result, establishing suitable quality control parameters is extremely challenging. We can improve the quality analysis of ethnomedicines using the metabolomics platform. High throughput screening, such as HPLC, LC-MS, HPTLC and GC-MS, is currently being used for quality control evaluation[11].

Since the natural product-derived medications typically consisted of compounds, one or two markers would not be sufficient to contribute to a good quality of medication. To avoid the development of inferior and adulterated natural product-derived drugs, quality control comprising the evaluation of various compounds utilizing metabolic profile has become increasingly popular. Using advanced analytical techniques (such as HPLC, LCMS, GCMS and NMR) and multivariate statistical analysis, the metabolic profiling information can then be applied to the quality assessment of various kinds of natural products and the prediction of various bio-activities of those compounds such as anti-oxidative, anti-cancer, nephroprotective, hepatoprotective and anti-inflammatory etc, can be made[12].

To maintain effective quality control of ethnomedicines, a consistent technique for metabolic profiling and fingerprinting must be established in order to explore promising therapeutic leads for the pharmaceutical sector[13]. It goes without saying that combining ethnopharmacology with modern metabolomics research will open up a world of possibilities for standardization and replication of multi-component extracts and formulations for the validation of ethnomedicines at large scale. The lack of a suitably validated analytical method for standardization of complicated chromatograms containing various metabolites present in natural products is a major limitation of assessment[14].

In a recent study by Zahiruddin et al. (2017) to perform targeted and untargeted metabolic profiling of Iridoid rich fraction (IRF) of *Picrorhiza kurroa* by UPLC-MS, comparing m/z values, literature survey and validating with a publicly available database, the mass spectrum of each metabolite separated by UPLC-MS was tentatively determined. IRF's chromatograms from UPLC-MS showed that 26 metabolites were identified. The findings of the study suggest the basic metabolic profiling of IRF of *P. kurroa*[15]. Another study by Li et al. (2013) developed a quality standard based on 'seven markers' that qualified the majority of samples. A panel of critical constituents or markers in the TCM product was relatively consistent within a statistically acceptable range, according to the proposed strategy. As a result, the metabolomics-based methodology will complement the quality control standard, which is based on the concentration of various important constituents or their overall content, and will help in improving herbal products consistency and clinical efficacy[16]. Singh et al., validated the standardization parameter for crude seeds of *Amomum subulatum* by analyzing alpinetin as a main flavonoid constituent through HPLC and HPTLC methods[17]. In the studies conducted by Kamal et al., validated Habb-e-Khardal and Qurs-e-Hummaz (Unani tablet) based on the main ingredients as piperine, guggulsterones E and Z and berberine using HPLC method and set the quality parameter for the these formulation concerning to authenticity[18,19]. Arjuna is the Ayurvedic formulation vigorously used in cardioprotection. A study conducted for development and validation of a stability-indicating HPTLC method for analysis of arjunolic acid in arjuna tablets which validated standardization and quality control aspects for the formulations which contain arjunolic acid or arjuna as an ingredient[20]. Metabolic profiling of some targeted and untargeted metabolites of ethno-medicinally used natural products have been listed in Table 1.

Metabolomics in the standardization and authentication of ethnomedicine and formulations

The authenticity of ethnomedicine is one of the critical needs for ensuring quality, safety and efficacy to their regulatory aspects, even evading the drug of choices especially from those with multiple botanical origins[21]. In this context, pharmacopeia monographs represent several tests and acceptance criteria

Table 1: Metabolic profiling of some Ethno-medicinally used Natural Products.

Materials/ Natural Products/ Formulation	Part	Technique	Chromatographic condition	Major identified compounds/ No of compounds	Reference
Carica papaya Linn.	Seeds	GC-MS	HP-5MS column, split mode with ratio of 5:1, helium was used as a carrier gas with a constant flow of 1.5 mL/min.	23	[39]
Picrorhiza kurroa Royle ex. Benth	Rhizomes	UPLC-MS	Water's ACQUITY UPLC(R) BEH C18, 1.7 µm, 2.1 x 100 mm), with the pre-column split ratio 1:5. Acetonitrile and water in gradients elution mode	Picroside I, Picroside II and Apocynin/ 26	[15]
Pancharishta	-	GCMS	HP-5MS column, split mode with ratio of 5:1, helium was used as a carrier gas with a constant flow of 2.0 mL/min	144	[38]
Carica papaya Linn.	Leaves	UPLC-MS	Water's ACQUITY UPLC ™ BEH C18 (100.0 × 2.1 mm ×1.7 µm) column, 0.5% formic acid (A) and acetonitrile (B) in gradients elution mode	Carpaine, p-Coumaric acid, Vanillic acid, Carpamic acid, Kaempferol, Ferulic acid and Quercetin	[40]
Musa paradisiac Linn.	Fruit pulp	GC-MS	DB - 5MS capillary column (30 m × 0.25 mm × 0.25 µm, split mode with ratio of 5:1, helium was used as a carrier gas with a constant flow of 1.0 mL/min.	56	[41]
Camellia sinensis Linn.	Leaves	NMR	Spectra were recorded at 27°C with a 400 MHz JEOL GX spectrometer, Methanol-d4 was used as the internal lock, recycle delay of 2 s per scan and pulse angle was 50°.	Theanine, L quinic acid, L theogallin and caffeine	[42]
Hyphaene thebaica (L.) Mart.	Fruits	HPLC	The analytical column C18 (250 × 4.6 µm × 5 µm) with a C18 guard column, mobile phase acetonitrile (A) and 2% acetic acid in water (B) in gradient mode	Vanillic acid, Syringic acid, trans-Cinnamic acid, Caffeic acid, p-Coumaric acid and Ferulic acid	[43]
Gymnema sylvester (Retz.) R.Br. ex Sm.	Leaves	UPLC-MS	Water's ACQUITY UPLC ™ BEH C18 (100.0 × 2.1 mm ×1.7 µm) column, 0.5% formic acid (A) and acetonitrile (B) in gradients elution mode	Gymnemic acid IV and Stigmasterol	[44]
Cichorium intybus Linn.	Seeds	UPLC-MS	ACQUITY UPLC® BEH C18 (1.7 µm, 2.1 mm × 100 mm), acetonitrile and water as the mobile phases in gradient elution mode	Cichoroside, glucose-6-phosphate, 11,13-dihydro-lactucin and 2',6 dihydroxyflavone	[45]

ranging from botanical/pharmacognostic identification to chemical characterization and provide several evolutionary parameters which accelerate the base of ethnomedicine authenticity[22]. As we are aware of the multiplicity of phytoconstituents in ethnomedicine with different molecular integrity and among hundreds of the chemicals, few varieties of constituents are emphasized to reveal the authenticity of ethnomedicines[23]. However, the consistent use of modern analytical techniques such as LC-MS, GC-MS and NMR which are potentially associated with qualitative and quantitative evaluation of ethnomedicine provide us with accurate and precise scientific evidence in consideration of authenticity[24]. Although in chemical analysis, few markers represent the whole scenario and validate the regulatory prospects involved in authentication. Besides, a single analytical technique is limited and inherent to certain compound classes, mostly because of chromatography, ionization techniques and detector capabilities that will not be responsible for the comprehensive conception of the metabolome[25]. Despite all, repeatability in the analysis of targeted and untargeted drugs not only formalizes us with the comparative and correlative evaluation but also, robust the validation symmetry in the authentication of ethnomedicine particularly to those belonging to the same category or species[26]. During analysis, selection of appropriate roadmap of analytical methods from harvesting the plant material to the choice of analytical technique plays an essential role in the metabolomic study for authentication of ethnomedicine particularly to those belonging to the multiple botanical origins and avoid the general oversteps opposed as experimental and technical errors[27]. Harvesting of the sample is one of the critical steps to target the metabolites based on the authentication being processed, as the metabolites are sensitive to collection and latitude zone, intrinsic enzymatic reactions and other metabolic changes. Liquid nitrogen is used to prevent any metabolic changes in plant material by quenching immediately after harvesting[28].

Moreover, sample preparation for metabolomic analysis and the metabolites on which authentication is dependent is one of the important analytical steps for known drug samples of ethnomedicine while multivariate analytical approaches are required for comprehensive evaluation of suspicious samples[24]. Multivariate statistical analysis is obligatory to reduce such complications in data acquisition from metabolic profiling and to simplify the acquisition analysis of detection and comparative evaluation of the different patterns of changes related to the environmental or genetic factors in metabolite compositions[29].

The recent trend of analytical techniques to evaluate the authenticity of ethnomedicine has been well summarized and comprehended in the context of metabolomics. In a study conducted by Li G et al., 2018, licorice raw materials and dietary supplements

were identified and chemically standardized using UHPLC-MS/MS. The chemical constituents such as liquiritin, isoliquiritin, liquiritin apioside, isoliquiritin apioside, licuraside, liquiritigenin, isoliquiritigenin, glycyrrhizin, glycyrrhetinic acid, glabridin, glycycoumarin, licoricidin, licochalcone A and p-hydroxybenzyl malonic acid were determined as the standardized markers for the further evaluation of such species. Furthermore, Farag et al. (2012) did primary metabolite profiling of different species of licorice roots (*Glycyrrhiza uralensis, Glycyrrhiza glabra, Glycyrrhiza inflata, and Glycyrrhiza echinata*) using GC-MS to differentiate and set a framework for their quality assessment. Several metabolites such as saccharides, amino, fatty and phenolic acids were distinguished in the licorice roots. The resulting outcome reveals that cadaverine was found only in *G. inflata*, while myo-inositol was identified as marker constituent in *G. echinata*[30]. In the cited study, GC-MS was used in metabolomics for the comparative evaluation or discrimination of two different cultivars, *Curcuma aromatica* and *Curcuma longa*, several metabolites were identified to comprehend the quality parameter[12]. Further, the study deals with the GC-MS fingerprinting analysis of *Caulophyllum robustum*, two major components of the total alkaloid content such as aporphinoid and quinolizidine were detected as the key component for quality assessment[31]. A study conducted by Anwar et al. (2018), validated trigonelline as a potential marker and revealed the authenticity of the targeted drug and with those belonging to the multiple species.

Similarly, non-targeted metabolomics analysis was done to screen the multiplicity of phenolic and polyhydroxy metabolites present in pepper products. LC-ESI-MS/MS analytical technique was for the identification of a total of 186 phenolic and polyhydroxy compounds. At the mid not end of the analysis the identified constituents such as proanthocyanidins, anthocyanins, catechin derivatives, flavones, flavonols, flavanones, isoflavones and 3-O-p-coumaroyl quinic acid O-hexoside, quinic acid (polyhydroxy compounds), were found as the majority of constituents and represented as the regulatory markers in the authenticity of the plant. Further, among the selected 50 types of phenolic compound, except l-epicatechin and 4′-hydroxy-5,7-dimethoxyflavanone, malvidin 3,5-diglucoside (malvin) were present in high extant in freeze-dried pepper berries while pinocembrin was comparatively copious in another analyzed pepper products[32]. Due to exponential growth in the utilization of herbal products or formulation, a forward step for regulatory assessment is necessary to prevent the products from the mesh of spurious, adulterated products. Although researchers are highly associated with evading such challenges and use modern analytical approaches for quality-based standardization of ethnomedicinal products [13,33].

Majun Mupakhi ELA (MME) is the traditional Unani formulation. Chemical fingerprinting and quantitative analysis for MME was developed to magnify more comprehensive quality evidence. HPLC coupled with the UHPLC-DAD-Quadrupole-Orbitrap-MS method was developed to determine the chemical matrix and ability of components to scavenge radicals using an in vitro method. Gallic acid, daidzein and icariin were determined as the three characteristic components in commercial MMEs and claimed the one component as gallic acid which mostly affects anti-oxidant capacity MMEs[34]. UPLC-MS/MS qualitative and quantitative studies were performed to validate Itrifal (Unani formulation) concerning to their major markers such as gallic acid, tannic acid, catechin, quercetin and overall set the quality parameter for the standardization of Itrifal and its commercial formulation[35]. Safoof-e-Pathar Phori is one of another Unani formulation used in various auto-immune ailments, GC-MS metabolomic profiling was performed to validate the drug based on its majority of markers and the author claimed its authenticity concerning to another commercial or suspicious products[36].

Arishta is the famous traditional Indian ayurvedic fermented formulation used to treat various ailments against body dysfunction. Further, abhayarishta is well-known for its cardioprotective activity. Due to increasing spuriousness and adulteration which halt the quality of formulation, several emphases were accompanied to determine the quality standard of such important ayurvedic formulation. In a study conducted by Ranjan et al., 2010 quality-based standardization of abhayarishta was done using HPLC-MS method. Several metabolites such as phenols and tannins were determined and among all the identified chemicals, chebulic acid, gallic acid, ellagic acid and ethyl gallate were found as the major constituents. The authors even reported an increasing amount of these constituents during preparation. Further after the final stage of fermentation, 5-hydroxymethyl furfural was reported as the fermented adduct[37].

Pancharishta is the traditional Ayurvedic polyherbal formulation used as a digestive tonic. Khan et al., evaluated the comparative metabolomics profiling at different stages of preparation for understanding the impact of different steps and ingredients HPTLC, HPLC, GC-MS and UPLC-MS analytical approaches. Gallic acid, ellagic acid, tannic acid, kaempferol and quercetin were quantified as the major ingredients of pancharishta using HPTLC and HPLC methods. Further, several polar and nonpolar metabolites of pancharishta were analyzed using UPLC-MS and GC-MS, respectively and reported 144 identified metabolites using GC-MS while among them 26 were found common metabolites at different stages of analysis. Besides, 43 metabolites were qualitatively identified by UPLC-MS analysis. Further, the authors suggest the proposed method will be useful for standardization and quality control of formulations or the formulation pertains to similar herbal ingredients profile[38].

Summary

In this review, metabolomics have been comprehended with standardization and authentication of ethnomedicine. Although several pieces of evidence have been accompanied as a supportive tool to improve the quality based standardization of ethnomedicinal raw materials/product/formulations. Furthermore, the standardization based on marker compounds/targeted and untargeted was predicted as a key factor for validation concerning the authenticity of ethnomedicine. Besides, the studies associated with single marker and technique based evaluation of ethnomedicine for their standardization and authentication can not be considered as the validated evidence for their further applicability. Herbal medicines are associated with the rich matrix of constituents and their assessability without having the comprehensive evaluation of marker constituent's verities do not represent the accurate, precise and robust evaluation. Prediction of targeted and untargeted metabolites based on their quality and quantity represent the whole scenario of metabolomics which could be a considerable factor in authentication of ethnomedicine. Multivariate statistical analysis based evaluation of the wide dimensionality of data sets represents the systematic approach of principally defined components for better authenticity, efficacy and consistency.

Conclusion

The present prospective study concludes the role of metabolomics in standardization and authentication of ethnomedicine. It further suggests various fascinating approaches to evade the challenging endeavor in quality and quantity based assessment, the

comprehensive evaluation of huge dimensionality of data set with the present and future prospective of ethnomedicine concerning standardization and authentication will severely be helpful in setting the future of traditional medicine in the modern era.

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POTENTIAL OF ETHNOMEDICINES TO BE DEVELOPED AS NUTRACEUTICALS

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India is the largest medicinal plants producer. There are currently about 2,50,000 registered medical practitioners of the Ayurvedic system, as compared to about 7,00,000 in modern medicine. In India, around 20,000 medicinal plants have been recorded; however, traditional practitioners use only 7,000–7,500 plants for curing different diseases. The proportion of use of plants in the different Indian systems of medicine is Ayurveda 2,000; Siddha 1,300; Unani 1,000; Homeopathy 800; Tibetan 500; Modern 200; and folk 4,500. In India, around 25,000 effective plant-based formulations are used in traditional and folk medicine. More than 1.5 million practitioners are using the traditional medicinal system for healthcare in India.

Ethnomedicine/Traditional medicines:

Ethnomedicine/Traditional medicines cover 'healthcare systems that include beliefs and practices relating to diseases and health, which are products of indigenous cultural development and are not explicitly derived from a conceptual framework of modern medicine'. Ingredients used in the preparation of ethnomedical remedies provide attractive molecules for the development of new nutraceutical/pharmaceutical products. They contain pharmacologically active compounds, which could be transformed into modern therapeutic agents and wellness products. Herbal medicinal plants used in ethnomedical practice are abundant and unique in nature for the selection of lead compounds for drug development. They are medicinal agents, even as crude unprocessed materials. Furthermore, they can be developed into dietary supplements, nutraceuticals and phytomedicines with precisely defined characteristics and consistent quality but with pharmacodynamic properties that are different from those of pharmaceuticals containing isolated single chemical compounds.

Ethnomedicines comprise a variety of health practices, approaches, knowledge, religious therapies, manual techniques and beliefs on plant, animal or mineral-based medications to treat, identify or prevent diseases (WHO, 2001). About 50,000 species out of half-million flowering plants are used as medicinal plants. The World Health Organization has reported that more than 60% of the world's population in developing countries depends on medicinal plant species to treat various ailments (WHO, 2010).

Evolution of Ethnomedicine:

Since ancient times, conventional food and herbal extracts have been recognized as a fundamental part of the holistic approach to achieving complete wellness and health, especially in the ancient ayurvedic system in India, along with traditional Chinese, Roman and Greek medicine. Our ancestors used various types of ethnic medicines to cure multiple diseases, and this practice was further inherited in today's society where everything can be scientifically validated. Modern drug discoveries are more or less based on ethnomedicine. This folklore medicine system could be a breakthrough in treating and recovering some of the medical needs. The practice of the folklore medicine system includes Ayurveda, Siddha medicine, Unani, ancient Iranian medicine, traditional Chinese medicine, acupuncture, Persian, Kampo, traditional Korean medicine, Muti, Ifa, traditional African medicine, traditional Australian Aboriginal, Islamic medicine, etc. All these traditional medicine products can be evaluated for drug discovery. The bioactive molecules present in natural products are of great interest in synthesizing modern drugs. The bioactive molecule such as polyphenols can possess antidiabetic, antimicrobial, antioxidant and anti-inflammatory properties. The chemical compounds (flavone and flavopiridol) isolated from a plant species *Dysoxylum binectariferum* Hook can prevent cancer cell formation by the mechanism of inhibiting the class of protein kinases. A certain polysaccharide compound such as lentinan derived from *Lentinula edodes*, krestin derived from *Coriolus versicolor*, polysaccharopeptide (PSP) derived from *Coriolus versicolor* and Schizophyllan derived from *Schizophyllum commune* have been clinically tested and succeeded against cancer. More than 50% of the modern drugs are derived from natural products, and researchers are now focused on drug discovery from herbal medicines.

Nutraceuticals:

The term 'nutraceutical', a hybrid term introduced in 1989 to designate the link between 'nutrition' and 'pharmaceutical agents', has actually no universally accepted regulatory definition. Nutraceuticals are known as bioactive substances that are present in common food or botanical-based sources that can be delivered in the dosage format of dietary supplements or functional food, supplying beneficial effects in addition to the nutritional essential components. Nutraceuticals comprise a wide range of bioactive

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derivatives accumulated in edible sources including antioxidants, phytochemicals, fatty acids, amino acids and probiotics. The major pharmacologically active ingredients include carbohydrates, lipids, polyphenols, terpenes, steroids/oils and alkaloids. Nutraceuticals are well-known for their role of being involved in disease treatment and prevention, anti-aging properties and malignancy prevention.

Transition through Herbal Medicines to modern Nutraceutical products:

Ethnomedicinal plants and herbal formulations are the most common ingredients for the development of a potential Herbal Medicine (HM). Therapies leading to the remedy of various ailments using herbal medicine have been in practice from the prehistoric ages. In India, approximately 65-70% of the rural population depends on herbal medicine in the form of Ayurveda, Unani, Siddha and other indigenous ethnic systems. Globally, the margin of herbal medicine utilization is quite fascinating due to the side effects of using their synthetic counterparts for an extended period. Over time, the necessity of using HM became integral, and the drug development progressed accordingly. In 2016, the value of the global HM market was USD 71.19 billion which was USD 63.05 billion in 2014. Witnessing that fact in the global HM market, the level is expected to grow significantly in the future. This chapter aims to consolidate the discovered herbal-origin drug leads and their possible role in the betterment of the herbal medicine system.

Real-life case studies:

As is the case for prescribed medicines, the evidence obtained from high-quality Randomized Controlled Trials (RCTs) represents the gold standard for assessing nutraceutical clinical efficacy. In recent years, several systematic reviews and meta-analyses have provided researchers and healthcare professionals with updated conclusions. There are many herbal traditional medicines that have been included in this list, but due to the limited scope, I am citing 4 case studies with strong evidence-based portfolios.

Brahmi/Bacopa:

CDRI 08®, a unique standardized extract of Bacopa is the result of over 40 years of research. It demonstrates benefits for enhancing memory retention and recall, improving mental clarity and focus, as well as assisting learning, concentration and attention. Two leading pharmacy brands, KeenMind® and Memo Plus Gold® contain this special CDRI 08 extract which is made from an Indian Ayurvedic herb, *Bacopa monnieri* (Brahmi). It is a natural nootropic (well-tolerated cognitive enhancer) designed to improve and protect brain function. Numerous double-blinded placebo-controlled randomized studies on CDRI 08 and KeenMind® have provided an excellent platform to assess the utility of treatment in humans for maintenance and improvement of cognitive functions and normal cognitive aging. Both CDRI 08 and products are very useful to facilitate learning and concentration, particularly in children and students. This can be used for mature and elderly individuals to aid memory and reduce the decline in mental performance. For those with intellectually demanding jobs or who are under pressure, CDRI 08 supplementation is promoted as the ideal choice.

Fenugreek/Trigonella:

Fenugreek belongs to the Fabaceae family. The name, Trigonella, comes from the Latin language that means 'little triangle', due to its yellowish-white triangular flowers. The main ingredients of the seed contain steroidal saponins, alkaloids, mucilage and fibers. The most important steroidal saponins are diosgenin and yamogenin. Trigonelline is the alkaloid of this plant that has been extracted at up to 36% concentration. The amount of protein in this plant is high (22-25%), and its protein is rich in lysine, arginine, tryptophan, and to some extent, histidine. 4-hydroxyisoleucine (4-HI) constitutes about 80% of the total content of free amino acids in fenugreek seeds and is exclusively found in this plant. Fenugreek also contains galactomannan, a highly bioactive molecule. Fenugreek contains a wide variety of flavonoids and other phenolics compounds such as glycoside, orientin, isoorientin, vitexin, apigenin and quercetin.

The medicinal value of fenugreek seeds is mentioned in Ayurvedic texts as well as in Greek and Latin pharmacopoeia. Since ancient times, fenugreek has played an extensive role in treating and preventing diseases. Numerous studies conducted so far and a list of reviews and original articles in reference have confirmed many of these traditional applications and have shown the clear therapeutic value of this plant. Based on convincing evidence on increased serotonin turnover in the brain, several studies demonstrated anti-anxiety and antidepressant-like effects of 4-HI. Fenugreek has a considerable antidiabetic effect. It (galactomannan component) can slow down the absorption of sugar in the gastrointestinal tract, whereas the 4-HI component stimulates insulin release, lowering the blood sugar in diabetic patients. Low molecular weight galactomannan-based fenugreek seed extract is reported to prevent fat accumulation. It is used for kidney complications due to its high antioxidant property. The antioxidant property of the plant has been attributed to the presence of many active phytochemicals, including flavonoids, plant sterols, vitamins, coumarins, terpenoids, carotenoids, curcumins, lignin and saponin.

The Herbalgram (2014, Vol.103, page 33) also concluded that IBHB, a standardized fenugreek seed extract (Indus Biotech Pvt Ltd., Pune, India), slows the progression of Parkinson's disease when taken as an adjunct to L-dopa therapy and has a good safety profile. Several recent clinical trials with Andropique® demonstrated the efficacy of the special extract of fenugreek to significantly increase free and bioavailable testosterone levels within physiological limits of the body. This product also showed to enhance/promote/increase body fat loss and reduce muscle fatigue. A few recent randomized placebo-controlled clinical trials demonstrated standardized extracts (Libifem® & Testofen®) of *T. foenum-graecum* seed may be a useful treatment for increasing sexual arousal and desire in women and middle-aged and older men by increasing serum testosterone level.

Cinnamon:

Cinnamon (*Cinnamomum verum; C. zeylanicum*) is a small evergreen tree, 10-15 meters tall, belonging to the family Lauraceae, native to Sri Lanka and South India. These plants are economically important due to their broad uses in the food and pharmaceutical industries. The aroma and essence industries are the major users of cinnamon due to its fragrance, but this can be incorporated into different varieties of food products and also as functional food ingredients in vitamins, minerals, probiotics, phytosterols and antioxidants. Cinnamon has been explored for medicinal use in the last decade. Cinnamon consists of a variety of resinous compounds including cinnamaldehyde, cinnamate, cinnamic acid and numerous essential oils. The spicy taste and fragrance are due to the presence of oxidized cinnamaldehyde. As cinnamon ages, it darkens in color, improving the resinous compounds. The presence of a wide range of essential oils, such as trans-cinnamaldehyde, cinnamyl acetate, eugenol, L-borneol, caryophyllene oxide, b-caryophyllene, L-bornyl acetate, enerolidol,

b-cubebene, a-terpineol, terpinolene and a--thujene has been reported.

In addition to being used as a spice and flavoring agent, cinnamon is also added to chewing gums due to its mouth refreshing effects and ability to decrease bad breath due to its wide range of anti-microbial properties. Cinnamon is a coagulant and prevents bleeding. Cinnamon also increases blood circulation in the uterus and advances tissue regeneration. In native Ayurvedic medicine, cinnamon is considered a remedy for respiratory, digestive and gynecological ailments.

Cinnamon bark research has moved many miles ahead from culinary use as a spice and traditional medicinal use. Several of its medicinal properties and safety are now validated through modern scientific methods. These include anti-diabetic, anti-inflammatory, cardioprotective and neurological disorders.

Cinnamon bark extract already showed strong clinical evidence in the treatment of diabetes mellitus for sugar control and prevention of complications. The primary driving force for the potential of cinnamon bark for immune system benefits is polyphenols, especially proanthocyanidins. The true multifaceted clinical potential of cinnamon polyphenols has surfaced only recently with clinical evidence for immune/allergic inflammatory conditions such as allergic rhinitis and chemotherapeutic side effects. The ability of cinnamon polyphenols to protect the immune system is now being explored for various prophylactic applications/uses against chronic allergic rhinitis conditions, viral infections and side effects of chemotherapy to improve quality of life. BreathMor® is the leading brand in this category and has received approval in many leading countries.

Saffron:

The dried stigma of the plant *Crocus sativus* L. (Iridaceae), commonly known as saffron, is used as a food spice and in folk medicine for various purposes. From over 150 phytochemicals present in saffron, crocetin, a carotenoid precursor of the carotenoid crocin, is the primary bioactive metabolite and is responsible for saffron's characteristic color. Other relevant bioactive components are picrocrocin and safranal. Saffron flower tepals and stigmas also contain flavonoids and anthocyanins.

Potential therapeutic applications of saffron and its compounds have been extensively investigated *in -vitro* and *in-vivo* studies, reporting several properties including immunoregulatory, anti-inflammatory, antioxidant, cardioprotective, anti-atherogenic, antibacterial, antidiabetic, hepatoprotective, antidepressant, anti-anxiety and neuroprotective activities. The therapeutic effects of saffron and its extracts have been studied clinically as well. The most researched clinical applications relate to mental health, with the available current evidence suggesting benefits in the treatment of depression and degenerative disorders of the central nervous system. A unique natural saffron extract (affron®) standardized to the content of lepticrosalides, considered to be a perfect combination of the main bioactive components endorse saffron's manifold potential for reducing anxiety, relieving stress and mitigating depressive symptoms while improving mood, inducing positive feelings and enhancing sleep quality.

Conclusion:

Many regions around the world such as the Lesser Himalayas are a rich source of medicinal and food plant diversity, but the conservation status of these plant species and associated indigenous knowledge is very poor. Sustainable governmental support is essential to promote overall *in-situ* and *ex-situ* conservation strategies for this natural resource.

The acceptance of the science of nutraceuticals and subsequent investment has been growing, with increased interest in finding novel therapeutic options by utilizing new technologies and scientific methods. The scientific exploration of their safety, bioactivity and bioavailability perspective is crucial because it will contribute to translating these hypothetically potential natural nutraceutical compounds into implementable, validated, regulated and approved effective medicinal products.

Nutraceuticals manifest a novel and exhilarating research field for the discovery of innovative health products with tremendous potentials for health benefits including safety, efficacy and economy. Globally, researchers have realized the fact that proper nutrition and dietary supplements can prevent and in some cases, cure chronic diseases. Several types of nutraceuticals have been isolated from natural sources using biotechnology and genetic engineering tools which provide pharmaco-economic benefits. These products, besides their nutritional aspects, provide tremendous health benefits via manipulating several physiological pathways. The use of scientifically validated and clinically trialled nutraceuticals can definitely improve health and prevent certain diseases, and some have exhibited the same efficacy as that of conventional pharmaceuticals. Generally (not always), nutraceuticals have lower incidences of side effects, adverse effects and drug interactions as compared to both complementary medicines and conventional pharmaceuticals.

Many pharma industries around the world including Ranbaxy, Pfizer, GSK and Abbott have taken the initiative of synthesizing a range of nutraceutical products for different age consumers. The preventive role of these products is uncovered by researchers to a great extent, but their safety and efficacy at a clinical level should be well established before products are delivered in the pharmacy. Intelligent use of advanced and high-throughput technologies can help industries to understand the underlying mechanisms of action and develop this exciting area of research to new horizons for the betterment of humanity, both in terms of economic benefits as well as health outcomes.

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PHARMACOPEIAL AND REGULATORY ASPECTS OF ETHNO MEDICINES AND PHYTOPHARMACEUTICALS

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Abstract

The pursuit of a healthy and long life is as old as humankind, which brings the interest towards various medical practices since ancient times in several parts of the world. In India, Ayurveda is one of the oldest sciences of life having its own healthcare practice. Though it has been used traditionally and has always had the trust of consumers, sufficient research has not been done to validate its products and practices. From the past decade, the growing interest towards the use of these medicines demands the need for their regulations. As a result, Government of India has included the traditional medicines rechristened as AYUSH (Ayurveda, Yoga, Siddha, Unani and Homeopathy) under various acts like the Drugs and Cosmetics Act, Drugs and Magic Remedies Objectionable Advertisement Act and Indian Patents Act. Furthermore, India has several regulatory authorities and Pharmacopeial commissions that regulate the quality and safety of traditional medicines. This article focuses on the various regulatory aspects of ethnomedicine that must be considered during every step of drug development, manufacture and marketing. Phytopharmaceuticals and their regulations have also been included in this article.

Introduction

Ethnomedicine is a term that refers to the traditional healthcare practice that involves the use of minimally processed natural products to prevent and treat diseases, as well as maintain optimal physical and mental health. Worldwide, India is well known for its various cultural practices of medicine such as Ayurveda, Yoga, Siddha, Unani and Homeopathy. In India, even in today's scenario, a good amount of the population considers ethnomedicine (example: Ayurveda) as an alternate medicine for allopathy and its use is higher in the rural and semi-urban areas. The knowledge of ethnomedicine is age-long and it has been transmitted orally so, it is highly desirable to document this knowledge.[1] In addition, the other main drawback is related to the lack of proper standards for practice, research, manufacturing and dispensing these medicines. Therefore, to extend government support for framing promotion policies and providing the standards of these medicines, Government of India (GOI) established a full-fledged Ministry of AYUSH in 2014. AYUSH is the acronym for Ayurveda, Yoga, Unani, Siddha, Homeopathy (AYUSH) and Sowa Rigpa.[2] The main objectives of this ministry include promoting high-standard research, establishing educational institutions all around India and improving the Pharmacopeial standards of these medicines. Additionally, to maintain the quality of these medicines, a separate chapter IV A was introduced in the 'Drugs and Cosmetic Act', in 1964.[1] While on one side AYUSH continued with its own practices and principles, the need was felt to explore medicinal plants to provide a fillip to the sagging output of the Pharma Research and Developments (R&Ds) by a way of introducing a new class of drug Phytopharmaceuticals which could be developed following the same route as New Chemical Entities (NCEs). Considering the importance of the Phytopharmaceuticals, Central Drug Standard Control Organization (CDSCO) has already published a gazette notification setting the guidelines for their development.[4]

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Dr. Chandra Kant Katiyar is CEO Health Care (Technical) of Emami Ltd at Kolkata. He has about 30 years of experience in the field of Ayurvedic/ Herbal drugs spanning across companies like Dabur India Ltd to Ranbaxy Research Labs and currently to Emami Ltd. Dr Katiyar has made significant contributions in the field of regulatory affairs with the Ministry of AYUSH and Ministry of Health and Family Welfare. He has also played a pivotal role in the introduction of Phytopharmaceuticals as a new class of drug and Nutraceuticals. He has been member of Ayurvedic Pharmacopoeia Committee, Herbal Committee for Indian Pharmacopoeia and South East Asia Expert Panel on Dietary Supplements for United States Pharmacopoeia. Dr Katiyar is also member of Editorial Boards of Journals like Journal of Ethnopharmacology, Frontiers of Pharmacology and Journal of Ayurveda and Integrative Medicine. Dr Katiyar is Vice President, Society for Ethnopharmacology India and also has been President of Society for New Age Herbals for two terms.

Regulatory aspects of Ethno medicines

It is critical for regulating each stage of drug development, manufacture, and distribution to provide the public with high-quality medicines. There are various regulatory standards for the AYUSH, which are provided in the Drugs and Cosmetics Act, 1940; Drugs and Cosmetics rules, 1945; and Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules. Particularly, the provisions related to Ayurveda, Siddha and Unani have been given in chapter IV A of Drugs and Cosmetics Act, 1940, and the second schedule particularly 4 A provides the quality standards for homeopathic medicines. Rules from 151 to 169, Schedule E(I), Schedule T, and T A are included in Drugs and Cosmetics Rules, 1945 particularly for Ayurveda, Siddha and Unani (ASU) medicines.[5] Similarly, Homeopathic drugs are also covered under Rules 30AA, 67, 85 (A to I), 106-A, Schedule K and Schedule M-I.[6] Very recently it has been decided to bring the controls of homeopathic medicines under AYUSH. Regulatory changes to support the process have already been initiated. The overall picture of the steps on the various aspects of product concept development to marketing and sales are represented in (Figure 1).

Various national committees are involved in advising the Central and State Governments to regulate the pharmacopeias and quality standards of ASU and Homeopathic medicines. Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB), Ayurveda, Siddha,

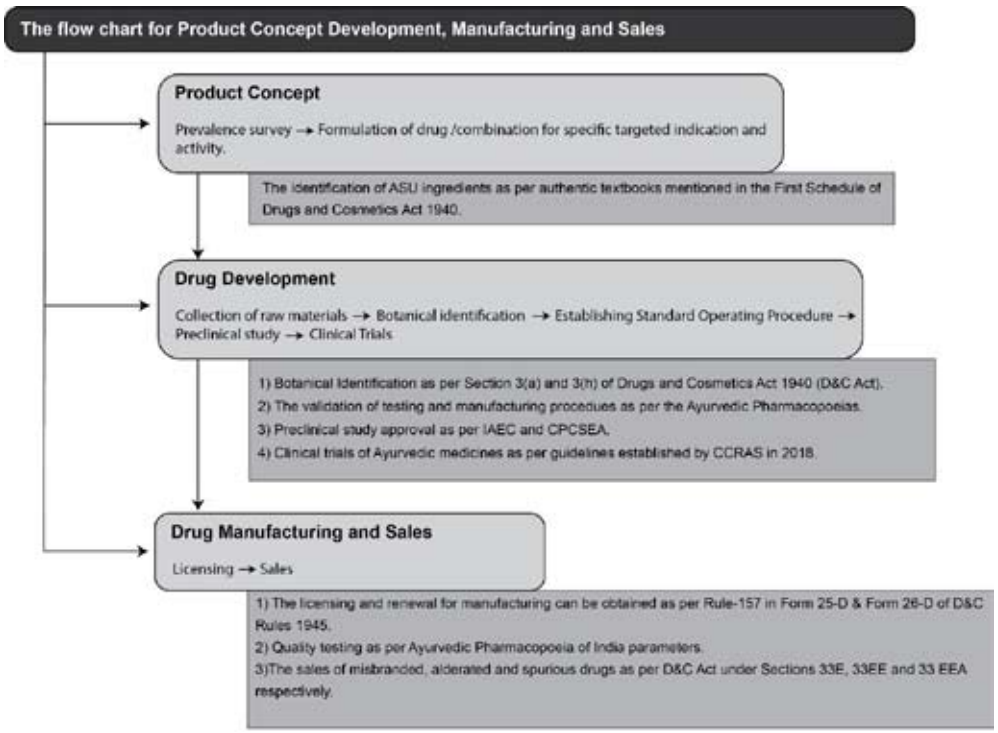

Figure 1: This illustration shows the steps on the various aspects of product concept development to marketing and sales.

Unani Drugs Consultative Committee (ASUDCC), Pharmacopoeia Commission of Indian Medicine and Homeopathy are some of the major committees that play a very important role in regulating and maintaining the standards of AYUSH. Union Government has taken up major reforms in this area and has recently proposed a merger of all Pharmacopeia Committees into one body. It has been done to bring uniformity in the quality standards of raw materials used under different systems of medicines.

2.1 Good manufacturing Practices

To provide high quality of traditional medicines, proper standards must be maintained from the initial step of manufacturing. Therefore, a set of guidelines and procedures for good manufacturing practices (GMPs) are provided in Schedule T under Rule 157 of the Drugs and Cosmetics Rules, 1945. This schedule particularly focuses on AYUSH medicine such as Ayurveda, Siddha and Unani. It consists of two parts (I &II), where part I primarily lays emphasis on various manufacturing practices and part II provides the recommended list of materials, machinery and equipment for the production of various categories of traditional medicines.

Part I suggests that the factory or the manufacturing plant should have sufficient and separate place for each section like storage, manufacturing area and quality control department. Also, it provides detailed information about the proper building, location and facilities that are essential for a perfect manufacturing unit. It also suggests that quality control measures have to be taken carefully to store the raw materials in the respective containers by categorizing them. Furthermore, measures regarding the health, clothing and hygiene of the workers in the production unit are also provided.[7] The suggestions regarding the maintenance of various records and the precautions for reducing contamination are also given. Similarly, GMPs for homeopathic drugs are provided in schedule M1. In order to augment the exports of AYUSH products the Ministry of Health and Family Welfare jointly through CDSCO and Ministry of AYUSH, have introduced the World Health Organization (WHO) GMP and Certificate of Pharmaceutical Products (CoPP). So far, almost 15 to 20 companies have been granted approval for WHO GMP compliant facilities and CoPP for hundreds of products. This step of GOI has provided a stimulus to exports of AYUSH medicines.

2.2 Drug Development

Although not mandatory, some of the Ayurvedic companies who believe in scientific development of products do follow almost similar drug development routes like allopathic formulations. The process includes pre-clinical and clinical development of the products.

2.2.1 Pre-clinical studies

Drug development is a step-by-step process that includes the evaluation of both safety and efficacy. Preclinical evaluation majorly involves the testing of drugs on animals. The safety evaluations on animals are essential to determine the adverse effects of the medicines on various body functions. Before conducting the animal tests, the study should get approval from the Institutional Animal Ethics Committee (IAEC), or the study protocol should meet the standards of the local governing body. In India, to maintain the animal house facility, guidelines provided by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) must be followed.

As some plants used in the preparation of the ayurvedic formulations are harmful to humans, Ayurveda has recommended their detoxification process called '*Shodhan*'. This process is followed for every known toxic substance be it of herbal, mineral or animal origin. Such substances have been listed under Schedule E (1) of Drugs and Cosmetics Rules. As per rule 161, the label of any product containing Schedule E (1) listed toxic ingredients has to carry a warning consciously within a box mentioning "To be taken under medical supervision only"[7]. Rule 158 B provides the requirements of classical and proprietary AYUSH product developments including the need of toxicity studies. To test such ayurvedic formulations, certain methodologies have been recommended by Central Council for Research in Ayurvedic Sciences (CCRAS) of the Ministry of AYUSH.[8]

2.2.2 Clinical trials

Indian Council of Medical Research (ICMR) has provided elaborate guidelines on human clinical trials of all kinds of drugs including AYUSH. These guidelines are related more to the administrative and regulatory pathways. However, the Good Clinical Practices (GCP) guidelines for clinical trials of Ayurvedic

interventions are published on the AYUSH website under the CCRAS in 2018.[9] These detailed guidelines include clinical trial registration, types of clinical trials, pre-requisites for a clinical trial (like formulation drug or therapy evaluation protocols as a part of the clinical trial, data on pilot or preliminary study, study protocol, study objectives, study outcomes, study design, the patient or participant recruitment process for clinical trials, various phases of clinical trials, concomitant drug use, rescue drug use, project data safety monitoring by Data Safety Monitoring Board (DSMB).[9] These guidelines also include the ethics and safety considerations that come under the Institutional Ethics Committee (IEC)/ Institutional Review Boards (IRBs), like the informed consent process, waiver consent form, and regulation on the selection of vulnerable groups for clinical trials like pregnant women, children, etc. There are four phases of clinical trials guidelines for Ayurvedic medicines. Phase-I (Human Pharmacology Trial) includes evaluating the safety of the drug candidate and the maximum tolerable dose. Phase-II (Therapeutic Exploratory Trial) which includes testing the therapeutic efficacy of these drugs while measuring short-term side effects and adverse effects.[3] While Phase-III (Therapeutic Confirmatory Trial) includes confirming the therapeutic efficacy of the drug by establishing the dose-response relationships by testing it on more populations with a disease condition at various stages, and also evaluating the effect of using the test drug in combination with other drugs. Finally, Phase-IV (Postmarketing Trial) happens after the drug is released into the market. All these guidelines make the process of a clinical trial of Ayurvedic medicines more scientific and authentic to the researchers and doctors for easy promotion of these drugs.

2.2 Drug Selling, Advertising, and Labelling

Manufacturing license for Ayurvedic products is issued by the licensing authorities of states for "Manufacture and Sale" of the products. It is to be noted that therefore no separate license is required for the sale of Ayurvedic products. Drug selling, advertising and labelling are crucial steps for the safety and commercial success of a drug. The regulations on the Ayurvedic, Siddha and Unani drugs are mentioned in the Drug and Cosmetics Act 1940 under Chapter-IVA. This chapter includes a prohibition on selling drugs under section 33E for misbranded drugs, 33EE for adulterated drugs and 33 EEA for spurious drugs.[10] The regulations on medicinal product advertisements are very much necessary as they might mislead people and make them purchase the wrong drug for diseases, spending more in vain. The objectionable advertisements are regulated by the Drugs and Magic Remedies Objectionable Advertisement Act 1954, which prevents the manufacturers from advertising to cure 56 disease conditions that cannot be cured only with drugs. The Ministry of AYUSH has also entered into a Memorandum of Understanding (MoU) with the Advertising Standards Council of India (ASCI) to monitor the advertisement of AYUSH products and report the non-compliance to the Ministry.

The labelling regulation requirements of the drugs to make the product more authentic and easy to use come under the Drugs and Cosmetics Rules 1945, Rule-161, which defines the naming, weight/volume, manufacturing date, expiry date, license number, batch number. Similarly, the license approval to manufacture ayurvedic medicines comes under the Drugs and Cosmetics Rules 1954, Rule-157 in Form 25-D for a fresh application of 25-D license 24D is prescribed. The renewal of the license for Ayurvedic medicines comes in Form 26-D and for Homeopathic medicine comes in form 26-C.[7] Biodiversity Act of India (2002) makes it mandatory to seek its approval before granting patents by the Indian Patent Office. The provision is intended to prevent biopiracy but it is unfortunate to note that thousands of applications are pending with biodiversity authority and they are not taking any action. This discourages R&D investment in the sector.

Phytopharmaceuticals

Many of the pharmaceutical drugs have their origin from medicinal plants, but most of these drugs act on a single target. It is also a fact that pharmaceutical R&D in terms of new drugs have gone down despite high investment. The need for drugs hitting multiple targets and inculcating good science in medicinal plants to provide an alternative to New Chemical Entities (NCEs) has led to the introduction of a new class of drugs called Phytopharmaceuticals.[11] Figure 2 represents the combined product of traditional medicine and strict regulations of allopathic medicine, forming phytopharmaceuticals and their benefits. The development pathway of phytopharmaceuticals is the same as NCEs.

Phytopharmaceuticals are the novel category of drugs that were first introduced in India. By amending the Drug and Cosmetics Rules, the Ministry of Health and Family Welfare, (GOI) issued a Government notification citing the studies required to be submitted as part of the dossier for application of Phytopharmaceuticals as a new drug under Rule 122 E by The Gazette Notification G.S.R.918(E) of November 30, 2015.[12] "Phytopharmaceutical drug includes purified and standardised fractions with defined minimum four bio-active or phyto-chemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route".[12] They are authorized by the Drug Controller General of India (DCGI) and licensed by state authorities. So, they are mandatorily subjected to undergo pre-clinical studies on animals and also the clinical trials as per the Schedule Y of Drugs and Cosmetics Rules 1945.[4] As per Schedule Y, based on the Central Drugs Standard Control Organization (CDSCO) guidelines there are four phases of clinical trials for Phytopharmaceuticals similar to that of conventional medicines. The records of raw material procurement, stability data, safety and efficacy data should be maintained as per the Indian Council of Medical Research (ICMR). These measures would ensure that more of our ancient medicinal drugs would get prescribed with more confidence by the doctors, thus making it a very good mainstay or complimentary option for allopathic medicines and also increase the chance of validating more ayurvedic extracts for drug development thus increasing the chance of more drug candidates getting into the market. As of today, there is no phytopharmaceutical drug in the market, however, 10 to 12 products are at various stages of development, and one product from SUN pharma has already completed its Phase II clinical trials.

Conclusion

The traditional medicine knowledge of India is one of the most valuable knowledge for developing more drug alternatives for a particular disease. The regulatory aspects of ayurvedic medicine have been developed a lot since the foundation of the Department of AYUSH under the Ministry of Health & Family Welfare and CCRAS. It is known that the ingredients used in the ASU and Homeopathic formulations might be harmful and their quality also

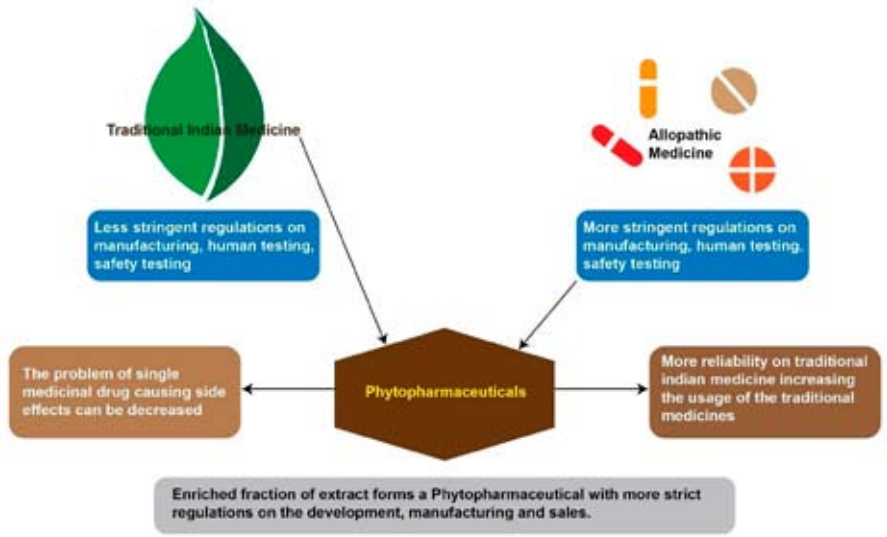

Figure 2: This diagram represents the combined product of traditional medicine and strict regulations of allopathic medicine, forming phytopharmaceuticals and their benefits.

would impact the efficacy and safety of the formulation. India has already focused on developing the regulations on the practice of using and manufacturing these drugs. The introduction of Phytopharmaceuticals which have similar regulatory norms as that of allopathic drugs is another major step towards making traditional medicinal extracts more research-validated and accepted by doctors to prescribe them. The Indian Council of Medical Research (ICMR) has signed an MoU with Emami Ltd., an Indian Ayurvedic business, to collaborate on the development of a Phytopharmaceuticals medication for pre-diabetes. Such collaborations and advances in AYUSH medicine can improve the sales and marketing of these drugs. Various challenges are associated with AYUSH medicines such as the import of raw materials, prohibition on prescribing ayurvedic medicine by allopathic doctors by the Honorable Supreme Court. These challenges are needed to be addressed for the effective usage of AYUSH medicines. More guidelines for pre-clinical and clinical trials for all types of traditional drugs are yet to be achieved. The regulatory norms of Indian traditional medicine require a more stringent build-up for better utilization of our ancient knowledge.

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Dr.Rangari honoured with D.Litt.

Prof. Vinod D. Rangari, Professor and Head, Department of Pharmaceutical Sciences, Guru Ghasidas Central University, Bilaspur (C.G.) has been awarded a degree of Doctor of Literature - D. Litt. (Vidyavachaspati). The degree has been awarded by Kavi Kulguru Kalidas Sanskrit University, Ramtek, Nagpur, on his research work associated with 84,000 aggregates of existential reality and relativity. The research was the self-revelation of the author, published in the book entitled, 'Encounter with Satipatthana: The 84,000 Dhammakkhandha of Buddhism', by Embassy Books, Mumbai. The research unravels the 2600 years mystery of the magic figure 84,000 and practically reveals it's relativity with the psycho-cosmic topography of enlightenment and wisdom. The research can be summarised as a road-map to attain a life of purity, truthfulness, happiness and peace.

Dr. Rangari has thankfully acknowledged his family members, friends, university colleagues and Vice Chancellor, Guru Ghasidas Vishwavidyalaya for the support.

HERB-DRUG INTERACTION: NEED OF THE HOUR

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Abstract:

The usage of herbal remedies has become very common and the interest of researchers has tremendously increased in herbal research. Herbs are believed to be free from side effects compared to synthetic drugs, thus their usage is increasing day by day. The concomitant use of herbal remedies along with synthetic prescription drugs is commonly observed especially in chronic disease conditions such as diabetes, arthritis, obesity, etc. However, herbs are known to interact with drugs when administered concomitantly. Several studies have been reported for such herb-drug interactions that include both pharmacokinetic and pharmacodynamics interactions. One of the basics for such herb-drug interaction studies is CYP450 enzymes. The common metabolic enzymes are considered as one important factor while designing such studies. However, various methodologies have been reported for herb-drug interaction studies. Despite the advanced methodologies and analytical techniques, there are a lot of challenges in carrying out herb-drug interaction studies including variations in CYP enzymes in laboratory animals and humans, lack of bioanalytical methods, complex biological events, etc. However, systematic and focused studies should be designed to explore potential herb-drug interactions. Undoubtedly, this area of research is not much explored and needs to be focused on.

Introduction:

While many herbal remedies are considered natural, they can interact with other pharmaceuticals, resulting in potentially hazardous adverse effects and/or reduced medication benefits. The global herbal medicine market is predicted to reach USD 411.2 billion by 2026, with a CAGR of 20.5% forecast between 2020 and 2026. The market is growing due to increased government support and financing for research and innovation. The knowledge of traditional medicine and the utilization of plants as a source of medication is an innate and extremely essential component of the healthcare system in India, which is rich in natural resources. A total of 1500 medicinal plants have been recognized by the Indian system of medicine, of which 500 are widely used (Agrawal OP, Raju PS, 2006).

In India, it is estimated that there are around 7800 medicinal pharmaceutical production units, which consume about 2000 tonnes of herbs each year (RamakrishnappaK, 2005). According to a recent WHO estimate, 70-80% of the world's population, particularly in impoverished countries, rely on traditional medicine, primarily plant medications, for their main healthcare requirements (WHO/EDM/TRM/2002.1, WHO: Geneva; 2002).

As the use of plants becomes more widespread, interactions between medicines and allopathic pharmaceuticals must be addressed and thoroughly examined. When taken with prescription medicines, several herbal supplements can have potentially hazardous adverse effects. Patients are more likely to be harmed by alternative therapy when it is not overseen by physicians or alternative therapy practitioners, especially if they are utilizing herbal and prescription drugs that have hidden interactions. These encounters may go unnoticed until a patient is injured or a life-threatening situation arises. Herbal medications interact with drugs in two ways which include pharmacodynamic and pharmacokinetic interactions

Pharmacodynamic (PD) herb-drug interactions:

When a herbal substance has an additive, synergistic, or antagonistic activity to a conventional drug, these interactions can arise. Pharmacodynamic interactions influence organ systems, receptor sites, and enzymes and are associated with the pharmacological activity of the interacting drugs.

Pharmacokinetic (PK) herb-drug interactions:

These interactions happen when a herbal medication alters a drug's absorption, distribution, metabolism, protein binding, or excretion, resulting in changes in the drug's or its metabolites' levels. Drug transporters and metabolising enzymes are involved in the majority of the current evidence of pharmacokinetic drug interactions. Although enzymes like glutathione S-transferases and uridine diphosphate glucuronyl transferases (UGTs) can play a role in drug interactions, the majority of herbal-drug interactions are caused by oxidative metabolism by the cytochrome P-450 system (CYP) or the effect of a herbal drug on the efflux drug transporter P-glycoprotein. The most common pharmacokinetic interactions include the inhibition or induction of drug metabolism mediated by the key enzymes cytochrome P450 (CYP) (Wanwimolruk and Prachayasittikul, 2014). The regulation of cytochrome P-450 enzymes (CYP)-mediated drug clearance as the main mechanism responsible for such types of interactions has been indicated in some recent studies (Pandit et al, 2012).

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Role of Cytochrome P450 Enzymes in Drug Interactions:

The CYP450 enzymes are the most important catalysts in drug metabolism. CYP450 is a hemoprotein superfamily that includes 57 genes that are involved in the oxidative metabolism and metabolic activation of the vast majority of xenobiotics (drugs, food components, and contaminants) and endogenous substrates (e.g., steroids, cholesterol, and bile acids). The most common cause of drug interactions is the modulation (inhibition or augmentation) of CYP-mediated drug metabolism due to concurrent administration of other medications or exposure to exogenous substances. The first number after CYP denotes the family, the alphabet denotes the subfamily, and the number after the subfamily denotes the various enzymes of a subfamily polypeptide. There are at least 18 different CYP450 isozymes in the human liver, although only 10 of them (CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, CYP2F1, and CYP3A4) are responsible for the hepatic metabolism of most medications. P450 enzymes in animals differ from those in humans. Some individual CYP isoforms, however, share some affinities. Animal models are frequently employed in the preclinical development of novel medications to anticipate the metabolic activity of new substances in humans. To avoid or diminish harmful drug-herb interactions in the early stages of drug development, it's critical to identify drugs that can interact with herbs using appropriate in vitro and in vivo models. Humans, on the other hand, differ from animals in terms of drug metabolising enzyme isoform diversity, expression, and catalytic activity. The catalytic activity of CYP1A, CYP2C9, CYP2D, and CYP3A isoforms differ significantly between species, which should be taken into account when extrapolating metabolism data from animal models to humans. Toxicity endpoints linked to metabolism should be attainable in the species employed in metabolism investigations. It's possible that using human recombinant CYP proteins and expression systems isn't the most accurate way.

Mouse, rat, rabbit, dog, and monkey are the most widely utilised species in metabolism studies, with guinea pig and hamster being employed to a lesser extent. In comparison to humans, none of them have a flawless CYP profile.

Xenobiotics, medicines, and a range of dietary or herbal components can all affect the CYP450 system (Lehmann, 1998). As a result, drug clearance and effect are altered (Rendic, 2002).

- One or more CYP isoforms may use a chemical as a substrate. When the main isoform is saturated, the secondary enzyme uses it as a substrate(s).
- A substance can be a CYP isoform inducer, either of which is a substrate for, or it can induce multiple enzymes at the same time. The induction mechanism accelerates the metabolism of the enzyme's substrates.
- A substance could potentially be a CYP450 enzyme inhibitor. Inhibition occurs through a variety of pathways, and a molecule may inhibit several isoforms, including those for which it is a substrate (Zhou, 2003).

If the substrate is a prodrug activated by CYP-mediated metabolism, inhibition of its metabolism can lower its effects, whereas induction can either increase or decrease its effects and toxicity, depending on the effects of induction on the active metabolite's further metabolism or excretion.

Mechanisms of Herb drug interactions:

Induction and inhibition of metabolic enzymes (enzyme-mediated HDIs)

Mechanisms of CYP450 inhibition:

Drug metabolism could be inhibited by different mechanisms including:

(i) Reversible enzyme inhibition

(ii) Reduction of enzyme available for metabolism by irreversible inhibition or suppression of its synthesis

(iii) Reduction in the supply of enzyme cofactor(s)

(iv) Inhibition of drug metabolism could result in an increase in drug plasma concentration (which may result in drug toxicity) and a decrease in the concentration of its metabolites, which could be clinically significant in cases of active or toxic metabolites

Mechanisms of CYP450 induction:

Drug metabolism could be enhanced by different mechanisms including:

(i) An increase in the amount of enzyme available for metabolism (induction), which could be achieved by transcriptional activation, mRNA, or protein stabilization

(ii) Activation of enzyme metabolic activity, which is different from induction in that the amount of the enzyme available for metabolism is not altered but its catalytic activity is stimulated in the presence of the activator

(iii) An increase in the supply of enzyme cofactor when it is the rate-limiting step of metabolism. Induction may increase the amount of P450 present and enhance the speed of oxidation and clearance of a drug. Prediction of the time-course of enzyme induction is difficult because of several factors, including the drug half-life and enzyme turnover, which determine the time-course of induction. The time-course of induction depends on the time required for enzyme degradation and new enzyme production.

Inhibition and induction of transport and efflux proteins (transporter-mediated HDIs):

The ABC family of drug transporters plays a critical role in the absorption, distribution, and excretion of a wide range of drugs. The most researched member of this family is P-gp, a 170-kDa plasma glycoprotein expressed by the human MDRI gene. The apical epithelial surfaces of the bile canaliculi of the liver, the pancreatic ductal cells, the proximal tubules of the kidneys, the columnar mucosal cells of the small intestine, colon, and the adrenal glands have the highest concentrations (DeGorter, Xia, Yang, & Kim, 2011; Marzolini, Paus, & Buclin, 2004). It is mainly accountable for drug absorption, metabolism, and excretion from the colon, liver, brain, and kidneys. These proteins are involved in the direct excretion of drugs and their metabolites through the gastrointestinal, hepatobiliary, and urine systems (Szakács, Váradi, Özvegy-Laczka, & Sarkadi, 2008). As a result, co-administration of herbs may cause P-gp to be modulated, or its competitive affinity for its binding sites may change the pharmacokinetic profile of therapeutics.

Herb drug interactions that are mediated by both enzymes and transporters:

Some herbal products have been shown to affect both transporter and CYP functions. P-gp and CYP3A4 both serve as an effective barrier for the majority of orally absorbable drugs, despite an extensive overlap in their substrate molecules (Christians,

Schmitz, & Haschke, 2005). When conventional drugs and herbal products are administered together, there are changes in the normal activity of P-gp efflux and CYP, which has an effect on the pharmacokinetic disposition of CYP3A and P-gp substrate drugs, resulting in decreased efficacy and/or the occurrence of toxicity (Markowitz et al., 2003).

Effects on gastrointestinal functions:

Herbal medicines can also affect the absorption and disposition of concomitantly administered prescription treatments by changing the pH of the gastrointestinal tract and other biochemical factors that affect the dissolution properties as well as the absorption of pH-dependent drugs. Furthermore, complexation and chelation can result in the formation of insoluble complexes and their competition with site-specific complexes. The rate of absorption of medicines is greatly influenced by specific substrates at absorption sites. Anthranoids found in plants like Cassia (*Cassia senna*), Rhubarb (*Rheum officinale*), and Cascara (*Rhamnus purshiana*) as well as soluble fibres like Guar gum and Psyllium, have been shown to reduce GI transit time, lowering medication absorption. Significant alterations in medication absorption have been recorded in simultaneous administration with prescribed pharmaceuticals as a result of shortened GI transit time (Fugh-Berman, 2000).

Modifications in renal clearance:

All products have the potential to interfere with renal functioning, causing changes in medication clearance through the kidneys. The inhibition of tubular secretion and/or reabsorption, or interference with glomerular filtration are responsible for such type of interaction (Bagnis, Deray, Baumelou, Le Quintrec, & Vanherweghem, 2004). Furthermore, certain herbal products are used as diuretics. These herbal medications' diuretic mechanism is complex and non-uniform. Some herbal medicines do not impact electrolyte secretion but increase GFR, whereas others function as direct inducers of both tubular secretion and GFR (Al-Ali, Wahbi, Twaij, & Al-Badr, 2003; Crosby et al., 2004).

In vitro models:

In vitro methods are significant because they provide background and anticipatory knowledge for *in vivo* predictions while also being cost and time effective. Herb-drug interactions can be predicted using a variety of *in vitro* methods. Subcellular fractions such as liver microsomes, cytosols and homogenates, precision-cut liver slices, isolated and cultured hepatocytes or liver cell lines, and cDNA-expressed enzymes are among the methods used (Rodrigues, 1994; Gustavsen, 2016). To make better predictions of drug-herb interactions in humans, primary cultures of human hepatocytes (PCHH) must be used in *in vitro* models (Venkataramanan et al, 2003; Wentworth, 2000). The following are a few *in vitro* procedures (Turpeinen, 2006).

Human-derived in vitro techniques:

Primary hepatocytes:

Because of the good *in vitro-in vivo* correlations in the metabolic activity of a number of drugs, cultured human hepatocytes are now the most suggested techniques for studying CYP-mediated metabolism and induction. Hepatocytes require specialized matrix topologies and challenging technical abilities to maintain normal cellular physiology and intercellular connections. Despite the development of various cryopreservation applications, the time required to effectively utilise a single hepatocyte batch is still fairly short.

Immortalised cell lines:

The liver-derived HepG2 and BC2 cell lines, as well as the lung-derived A549 cell line, are probably the most commonly used for metabolism research. Several genetically engineered cell lines and coculture systems have been produced to boost the expression patterns and levels of DMEs (Drug Metabolising Enzymes). Most of these techniques, however, have failed or have been demonstrated to have a very limited metabolic capacity. HepaRG, a human hepatoma-derived cell line, was recently introduced and shown to have various liver-specific functions as well as physical similarities to normal human hepatocytes.

Liver slices:

Induction studies can also be performed on liver slices. When studying whole-cell metabolism for a short length of time, liver slices are a useful tool.

Subcellular fractions:

Liver homogenates or subcellular fractions, including microsomes, can be produced from liver materials. All Phase I and Phase II enzymes are present in liver homogenate. Microsomes are formed from the endoplasmic reticulum and contain CYPs and UGTs following homogenization and differential ultracentrifugation. Microsomes are the most commonly utilised in vitro system for drug metabolism investigations, along with liver homogenates.

cDNA-expressed CYPs:

For certain years, isolated heterogeneous human CYP enzymes have been commercially available, expressed as single enzymes at a time from cDNA in bacterial, yeast, and mammalian cells. In early drug development, recombinant CYPs have been used as a frontline tool.

Novel cell-based technologies:

Preliminary research on the expression, inhibition and regulation of CYPs in bioartificial liver systems, stem cell-derived cultures, and tests has already been reported, making these technologies a compelling option for future drug metabolism research.

Computational *in silico* methods:

In silico approaches are increasingly being used to research CYPs, Phase II enzymes, P-gp, and their interactions with xenobiotics, such as herbs (Ekins and Wrighton, 2001; Raunio,2015).

Challenges:

- Selection and search of an optimal and exact animal species to mimic drug metabolism in man is still a challenge in pharmacokinetic herb-drug interaction
- Modulation of drug-metabolizing enzymes and transporters by herbal products maybe due to interaction with any component of herbal products; therefore, identification of relevant constituents is necessary in order to make accurate predictions of HDI
- The assessment of responsibility for interaction between herbal products is difficult because of the variability in the composition of herbal products, the uncertainty of causal components and often little knowledge of constituent pharmacokinetics
- Composition of plant products to ensure reproducibility of studies and allow comparisons to be made between studies
- Herbal products that experience widespread pre-systemic (first pass) clearance through metabolism, so this high elimination/low bioavailability results in low circulating

concentrations of the parent plant component. Therefore, the concentration of the perpetrator's constituents, if measurable, can be a substitute less than the optimum concentration at the site of interaction

- The development of the bioanalytical method is a critical step, because both the herb and the drug have different physicochemical properties, and it is difficult to set up the chromatographic parameters

Conclusion:

Herb-drug interaction is a very important area of research that should be given more focus to achieve a rational use of herbal remedies. Although few studies are reported on a few herbs for their interaction with synthetic drugs, many herbs are yet to be studied for interaction with suitable synthetic drugs. The challenges in herb-drug studies should be addressed using modern approaches and advanced analytical techniques. CYP enzymes mediated interaction studies though seem to be more useful, the complete understanding of biological events is always questionable. Moreover, the research should be more focused on selected target diseases, herbs and drugs so that the complete interaction pattern in selected herb-drug combinations in a particular disease can be explored.

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IPA BUILDING PROGRESS REPORT

WORK STATUS AS ON JULY 2021 & PROPOSED ACTIONS FOR THE IPA BUILDING PROJECT

1. The Lift work will be ready for testing by end of July 2021.
2. The Fire Fighting work will be done by end of July 2021.
3. The Fire Retardant door work shall begin on site by 1st week of August 2021.
4. The external painting work is done.
5. The concrete road works around the building will be over by end of July 2021.
6. The balance tiling & other interior civil work shall resume mostly by end of July 2021.
7. The Pump room work shall start by end of July 2021.

LEVERAGING NDDS PLATFORMS FOR MAXIMISING THE POTENTIAL OF ETHNOMEDICINES

Dr. Varsha Pokharkar, Ms. Preeti Tamane
Poona College of Pharmacy, Bharati Vidyapeeth (Deemed to be University), Pune.

Ethnomedicines: A rich potential resource of drug leads

Traditional medicine practised indigenously in different parts of the world has revealed that plants possess great potential to be developed into therapy for various ailments. Origin of about 75% of antimicrobial and 60% of anticancer drugs approved for clinical use from 1981 to 2002 could be traced back to nature (S. Singh and Tripathi 2017).

Several initiatives are being undertaken worldwide in order to leverage ethnomedicinal wisdom for the development of effective therapies. The World Health Organization (WHO) has recognised, emphasised and advocated the use and modernization of traditional medicines time and again. The goals adopted by WHO in its '*Traditional Medicine Strategy (2014-2023)*', are to harness the potential contribution of traditional medicines (TM) to health, wellness and people-centred healthcare and promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, wherever appropriate (WHO 2013). In India, considering the vast knowledge of indigenous medicines, the TKDL (Traditional Knowledge Digital Library) was introduced in 2001 with the objective for preservation, protection and promotion of traditional, knowledge-based innovations and practices. Ethnomedicines, if leveraged carefully, have the potential to become the backbone of the healthcare systems worldwide soon and for generations to come.

Challenges associated with formulation development for ethnomedicines:

In order to be used successfully in modern medicine; verification, validation and establishment of scientific evidence of the activity of ethnomedicinal plants is extremely necessary. This starts with the standardization process which involves identifying and quantifying the active compounds, followed by the establishment of pharmacological activity through well planned experimental models. This establishment of activity helps in identifying the best method of drug administration which in turn is useful in deciding the most suitable drug delivery system for herbal medicine (Fibrich and Lall 2017). However, the development of ethnomedicines for use in modern times is associated with several challenges since information about the use, preparation and administration of ethnomedicines is not very well documented in most cases.

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Professor, Poona College of Pharmacy, Bharati Vidyapeeth, Pune

Dr Varsha Pokharkar is Professor and Head, Department of Pharmaceutics, Poona College of Pharmacy. Her research areas include nano particulate delivery systems, controlled release drug delivery systems, phytoformulations and Preformulation aspects. She was recently listed among the top 2% scientists in the world in her field in a study conducted by Stanford University and Mendeley database. She has to her credit several research grants and awards.

Quality control of botanicals, validated processes of manufacturing, customer awareness and post-marketing surveillance are the key points, which could ensure the quality, safety and efficacy of modernized ethnomedicines (P. Mukherjee et al. 2016).

The challenges associated with formulation development for ethnomedicines can be broadly classified into three major areas as illustrated in Fig. 1.

Raw Material Related Challenges:

Phytochemical variability (arising due to collection in different seasons and geographic locations), misidentification, adulteration and substitution (A. Singh et al. 2019) has been a continuous challenge in quality assurance of the herbal raw materials. Commercialization and increasing demands (Govindaraghavan 2008) have even led to a rise in these issues and have also given rise to malpractices such as biopiracy. Lack of quality assurance has also lead to safety concerns with the use of ethnomedicines (Eldeen, Effendy, and Tengku-Muhammad 2016). Ethnomedicines are often poly-herbal in nature and thus, identifying the exact biological marker is often a challenge thus standardization concerning the same is difficult. Standardization of each raw material with respect to each of the chemical markers is often tedious for multicomponent formulations.

Formulation Challenges:

Most ethnomedicines are traditionally used as extracts instead of single constituents, or as a combination of multiple plant extracts, making it difficult to identify the constituent(s) responsible for the therapeutic activity. In most extracts, only a few components are therapeutically active while others function as bioenhancers. Mechanisms of action are often unknown or involve multiple pathways.

Natural compounds often present challenges like inherent low solubility, poor penetration into the targeted cells, high hepatic clearance due to first-pass effect and narrow therapeutic index. Additionally, undesired pharmacokinetic profiles and drug resistance are also major obstacles observed during the development of phytochemicals into formulations for clinical use (P.K. Mukherjee et al. 2019). Several plant extracts and phytomolecules, despite having excellent bio-activity *in vitro* demonstrate less or no *in vivo* actions due to their poor lipid solubility and/or improper molecular size, resulting in poor absorption and poor bioavailability (Ajazuddin and Saraf 2010).

Regulatory Challenges:

Several traditional formulation techniques are obsolete and not acceptable to regulatory authorities. Traditionally used processes for the preparation of formulations are small-size batch processes, which are difficult to scale up. In-process quality controls are not well defined for the formulation procedures, which makes it difficult to convert the process to commercial scale and thus, reduces the regulatory acceptability.

Leveraging NDDS Platforms for Development of Ethnomedicines:

Solubility and permeability challenges presented by phytoconstituents can be overcome by leveraging novel drug

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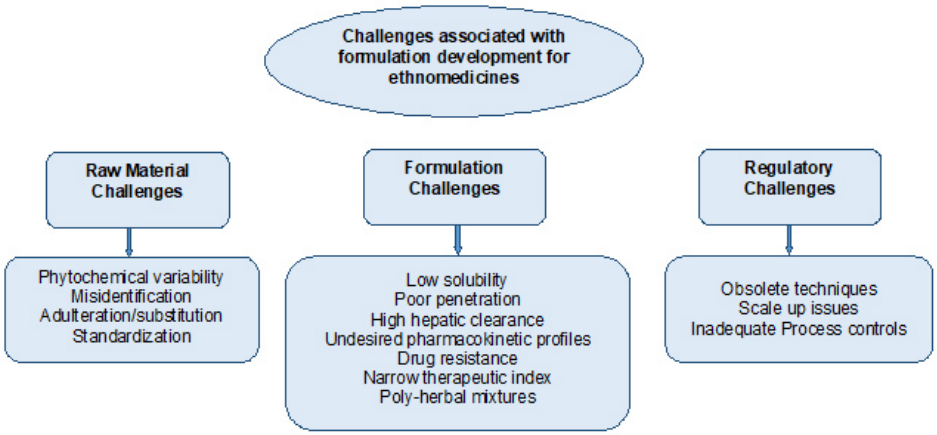

Fig. 1: Challenges associated with formulation development for Ethnomedicines

delivery systems. NDDS not only help in modulating the pharmacokinetics of these drugs but also in improving the target selectivity, reducing toxicity and enhancing the therapeutic efficacy. NDDS may also help in the enhancement of stability, improving tissue macrophages distribution, sustained delivery and protection from physical and chemical degradation of the herbal moieties (Ajazuddin and Saraf 2010). An understanding of the identity, purity, safety, physicochemical and biological properties of the ethnomedicines is important for the development of safe and efficacious NDDS.

Success Stories:

Phytosomes®

These are proprietary biomimetic food-grade delivery systems developed by Indena S.P.A. Italy, to optimize the bioavailability and pharmacokinetic profile of natural actives by formulating them with the dietary ingredient *lecithin*. The company has developed customised Phytosomes® for some phytocompounds as well as extracts (Table 1). These Phytosomes® can further be incorporated into dosage forms like tablets, capsules, soft gels and granules (Indena 2021) as desired.

Liposomes

These are microscopic vesicular structures composed of concentric bilayers enclosing a liquid compartment. Liposomes offer the unique ability to entrap both hydrophilic and lipophilic compounds, thus promoting solubilisation of less soluble drugs and also enabling multiple drug loading. The liposomal drug delivery market is expected to reach 8 billion USD by 2027 (Transparency Market Research 2021) and hence is a promising platform that can be leveraged for the delivery of phytoconstituents. Two liposomal formulations loaded with phyto-components, approved by USFDA, are enlisted in Table 2.

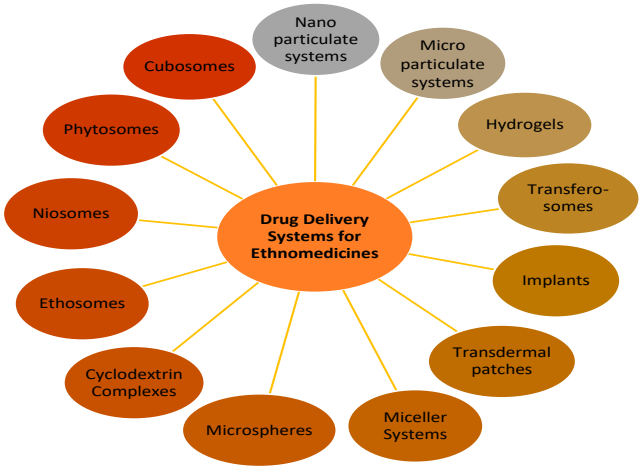

Fig. 2: Ethnomedicine containing NDDS in preclinical stages of research

Turmacin® and CurcuWIN®: Improved systems of the best-known ethnomedicine-Curcumin

Researchers continue to keenly attempt formulation development for Curcumin owing to its excellent therapeutic effectiveness in several conditions. Turmacin® and CurcuWIN® are two clinically-proven formulations developed for improved bioavailability and efficacy of curcumin. CurcuWIN®, a novel water-soluble curcuminoid composition, developed by OmniActive Health Technologies produced increased relative absorption of total curcuminoids 46 times over the standard curcumin. This product has been developed based on the company's patented UltraSOL Nutrient Delivery technology (https://omniactives.com/curcuwin/).

On the other hand, Turmacin® developed by Natural Remedies contains tumerosaccharides™ which are bioactive, water-soluble polysaccharides (with negligible curcuminoids), which effectively managed the symptoms of knee osteoarthritis and supported physical function of knee joints (Chandrasekaran et al. 2013). Turmacin® can be further converted in almost any suitable dosage form (https://naturalremedieshumanhealth.com/turmacin/).

Awaiting Clinical Success:

Several researchers across the world are actively envisaging formulation development for extracts as well as individual phytoconstituents or combinations thereof. These include micro and nano-particulate systems (including self-emulsifying systems), hydrogels, micellar systems and microspheres (Alexander et al. 2016). Recently transfersomes, ethosomes, niosomes, cyclodextrin complexes, implants, transdermal patches (Sen and Chakraborty 2019) and ribosomes (Garg, Saraf and Saraf 2007) have also been investigated for safe and efficacious delivery of phytoconstituents (Fig. 2).

Although several such systems have been reported to be efficacious in various preclinical studies, few have reached clinical stages. The stability and scale-up of such formulations are a major hurdle in their translation to the clinic.

Nonetheless, some ethnomedicines are in phase III clinical trials and may be expected to be approved for clinical use in the near future (Table 3).

Collateral Considerations for Effective NDDS Development

Systematic approaches need to be envisaged to develop efficacious formulations for ethnomedicines. Collateral considerations during development can enhance the outcomes of NDDS research, resulting

Table 1: Proprietary Phytosomes® exhibiting clinically proven improvement in drug pharmacokinetics

Trade Name	Encapsulated Phytoconstituent /Extract	Pharmacokinetic advantage
Siliphos®	Silybin	Silybin presents optimized biosorption when administered as Phytosome® compared to the unformulated extract.
Greenselect® Phytosome®	Catechin extract from green tea	Improved peak plasma levels and maintenance of optimal plasma levels of epigallocatechin gallate.
Merivar®	Curcumin	Optimised absorption and plasma levels of curcumin.
Casperome®	Purified mixture of triterpenoid acids from the gum resin of *Boswellia serrata*.	Optimized Cmax and AUC for all boswellic acids.
Quercefit™	Quercetin from *Sophora japonica L*.	Optimised absorption and plasma levels of quercetin.
Vazguard™	Bergamot extract	Optimised biosorption of naringin.

Source: https://www.indena.com/?s=phytosome

Table 2: USFDA approved liposomal formulations of phytomolecules

Trade Name	Encapsulated Drug	Lipid Composition	Indication	Advantages	Company	Reference
MARQIBO KIT® (liposome injection) (USFDA approval in 2012)	Vincristine sulfate	Cholesterol and eggs sphingomyelin	Acute lymphoblastic leukaemia	Liposomal formulation showed higher maximum tolerated dose, superior antitumor activity and delivered higher amounts of active drug to target tissues compared to standard Vincristine	Acrotech Biopharma LLC, USA	(Silverman and Deitcher 2013)
ONIVYDE (liposome injection) (USFDA approval in 2015)	Irinotecan Hydrochloride (a semi-synthetic derivative of Camptothecin)	PEGylated liposomes fabricated from 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol N-(carbonyl-methoxypolyethylene glycol-2000)-1, 2-distearoyl-sn-glycero-3-phosphoethanolamine (MPEG-2000-DSPE)	metastatic adenocarcinoma of the pancreas	Liposomal formulation achieved similar intratumoral exposure at a 5-fold lower dose of irinotecan hydrochloride in mice	Ipsen Biopharm Ltd, UK	(Ipsen Biopharm Ltd. 2021)

Table 3: Selected ongoing interventional Phase III clinical trials in India for ethnomedicinal components

CTRI No.	Health Condition	Ethnomedicinal Component/ formulation
CTRI/2017/09/009730	Patients with Chronic Periodontitis	2% curcumin gel with nanocarrier 1% chlorhexidine gel (Chlorite)
CTRI/2019/06/019889	Mild to moderate gingivitis	5 % Jamun mouthwash
CTRI/2020/03/024221	Osteoarthritis of knee	Liposomal Curcumin
CTRI/2020/05/025336, CTRI/2020/07/026515	Coronavirus as the cause of diseases classified elsewhere	Resveratrol-Copper tablets Chlorophyllin tablets
CTRI/2021/01/030470	Oral submucous fibrosis	Silymarin 1% Curcumin 10 mg
CTRI/2021/04/033188	Coronavirus as the cause of diseases classified elsewhere	Cardamom-based Sachet containing Cardamom extract 200mg, Rosemary extract 200mg, Pepper extract 10mg and total cineol content 97 mg
CTRI/2021/05/033886	Dental caries	Curcumin gel coated on gel foam

Source: Clinical Trial Registry of India, accessed on 24-6-2021

in the translation of a greater number of formulations from bench to clinic. Some of the approaches are briefly discussed below:

Preformulation Studies

Preformulation studies are a very essential exercise before attempting the development of suitable dosage forms for conventional drugs. Such studies, if carried out before envisaging the ethnomedicinal formulation development, can yield useful information which can give direction to the formulation development process. Determination of saturation solubility, log P and pKa wherever possible will be useful in determining the appropriate dosage form. Drug excipient compatibility studies are also critical, especially in the case of multi-component formulations.

Quality by Design (QbD) based formulation development

The USFDA encourages risk-based approaches and the adoption of QbD principles in drug product development. QbD based formulation development involves a systematic approach that begins with setting the expectation from the end product (quality target product profile-QTPP) and defining the product specification (critical quality attributes-CQAs) in advance. This is followed by identifying the critical material attributes (CMAs) and critical process parameters (CPPs) which will impact the desired QTPP. At the same time, a tight check is kept on the quality of every ingredient and process involved in the formulation (Yu et al. 2014). QbD can be applied at every stage of ethno-pharmaceutical development, right from the extraction process to standardisation using different analytical techniques to formulation development. QbD ensures robust, repeatable and scalable processes and also yields stable formulations.

Network Pharmacology

Network pharmacology is an integration of systems biology and computational biology and is used to study drug interactions with multiple targets. The rationale and scientific evidence for the pharmacodynamics of several ethnomedicines is often unclear. A network pharmacology study of medicinal botanicals can be an effective approach to understand the scientific basis of such formulations and this, in turn, could facilitate the transition from the single target-based drug discovery to multi-target based rational formulation discovery (Patwardhan and Chandran 2015).

Synergy Research

Most ethnomedicines are a combination of multiple plant extracts. The successful conversion of these formulations to modern medicines for clinical use demands that a rationale is found for their comparative pharmacological and therapeutic superiority over isolated single constituents. The synergistic efficacy of these combinations can be evaluated and verified by different reported methods. This will further aid in the decision to select the correct drug delivery system. Once done, this should be followed by clinical studies performed in comparison with synthetic standard drugs (Wagner 2011).

Conclusion:

Standardization, physicochemical evaluation and systematic investigation of therapeutic activity of ethnomedicines are the keys to the development of clinically successful formulations. Leveraging NDDS for the development of ethnomedicines is a highly effective strategy to integrate traditional medicines into modern clinical practice. Orthogonal approaches to formulation development of ethnomedicines can yield safe and efficacious formulations which are stable and scalable.

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ETHNO-MEDICINAL PLANTS FROM THE NORTH-CENTRAL WESTERN GHATS OF INDIA FOR ALTERNATIVE HEALTH CARE

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Ethnomedicine is practiced by various ethnic groups all over the globe those who have no access or little access to other systems of medicine or western medicine that are compared with traditional medicine based on bioactive compounds in plants and animals. The ethno-medicine is sometimes used as a synonym for traditional medicine. The North Central Western Ghats in India comprises rich bio-cultural diversity and is also home to varied ethnomedicinal practices. The certification and analysis of traditional knowledge regarding the practice and use of plants in the treatment of various human diseases is a herculean task for which Government, NGO and Herbal Drug Companies are being part of the system. The survey on relationship between human and nature has made it conceivable to realize the undercurrent existence of the communities and the bionetwork in which they inhabit together. Over the last decade there has been a rise in ethnomedicinal studies, still small is known about use of ethnomedicines in traditional health care system in India. Traditional system has unique and undeniably important cultural ingredients which use varieties of plant extracts, traditional knowledge and belief system for treatment as well as prevention of/from various disease and ailments.

Karnataka is blessed with some of the most splendid tropical forests of the Indian sub-continent. The state is endowed with varieties of forest vegetation with an enormous diversity of species and the floral diversity is so wide and varied, that in some districts, all types of forest from wet evergreen to dry thorn forest are encountered within a crow-fly distance of less than 100 km. About 60 of Karnataka's forests are situated in the Western Ghats, one of the mega biodiversity hotspots of the world. The remaining forests are situated in the Eastern Plains - although these have limited coverage - exhibiting high degree of plant diversity including varieties of medicinal plants. The total number of flowering plants (angiosperms) so far recorded in Karnataka is about 4,700 species belonging to 1,512 genera under 189 families. Out of these, over 600 species are endemic to southern India and 95 are exclusively endemic to Karnataka.

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Dr. Pramod J. Hurkadale is Professor of Pharmacognosy, KLE's College of Pharmacy, KLE Deemed to be University, Belagavi, Karnataka, India. Dr. Hurkadale has twenty one years of teaching and research experience in UG, PG and guided ten students for Ph.D programs under KLE University and supervised 25 students for Master's Program in Pharmacy. He has published and presented research papers in national and international journals/conferences and authored a book in Elsevier publishers and book chapter in Studium Press, USA. Dr. Hurkadale has been awarded Batch of the Best Award from Zydus-Indon Cadila Health Care Ltd, Ahmedabad and Best Teacher Award and Seed Money from KLE University, Belagavi. He has been Secretary to organize several workshops/conferences National and International which were sponsored by ICMR, AICTE, UGC, IPA, etc. and currently Coordinator for Society for Ethnopharmacology for Belagavi Chapter and Executive Council Member, Society of Pharmacognosy, India.

Forests of North Central Western Ghats of Karnataka Region

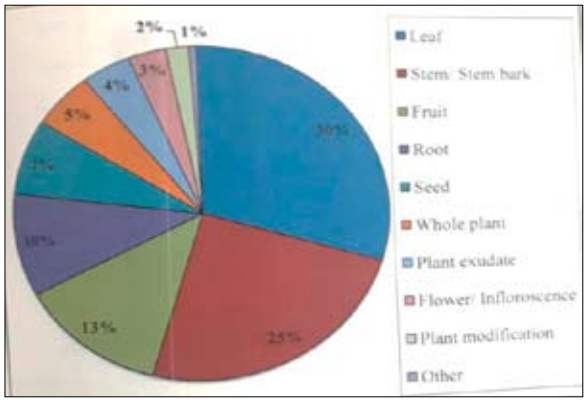
Agumbe, Arbail Ghat, Chorla Betta, Dandeli, Devimane Betta, Kankumbi, Yellapur Kaadu etc.

The forests of Karnataka are primarily deciduous and evergreen. Deciduous forests have preponderance of deciduous trees, whereas evergreen forests are dominated by evergreen trees. Deciduous trees completely shed their leaves for some time during the year; they have a distinct period of leaf lessness ranging from a few days to a few months. In tropical deciduous forests, leaf fall is primarily determined by reduction of water availability in the soil. Evergreen trees also shed their leaves but not all at the same time; they do not become leafless during any part of the year. In the driest parts of Karnataka, as also in the highly degraded forests of the state, there is predominance of thorny species. Appearance of thorny elements is reflective of the nature's adaptation to harsher conditions, where there is need for conservation of energy and water, besides warding off herbivorous intruders.

Types of Forest	
Southern tropical wet evergreen	Riparian fringing forest
Southern hill top tropical evergreen	Dry teak bearing forest
Southern subtropical hill	Very dry teak forest
South Indian subtropical hill	Dry Teak forest
Myristica swamps	Southern dry mixed deciduous
Cane brakes	Boswellia

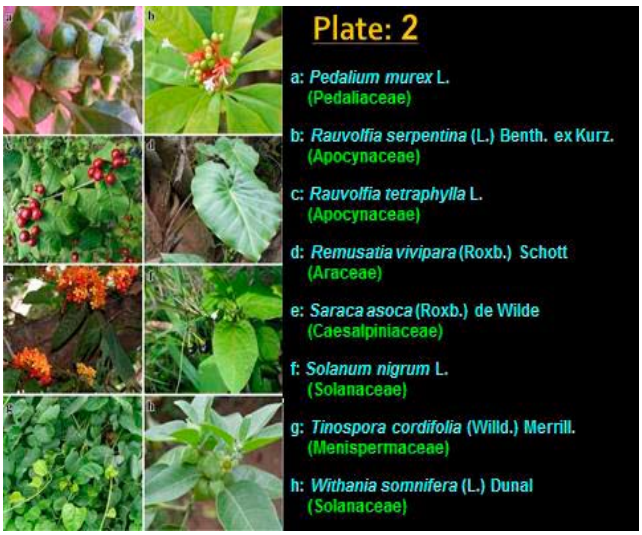
Sholas | Evergreen | Mangrooves

Ethnomedicinal Plant Parts Used



Wet Bamboo brakes	Hardwickia
Ochlandra reed brakes	Dry bamboo brake
Pioneer Euphorbiaceous scrub	Dry deciduous scrub
Mangrove	Dry savannah forest
Southern tropical semi-evergreen	Dry tropical riverain (fringing)
West coast evergreen Dipterocarpus	Secondary dry deciduous
Lateritic semi-evergreen	Euphorbia scrub
Moist bamboo brakes	Lateritic scrub
Southern tropical moist deciduous teak	Dry grass land
Very moist teak	Southern moist mixed deciduous
Moist teak	Southern thorn scrub
Slightly moist teak forest	Southern Euphorbia scrub

Medicinal Plants Used for Scientific Validation Study



The documentation of locally used ethnomedicinal plants of the above mentioned areas of Western Ghats resulted in further scientific validation to prove their efficacy and further develop herbal drug formulations in codified forms with the support of CCRAS, Ministry of Ayush that can emphasize these traditional healers and growers for conservation along with the sustainable utilization of threatened and endangered species.

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- Indian Society of Pharmacognosy, Karnataka

SFE – INDIA: GLOBALIZING LOCAL KNOWLEDGE AND LOCALIZING GLOBAL TECHNOLOGIES

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Ethnopharmacologyand Ethnomedicine – treasure of our ancient heritage and culture:

Ancient people threatened with several ailments that take quest to look forward to discover a wealth of useful therapeutic agents in the plant and animal. Ethnopharmacology is a multidisciplinary approach, where the medicinal use of plants, animals, fungi, microorganisms, and minerals explored and practiced by varied cultures of the human for their wellness. The knowledge of these medicinally active substances and their toxic potential was passed on by oral tradition and sometimes recorded in other texts. Ethnopharmacology is a multidisciplinary field comprising several aspects of newer drug development taking leads from nature mostly herbs and other natural products. This path was enlightened by our ancestors.

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Professor Pulok K. Mukherjee is working as the Director, Institute of Bioresources and Sustainable Development (IBSD), an autonomous Institute under Department of Biotechnology, Govt. of India consisting of its four centers in North east India Imphal, Manipur; Aizawl, Mizoram; Gangtok, Sikkim and Shilong, Meghalaya. Previously, he worked as the Director of the School of Natural Product Studies, and Head of the Department and Professor (on Lien) at the Dept. of Pharmaceutical Technology, Jadavpur University, Kolkata. He has authored/edited 7 books and 20 book chapters with reputed publishers including Elsevier, Academic Press, Wiley, Pharma Press etc. He has several national/international patents, and more than 220 research publications having total Impact Factor >271; h-Index- 68, i10-index - 349; citation over 22110 times. Prof. Mukherjee is a Fellow of the Royal Society of Chemistry (FRSC), Fellow of the National Academy of Agricultural Sciences (FNAAS), Fellow of National Academy of Sciences, India (FNASc) and has been awarded with many laurels from Govt. of India and abroad including prestigious Commonwealth Academic Staff Fellowship from Association of Commonwealth Universities [ACU], UK; TATA innovation fellowship, by Department of Biotechnology, Govt. of India; IASTAM Award for Contributions to Development of Ayurvedic and Herbal Pharmaceutics by Indian Association for the Study of Traditional Asian Medicine (IASTAM) and many others. Prof. Mukherjee is serving as Consulting Editor of Pharmacological Research, Associate Editor of the Journal of Ethnopharmacology, Phytomedicine Plus Elsevier Science. He is the member of the editorial board of several International journals including Phytomedicine, Pharmaceutical analysis, Synergy; Phytochemical Analysis, World Journal of Traditional Chinese Medicine, India J Traditional Knowledge and many others. He is associated as advisor/member to different organizations and administrative bodies of Government of India He is the Secretary of the Society for Ethnopharmacology, India (SFE-India) and President, International Society for Ethnopharmacology (ISE), Switzerland.

Ethno-medicine stands for a unique viewpoint for extensive and multidisciplinary research with the integrated approaches for development of newer drug from natural resources especially from medicinal plants. In the present scenario, "Ethnomedicine" is the important branch of natural science and its potential as alternative medicine. Traditionally used medicinal plants are the rich source of chemically diverse phytoconstituents, which are therapeutically active. Ethnopharmacology is not just a science of the past using an outmoded approach. It still constitutes a scientific backbone in the development of active therapeutics based upon the traditional medicines of various ethnic groups. The scientific validation of Ethnopharmacology and ethnomedicine through integration of translational research approach is required to explore the exploit our ancestoral medicine system for human wellbeing.

Traditional Medicine includes the longstanding remedies passed on and practiced by the Traditional Health Practitioners (THP) for prevention and treatment of diseases and is composed of several systems of medicine from different parts of the world. It has been estimated that two-thirds of the world's population seek healthcare from sources other than conventional biomedicine, while many of these individuals undoubtedly seek their remedies from various TM. In different parts of India, Traditional health practitioners are conserved due to their communication problem to main stream of the society and they are also not recognized by the common people due to lack of scientific evidence of their traditional practices.

India has its own ancient heritage of traditional system of healing. Indian Traditional system of Medicine comprises of wide knowledge base on folklore practices of traditionally inspired medicine. Drugs derived from traditional systems, 400 are of mineral and animal origin while the rest are of vegetable origin. India has a rich heritage of traditional medicine and traditional healthcare systems that have been proliferating for many centuries. Ayurved, Yoga &Naturopathy, Unani, Siddha and Homeopathy (AYUSH) are the official Indian traditional systems of medicine. Indian traditional medicine is mainly established on AYUSH, with the emerging interest of the world in adopting and studying traditional systems, and in enabling their potential to emerge from different healthcare perspectives.

The importance of ethnopharmacology is growing to maintain wellness for better quality of life when lifestyle and disease patterns are changing. Authentication and scientific validation of folk medicine including medicinal plants/herbs are fundamental requirement of industry and other organizations dealing with herbal drugs. The most important cause to accept the ethnomedicine is accessibility, associability and affordability. So, to ensure this wellness, proper scientific validated documents are the need of the hour to develop safe and efficacious quality products as alternative therapeutics in healthcare system (Mukherjee et al., 2015).

Society for Ethnopharmacology, India (SFE-India)was established in 2013 and has taken the initiative for dissemination of knowledge in this area and to bring them to the limelight of

scientific field to enrich the healthcare of the society. SFE used to organize workshops/seminars symposia etc. in different parts of India, where several scientists, technologists, doctors, government officials from different parts of the world shared their experiences with the Traditional Healthcare Practitioners (THPs) based on their different traditional healthcare practices with varied culture and biodiversity for their betterment. To recognize the traditional practices, SFE has proposed a global platform to explore and disseminate the ethnopharmacological knowledge in the development of ethnic health care practices so as to globalize the local Knowledge and localize the global technologies.

The Society for Ethnopharmacology:

The Society for Ethnopharmacology (SFE) India is a registered society under the West Bengal Society Registration act and affiliated to the International Society for Ethnopharmacology (ISE) Switzerland. It is an international scientific organization dedicated to the interdisciplinary study for evaluation of plants, animals, insects, and other organisms used in medicines of indigenous and modern, past and present, cultures. The society is also committed to the preservation and conservation of such practices for future generation.

After the grand success of the 12th International Congress of International Society for Ethnopharmacology (ISE) organized by the School of Natural Product Studies, Jadavpur University Kolkata in February 2012, the Society for Ethnopharmacology, India (SFE – India) was constituted in 2013. The Society is extremely grateful to Late Dr. APJ Abdul Kalam, former President of India, for his inspiration and support since its inception. Dr. APJ Abdul Kalam inaugurated the 12th International Congress (ISE) (Figure 1), where he addressed the gathering through his thought on *"Dynamics of Ethnopharmacology"*.

The Society for Ethnopharmacology, India (SFE - India) was constituted by the eminent academicians, researchers, industrialists and others with the vision of providing an environment for knowledge sharing among industrialists, researchers, students, healthcare practitioners, decision-makers and others interested in promotion of Ethnopharmacology and medicinal plant. The mission of the society is promotion and development of traditional medicine and medicinal plants through dissemination of knowledge and development of collaboration and cooperation with it's vision on

"Globalizing local knowledge and localizing global technologies"

Society of Ethnopharmacology (SFE) is dedicated to integrate stakeholders from diverse arenas like traditional healers, academia, and industry in a single platform for effective interaction which is very helpful for the promotion and development of Indian Systems of medicine at large. The major emphasis is being given on ethno-medicine and traditional health practices particularly highlighting learning from the nature, learning from our ancestors where tradition meets innovation. Society has taken several initiatives to provide free consultation to the cultivators to grow medicinal plants to improve their economic condition.

Major Objectives of the Society for Ethnopharmacology

Society of Ethnopharmacology (SFE-INDIA) is dedicated for the dissemination of knowledge and information through different educational programmes throughout India and also to serve as a bridge between industry and academia for development of products, process for value addition and promotion of medicinal plants as well as herbal medicines used in ancient system of medicine and folklore. It also promotes activities for sharing of experience on the scientific evaluation of Ethnopharmacology of Herbal Medicines for betterment of healthcare of the society. The society is also committed to the preservation and conservation of such practices for future generations. The major activities of the society are:

- ☐ Dissemination of knowledge for promotion and development of Ethnopharmacology and medicinal plants.
- ☐ To carry out the objectives of the International Society for Ethnopharmacology.
- ☐ Organizing conferences, seminars, symposiums, workshops etc. in different parts of India.
- ☐ Promotion and development of Ethnopharmacology, Herbal Medicines, medicinal plants and other natural products in India.
- ☐ Promotion of the healthcare of the society.
- ☐ Sharing knowledge on various issues on cultivation, production and validation of traditional medicine, quality & safety evaluation, pre-clinical screening & clinical studies and several other issues of natural products.
- ☐ Act as a resource at local level for individuals including students interested in Ethnopharmacology.
- ☐ Encourage career growth and knowledge empowerment of its members.
- ☐ Publishing journals, newsletters, documents, books, etc. for promotion of knowledge in the field of natural product research.

Awards Initiated by Society for Ethnopharmacology

To recognize the outstanding contribution in the area of medicinal plant research and Ethnopharmacology, the society has instituted several awards which are conferred during the International congress of the society every year. The following awards has been initiated and conferred by the Society for Ethnopharmacology, India:

a) SFE - Lifetime Achievement Award

b) SFE - Outstanding International Ethnopharmacologist Award

c) SFE - Outstanding National Ethnopharmacologist Award

d) SFE - ZANDU Award for "Best Research on Plant Drugs" – supported by Emami Ltd., Kolkata

e) SFE - Outstanding Service Award

a) SFE- Dr. Tuhinadri Sen Oration Award

b) SFE - Herbal Industry Leader Award

c) SFE – Special Recognition Awards

d) SFE – Outstanding Local Chapter Award

e) SFE- Young Ethnopharmacologist Award - *"Dr. PK Debnath Memorial Award"*

Glimpses of some Activities of the Society for Ethnopharmacology

The society organizes conferences, seminars, symposiums, workshops etc. in different parts of India and abroad for discussion and sharing knowledge on different issues for cultivation, production, quality evaluation, safety, clinical studies, biological screening and several other issues of natural product research.

The Society helps in forming bridge between the academia and industry for developing cost effective natural remedies. Presently the Society has several local chapters with dynamic coordinators for individual chapters and over 500 members across the country. For dissemination of knowledge, several chapters of the society have been made with active leaderships of the local chapter coordinators from different parts of India. The society has organized several seminars, conference etc. throughout the country since 2013. Some specific activities of the Society for Ethnopharmacology, India and its different local chapters are as follows:

- The 7th convention and international symposium *"Combating COVID-19 - Ethnopharmacology and Traditional Food & Medicine"* was held during December 17-19, 2020 by Institute of Bioresources and Sustainable Development (IBSD) Imphal, Manipur, India in association with Society for Ethnopharmacology (SFE - INDIA) and International Society for Ethnopharmacology (ISE). The conference was preceded in virtual mode which boasted with 60 lectures across 10 sessions. An ethnopharmacology conclave session with several traditional healthcare practitioners. A student interactive forum was organized with research scholars from more than 05 different countries. The event was successful with an attendance of more than 600 participants from more than 15 countries and 52 oral presentations across two sessions.
- The Institute of Bioresources and Sustainable Development in association with Society for Ethnopharmacology (SFE - INDIA) and International Society for Ethnopharmacology (ISE) started the International Webinar series on "Reimagine ethnopharmacology" to grow interest and globalize local research during the pandemic period. The series is conducted virtually on Saturdays at 6:00 PM (IST) to cover maximum time zones of the world. So far, 36 sessions have been conducted since May 2020, with the involvement and deliberation of more than 65 eminent scientists and policy makers from India as well as throughout the globe to grace the series with their highly informative talks. Collectively more than 10,000 participants from more than 40 countries have attended the series so far.
- The 7th International Congress of Society of Ethnopharmacology, India (SFEC 2020), New Delhi, India was organized by School of Pharmaceutical Education and Research; Jamia Hamdard, New Delhi, India during February 15-17, 2020. The theme of this event was *"Ethnopharmacology in development of scientifically validated quality products from Medicinal plants and Regulatory aspects"*. World renowned researcher has addressed various sessions on validation of quality products from medicinal plants. The major highlights of the congress were the keynote sessions with three lectures from Chairman SFE, President American Herbal Pharmacopoeia and Principal Advisor (THISTI), INDIA; the 08 plenary sessions with 57 lectures. The program was evidenced with a great success with the participation of speakers from more than 15 countries, more than 500 participants and 52 oral presentations across two sessions were made. Figure 2A represents a few glimpses of the event. A special session on "Food as Medicine – Exploring therapeutic potential" was an effective conglomerate discussed the effectiveness of foods as therapeutic agents. The congress also organized an effective Ethnopharmacology Conclave session and a Student Interactive Session.

- It was a great pleasure to invite Natural Products Scientists (NPS) from all over the world to attend the PSE-NPS 2020 Summit on "Natural Products for Healthy Living" held in Khulna University, Khulna, Bangladesh, during 16-18 January 2020. The PSE-NPS 2020 Summit was organized by the Pharmacy Discipline of Khulna University, in association with the Phytochemical Society of Europe (PSE). This program was cobadged with International Society for Ethnopharmacology (ISE) and Society for Ethnopharmacology, India (SFE).The conference focused on "Natural productsfor healthy living" to explore the prospects and challenges associated with research in natural products and dietary nutraceuticals. The summit was a huge success with 14 lectures from eminent scientists, 60 oral presentations and poster presentations by various research scholars across three days.

- International Conference on & *"Ethnopharmacology – Validation of Traditional Medicine"* was organized by Poona College of Pharmacy, Bharati Vidyapeeth, Pune, India in association with the Society for Ethnopharmacology, India at Pune, MH, India during November 29-30, 2019. Several eminent scientists had addressed several aspects on quality control and standardization, evaluation of safety and efficacy, pharmacovigilance and all other aspects on newer drug development from botanicals. The program was evidenced with a great success with the participation of more than 500 participants with around 150 posters and 25 oral presentations were made. A scientific exhibition of advanced analytical instruments, traditional formulations and book stall attracted all delegates. We would like to express our sincere thanks to Dr. Sathiyanarayanan L., Coordinator, Pune Local Chapter, SFE-India and other active members of the organizing committee for their efforts to make the event successful.

- The Bhopal Local chapter organized a National Seminar and Workshop on application of high throughput screening methods based on molecular markers in new drug discovery" at Truba Institute of Pharmacy, Bhopal, MP, India in association with Society for Ethnopharmacology, India during September 13-14, 2019. This seminar was attended by more than 400 participants with around 70 posters and 50 oral presentations. Eminent speakers had addressed several crucial and contemporary issues especially on quality evaluation, high throughput screening methods for newer drug development form natural products. We would like to express our sincere thanks to Dr. Rajesh Singh Pawar, Coordinator, Bhopal Local Chapter, SFE-India and his active team member for organizing this event.
- The 6th Convention of the Society for Ethnopharmacology (SFE) and National Seminar on "Translational Research of Traditionally used n Medicinal Plants with special reference to *Tinosporacordifolia"*, was organized by the School of Natural

Product Studies, Jadavpur University, Kolkata in association with the Society for Ethnopharmacology, India during September 7-8, 2019 at Jadavpur University, Kolkata (Figure 2A). Fourteen speakers spoke on five plenary sessions from all sphere of research on ethnopharmacology together with 72 scientific presentations, including oral and poster during this program. This program was attended by more than 400 participants from different parts of India.

- The 6th International Congress of the Society for Ethnopharmacology (SFE), was organized by the Society for Ethnopharmacology, India during January 13-15, 2018 in association with the Manipal Academy of Higher Education (MAHE), Manipal, Karnataka, India during February 8-10, 2019. The theme of the congress was 'Medicinal plant and Traditional Medicine-Ethnopharmacology at the interface of local and global needs'. This congress was focused on several crucial and contemporary issues on the scientific study based on of Ethnopharmacology and medicinal plants by the renowned scientists throughout the world. This program was attended by more than 350 participants. This program also associated with the Synergy Symposium on "Synergy Research on Natural Drugs and Compounds" and Ethnopharmacology Conclave followed by interactive session with Traditional Healers for documentation of Local Health Traditions (LHTs) and Ethno Medical Practices (EMPs). We will express our sincere thanks to Prof. N Udupa, Prof. S. Khan and other active members of the organizing committee for their efforts to make the event successful. Few glimpses of the event has been presented in Figure 2B.

- The International Conclave on "Ethnopharmacology, Ethnomedicine and Traditional Health Practices: Global Scenario" was organized by Society for Ethnopharmacology, Kolkata, India (SFE-India) jointly with World Ayurveda Foundation, Bengaluru, Karnataka at Ahmedabad, Gujarat, India as a part of 8th World Ayurveda Congress & AROGYA Expo (8th WAC), during December 16-17, 2018. The major thrust areas of the conference included "Learning from nature and our ancestor: Tradition meets Innovation". There was an interactive session between traditional health practitioners and the scientists. The program was accomplished with a great success with an overwhelming response of more than 300 participants from different states of the country.

- The 1st International Conference on "Globalisation of Traditional Medicine" was organized by the School of Health Science, Mae Fah Luang University in association with the Society for Ethnopharmacology, India at Mae Fah Luang University, Chiang Rai, Thailand during December 6-7, 2018. The scientific program deals with a variety of topics focused on development of health care through herbals will be addressed. We are very much thankful to all the colleagues of the School of Health Science, particularly Dr. Rawiwan, Organizing Secretary and her esteemed group members of Mae Fah Luang University, Chiang Rai, Thailand for taking keen initiatives with SFE India for organizing this event and developing the scientific program. This program had more than 70 scientific presentations with participation over 200 delegates from different parts of world.

- The Mumbai Local Chapter of SFE-India organized National Seminar on "Nutraceuticals: Recent Trends and Advances" at Bombay College of Pharmacy, Mumbai, MH, India on November 30, 2018. This program was attended by more than 250 participants and had several scientific presentations. We would like to express our sincere thanks to Dr. AlkaMukne, Coordinator, Mumbai Local Chapter, SFE-India and her active team member for organizing this event.

- The 5th Convention of SFE-India and the National Symposium on "Promotion and Development of Indian Medicinal Plants – special reference to Brahmi (*Bacopamonnieri*) was organized by the School of Natural Product Studies, Jadavpur University in association with Society for Ethnopharmacology, India (SFE-India) at Jadavpur University, Kolkata on September 7-8, 2018 (Figure 2C). This convention has evidenced with participation over 350 participants from different states of the country and had more than 105 scientific presentations including oral and poster session.

- 18th International Congress of International Society for Ethnopharmacology (ISE) and the 5th International Congress of the Society for Ethnopharmacology (SFE), India (ISE-SFEC 2018) was organized by the Society for Ethnopharmacology, India during January 13-15, 2018 in association with the Department of Pharmacy, Faculty of Pharmacy, University of Dhaka. The theme of the congress was 'Ethnopharmacology& Drug Development: Innovation meets Tradition' at NababNawab Ali Chowdhury Senate Bhaban, University of Dhaka. It was focus on several crucial and contemporary issues on the scientific study based on Ethnopharmacology and medicinal plants by the renowned scientists throughout the world. The scientists, educationists, students, regulatory bodies and manufacturers from 32 countries had attended. Moreover, about 150 Indian scientists, educationists, manufacturers and students were also participated in this big event. The total of 850+ delegates or participants attended this congress on traditional medicine including 650 from Bangladesh. Through this congress, our students, teachers, manufacturers and regulatory body have enriched their knowledge and expertise through exchanging their views and ideas with national and foreign participants. This acquired knowledge definitely will help us to produce quality traditional medicines for the people of Bangladesh. Speakers from different parts of the world had given emphasis on herbs and plants as essential drugs in primary healthcare as it is derived from nature, which is very safe and useful for human

health. We are very much thankful to Prof. Sitesh C Bachar, Prod. Abdur Rashid and other members of Dept. of Pharmacy, University of Dhaka for organizing this mega event.

- The 4th Convention of SFE-India; the National Symposium on "Ashwagandha" and Ethnopharmacology conclave on "

Uses of Medicinal Plants by Traditional Healers of India – Local Health Tradition" was organized School of Natural Product Studies, Jadavpur University in association with Society for Ethnopharmacology, India (SFE-India) at Jadavpur University, Kolkata on September 09-10, 2-17. This convention has evidenced participation of over 300 participants from different states of the country and had more than 110 scientific presentations including oral and poster session.

- SFE-India Nagpur Local Chapter organized a "National Conference of Traditional Community Health Practitioners

for Conservation of Lokswasthyaparampara" on 22nd July 2017 in association with Maharashtra State Biodiversity Board, Forest Development Corporation of Maharashtra, at Mission India Campus, Khadgaon, Nagpur. This program was attended by about 800 delegates comprising healers, physicians of various pathy, scientists, researchers from various institutes and students. SFE-India thanks to Dr. Prakash R Itankar, Coordinator, Nagpur, Local Chapter and his team for organizing this event.

- The 4th International Congress of Ethnopharmacology was held at UkaTarsadia University, Bardoli, Surat, Gujarat, India

during February 23-25, 2017 with the theme "Health care in 21st Century: Perspective of Ethnopharmacology and Medicinal Plant Research". The program was jointly organized by the Society for Ethnopharmacology, India (SFE, India) and the C.G. Bhakta Institute of Biotechnology &Maliba Pharmacy College, UkaTarsadia University, Bardoli, Surat, Gujarat. The 4th International Congress of Society for Ethnopharmacology focused on recent advances in Ethnopharmacology and related aspects. The Congress was attended by over 1000 delegates from several countries and different states of India with 78 plenary and special lectures, 105 oral and 400 poster presentations on diverse fields of the medicinal plants and ethnopharmacological research. SFE-India thanks to Dr. Ramar Krishnamurthy and his team for organizing this event.

- The International Conclave on "Ethnopharmacology, Ethno-medicine and Traditional Health Practices: Learning from

the Nature: Tradition to Innovation" was organized by Society for Ethnopharmacology, Kolkata, India (SFE-India) jointly with World Ayurveda Foundation, Bengaluru, Karnataka at Science City Auditorium, Kolkata as a part of 7th World Ayurveda Congress & AROGYA Expo (7th WAC), during December 3-4, 2016. The major thrust areas of the conference included Ethno-medicine, Ethnopharmacology & Drug development – Global perspectives, Traditional to Modern Pharmaceuticals. There was interactive session between traditional health practitioner and the scientists. The program was accomplished with a great success with an overwhelming response of more than 300 participants from different states of the country.

- The 3rd International Congress of the Society for Ethnopharmacology (SFEC 2016) was organized by National

Centre for Natural Resources (NCNR), Pt. Ravishankar Shukla University, Raipur, Chhattisgarh, India, during February 19-21, 2016 (Figure 2D). Prof. S K Pandey, Vice Chancellor, Pt. Ravishankar Shukla University was the Chairman, Dr. Atanu K Pati, was the organizing secretary and Dr. ShailendraSaraf, Coordinator, SFE-India, Raipur, Local chapter was the Joint organizing secretary of the 3rd International Congress of SFEC 2016, Raipur.

- 3rd Convention and the National Seminar on "Analytical techniques for drug discovery & development from natural

products" was organized School of Natural Product Studies, Jadavpur University in association with Society for Ethnopharmacology, India (SFE-India) at KP Basu Auditorium, Jadavpur University, Kolkata on September 24, 2016. The seminar was attended by more than 180 delegates with above 40 scientific deliberations.

- The 2nd National Convention of the Society for Ethnopharmacology, India on "Integrated Approaches for Promotion and Development

of Herbal Medicine." was organized by School of Natural Product Studies, Jadavpur University, Kolkata during December 5-6, 2015. The seminar was attended by more than 300 delegates from different parts of India with above 150 oral/poster presentations.

- The 2nd International Congress of the Society for Ethnopharmacology (SFEC) was organized by the Department

of Pharmaceutical Sciences, R. T. M. Nagpur University, Nagpur, India, during February 20-22, 2015. Dr. Prakash R. Itanakr, Coordinator of Nagpur local chapter was the organizing secretary of the 2nd International Congress 2015 (www.sfec2015.com). The congress was attended by over 1000 delegates from different countries of the world. SFE-India thanks Dr. Prakash Itankar, Coordinator, SFE-India Nagpur local chapter for organizing this event.

- The 1st National Convention of the Society for Ethnopharmacology, India on "Opportunities in Medicinal Plant Research" was organized by School of Natural Product Studies, Jadavpur University, Kolkata in association with Society for Ethnopharmacology, India during November 29-30, 2014. The seminar was attended by more than 500 delegates from different parts of India with above 200 scientific deliberation.

- The 1st International Congress of the Society for Ethnopharmacology, India was organized at Chennai in association with the Sri Ramachandra University, Porur, Chennai on "Globalization of Traditional Medicine: Present and Future perspectives" during March 7-9, 2014. The event has evidenced with the participation over 700 delegates from 20 different countries across the globe with more than 300 scientific presentation including oral and poster session. SFE-India would like to thanks Dr. Chamundeeswari and team of Chennai local chapter for organizing this event.

- Several invited lectures by distinguished speakers were arranged by the SFE-India, Kolkata on emerging topics on Ethnopharmacology and promotion of medicinal plants by the Society office at Kolkata and also in collaboration with School of Natural Product Studies, Jadavpur University, Kolkata in every year to discuss different aspects of Natural Product Research by eminent scientists throughout the globe.

Special issues developed in journals:

Society for Ethnopharmacology developed several special issues in peer reviewed National/ International journals for the promotion and development of Ethnopharmacology, Ethnomedicine and medicinal plants research. The following special issues were made with the collaboration and coordination with the eminent scientists, policy makers throughout the globe. Figure 3 represents different special issues developed by Society for Ethnopharmacology, India.

- A special issue on "Ethnopharmacology and validation of Traditional Medicine" was developed by Society for Ethnopharmacology, India and published in Indian Journal of Traditional Knowledge; Volume 14 (4), (October 2015). This special issue was edited by Dr. Pulok k Mukherjee; Dr. Tapan K Mukherjee. This issue is available in http://nopr.niscair.res.in/handle/123456789/32961.
- A special issue on "Ayurveda" was published in Journal of Ethnopharmacology, Elsevier Science, USA; Volume 197, Pages 1-306 (February 2017). This was an initiative by Society for Ethnopharmacology, India to promote Traditional Medicine. This special issue was edited by Dr. Pulok K Mukherjee; Dr. CK Katiyar and Dr. BhushanPatwardhan. This issue is available in https://www.sciencedirect.com/science/journal/03788741/197/supp/C
- A special issue on Ashwagandha will be published in Journal of Ethnopharmacology, Elsevier Science, USA. This is an initiative by Society for Ethnopharmacology, India to promote Indian Medicinal Plants at large. This special issue will be edited by Dr. Pulok K Mukherjee; Dr. CK Katiyar and Dr. BhushanPatwardhan. https://www.elsevier.com/journals/journal-of-ethnopharmacology/0378-8741/guide-for-authors

Figure 3. Special issue in journals developed by SFE-India

- A special issue on "Metabolomics and Ethnopharmacology in the Development of Herbal and Traditional Medicine" has been developed by the Society for Ethnopharmacology, India and published in Frontiers in Pharmacology (Ethnopharmacology). This special issue has been made based on the scientific deliberations made in 7th International Conference of SFE-INDIA (SFEC 2020), New Delhi. Dr. Sayeed Ahmed, Prof. Pulok K Mukherjee, Dr. C K Katiyar and Dr. Gudrun S. Ulrich-Merzenich serving as the Editor of this special issue. https://www.frontiersin.org/research-topics/14729/metabolomics-and-ethnopharmacology-in-the-development-of-herbal-and-traditional-medicine

Conclusion:

Thus, the Society for Ethnopharmacology, India (SFE-India) even though so young has made several outreach activities for development of different aspects on promotion of Tradition Knowledge, particularly focusing its main highlights on "Globalizing local knowledge; localizing global technologies"for a healthier tomorrow, capitalizing the very rich heritage and cultural resources of India, which is so ethnic, so ancient.

We cordially invite you all to join SFE-India and explore the opportunities.

For further details, you may visit www.ethnopharmacology.in

In Memoria

This article is dedicated in the memory of Shri. Sibeswar Saha (1935-2021), who was instrumental to develop the Society for Ethnopharmacology, India. We are very much grateful and thankful for his encouragement and support.

Letters to Editor

Congratulations to the PCI President and Appeal to All State Branches of IPA (Drug Information Pharmacist and Clinical Pharmacist posts in hospital)

It is a matter of pleasure for the Pharmacy fraternity that a Gazette notification has come last week making provisions of Engagement of 'Drug Information Pharmacist' and 'Clinical Pharmacists' in each hospital. This is in consonance with the demands of the Hospital Pharmacy Division of IPA since long to utilize the expertise of M. Pharm. and Pharm. D. qualified Pharmacists in hospitals to provide better Pharmacy services in the treatment of patients as a part of the hospital pharmacy services. A sufficient number of pharmacists are available to take up the job.

Hence let me first congratulate Dr. B. Suresh, President, Pharmacy Council of India to issue notification on 30th June, 2021 and its Gazette notification in Extraordinary section 4 on 5th July, 2021 related to engagement of 'Drug Information Pharmacist' and 'Clinical Pharmacist' in each hospital of our country. Besides providing job opportunities to our pharmacists, this notification provides a scope to prove our expertise among the medical fraternity for the treatment of patients as a member of healthcare provider, which will justify recognition, status and better pay scale.

In view of the Gazette notification, I would appeal to our Hon'ble Union Health Minister and all Hon'ble Health Ministers of each State and Authorities of all private/ corporate hospitals to honor this Gazette notification by making engagement of pharmacists as Drug Information Pharmacist and Clinical Pharmacists in their hospital to provide better services in hospitals.

Further, I would appeal to all the Presidents and Secretaries of each State branch of IPA to send a request letter to their Health Minister for its immediate implementation and to do a follow-up.

We should avail this golden opportunity for the betterment of our Pharmacy Professionals in general and our IPA member in particular.

Dr. R.N. Gupta
Chairman, Hospital Pharmacy Division
Vice President, Indian Pharmaceutical Association

While going through the website of the Pharmacy Council of India (PCI), I came across the following data on pharmacy colleges in India-(2019)

- 3077 Diploma Colleges (Total seats- 1,80,000 per year)
- 1961 Degree Colleges (Total Seats- I,25,524 per year) and
- 875 Post Graduation M. Pharm Colleges
- 267 Pharm. D Colleges,(Total Seats- 8010) started since 2008- five-year doctorate program
- Preparing – total 3, 14, 304 - budding Pharmacists per year
- Total number of Registered Pharmacists (as on 13.11.2017) – 9,07,1329((National Health Profile -2018, Government of India publication)
- **If we add to that around 3 lakhs new pharmacists produced during last two years, the total number of pharmacists presently would be approximately**
- **9 lakhs(old) + 6 lakhs(new)= 15 lakhs Pharmacists**

As against this, what is the status of employment potential available for the budding pharmacist? When we look at it, the present condition is very pathetic. Like in case of doctors and nurses, no specific ratio of number of pharmacists to number of patients/ beds, no revised job chart in a hospital is defined by the government. As a result, when pharmacists are hired in hospitals, they have no revised job profiles to put into practice what they have learnt, working conditions are poor and salaries are too low. Hence only minimum and mandatory numbers of qualified pharmacists are appointed both in public and private hospitals.

Surprisingly, if you look at the National Health Policy and The National Health Profile Report, 2018, it has not given serious thought to put into use the full potential of the current revised status of pharmacy profession as done all over the world and has not shown any keen interest and specific importance to hospital pharmacy profession.

Presently, in Indian private hospitals, to run pharmacy services in private hospitals only retail pharmacy license from FDA is required and that is also not mandatory in public hospitals. The overall lax regulation has resulted in a paradoxical situation. On one side, no employment to qualified staff having postgraduates and Pharm D. degrees and, on the other side, most community pharmacy services in slums and in rural areas are offered by unqualified staff called 'Zola Chaph' pharmacists.

Situation of Pharmaceutical Care in Indian Hospitals -

As against the global scenario, the hospital pharmacy services in India are in very bad conditions and it is the most neglected profession in Indian Health Care services in public as well in private sector.

Most hospital medical stores in private hospitals are managed by commerce graduates and materials managers. Barring few states like Maharashtra, in most Public Hospitals still the status of hospital pharmacist is no more than a compounder.

It is reported that there is poor job satisfaction among pharmacists working in different pharmacy sectors including community pharmacies, hospitals, pharmaceutical industries and academia. In India, pharmacies often operate without a registered pharmacist.

All The Pharmacy Professions are working in Silos-

Currently, the four pharmacy professions in India namely Hospital, Community, Regulatory and Education are working in silos. If we really wish to upgrade the status of pharmacy profession in India, we need to think very seriously now to bring all these four pharmacy faculties under a single umbrella and put efforts to establish a separate directorate of pharmacy services in each Indian state.

Establishment of Directorate of Pharmaceutical Services in all Indian States-

Through PCI and state level PCIs, and through IPA, we need to convince State Ministry of Health and concerned government authorities across India, to establish a separate state level Directorate of Pharmaceutical Services in all Indian states. The structure of the directorate is described in my article published in

Pharmatimes (CLINICAL ESTABLISHMENT ACT 2010: THE LIGHT OF HOPE FOR HOSPITAL/CLINICAL PHARMACY PROFESSION IN INDIA-Pharma Times - Vol. 52 - No. 06 - June 2020, 28- 31). This has always remained my dream to establish such a directorate of pharmaceutical services at each Indian state.

During 2009-2012, I was working as an Assistant Director (Drug Purchase Cell) in the Ministry of Medical Education and Health, State of Maharashtra. This post was a very high-level position and I had very good rapport with the minister and secretary. Using this as an opportunity, I started thinking about creating a few 'Class One and Super Class One posts' under the Directorate of Medical Education and Research (DMER), State of Maharashtra.

At that time, in Maharashtra state, the post allotment to pharmacy profession under Directorate of Health Services (DHS), under Directorate of Medical Education and Research (DMER) and under Municipal Corporation of Greater Mumbai (MCGM) were as follows:

Under DMER- There were six posts of Class Two Pharmacists,(one at each six-government run medical colleges). There was no post of Class One Pharmacist and there was one post of Assistant Director at state level, heading state drugs procurement department, which I was holding.

Under DHS – There was and still there is not a single post of Class One or Super Class One cadre. All posts are Class Three cadre.

Under MCGM- There are two posts of Superintendent and three posts of Deputy Superintendents in Corporation Medical colleges attached to K.E.M., Sion, Nair and Kasturba Hospital

Using my good contacts and due to sincere hard work, I was successful in introducing pioneering and effective policies in State's medicine procurement, which has been replicated later on by many states and central government procurement agencies under Ministry of Defense, Employees State Insurance Schemes, etc. This helped me a lot in convincing the ministers and secretaries and I was successful to create five posts under DMER for pharmacy profession –one additional posts of Assistant Director, (at the cadre of Super Class One) and Four posts of Class One called Superintendent of Pharmacy one at four medical colleges attached to hospitals namely, Sir J. J. Hospital and Grant Medical College, Mumbai, B.J. Medical College, Pune and at Government Medical Colleges at Nagpur and Aurangabad in Maharashtra State.

With this achievement, I retired in 2012, feeling very happy, thinking that I could take some good initiative for the betterment of my profession.

However, now more than nine years have passed, but unfortunately, still not only these newly created five posts but even the post of Assistant Director from which I retired (nine years back) have not yet been filled by the government!

Because, it is usual thinking of government authorities that as these posts are not filled during the last nine years, and no one from the department has shown interest or taken any initiative to fill them, so why not dissolve these posts? Similar approach is seen with MCGM authorities. The persons who were working on the above mentioned five posts had retired long back, however, still the posts have not been filled! This shows total indifference and casual approach on part of DMER and MCGM and also it seems that as if no one from these departments feels that these posts are needed.

It is therefore very crucial, important and necessary to raise this issue with concerned departments urgently, by the Central PCI, State PCI and IPA. If we fail to act urgently, soon, these posts will lapsed. It is pertinent to note here that Maharashtra is the only state in India where such higher-grade posts are available to the pharmacy profession.

Once we are successful in regenerating and filling these vacant posts in Maharashtra, efforts can be put firstly to create similar posts in all states and secondly and simultaneously start to work on initiating procedures for convincing Ministries of Health of all state governments to establish a separate Directorate of Pharmaceutical Services at each state as described in my article published in Pharma Times as above.

Dr. Suresh Saravdekar
Vice- Chairman, Hospital Division, IPA

Eight Faculty members from School of Pharmacy MIT World Peace University listed in World Scientists and University Ranking by AD Scientific Index 2021

Recently World Scientists and University Ranking was released by AD Scientific Index 2021. AD Scientific Index 2021 has been made by Murat Alper and Pvt. Sihan Dodger from University of Michigan, USA, Pvt. and they have contributed 'Alper-Dodger (AD) Scientific Index' for all the scientists across the world. The rankings are based on three key factors, namely, the H-index, the i10-Index and the number of general citations. The i10-Index measures the number of publications with at least 10 citations through Google Scholar and collected data from 5,65,553 researchers from 10,655 universities in 183 countries.

8 Faculty members; Dr. B. S. Kuchekar, Dr. A. R. Chabukswar, Dr. Jayant Khandare, Dr. Swati Jagdale, Dr. Satish Polshettiwar, Dr. Anil Pawar, Dr. AkshayBaheti and Dr. Vishnu Choudhari from School of Pharmacy, Dr. Vishwanath Karad MIT World Peace University, Pune are listed in World Scientists and University Ranking by AD Scientific Index 2021. The School of Pharmacy faculty has published more than 250 articles in various national and international indexed journals in the last 5 years and has very good citations.

Furthermore, the 'AD Scientific Index' provides the ranking and assessment of scientists by the subject and the branch and by universities, countries, regions and the world. It provides both the academic ranking and analysis results.

ASSOCIATION NEWS

IPA Andhra Pradesh State Branch

Report on 'World Environment Day' Celebration

World Environmental Day 2021 on the theme 'Ecosystem Restoration' was celebrated on 5th June, 2021 by VPC-SAC of Vignan Pharmacy College in association with IPA-AP State Branch with the prime motto— 'It's time to be Greeny'. The event began with the introductory remarks by SAC Coordinator Dr. P. Sowjanya. Dr. P. Srinivasa Babu, Professor and Principal of Vignan Pharmacy College welcomed the participants. Dr. Santanu Gupta, Assistant Professor, Sikkim Manipal Institute of Technology, Sikkim Manipal University was the Chief Guest of the program. The emergence of COVID-19 and its disastrous consequences of ecosystem loss was brought to the forefront. Students were enlightened and encouraged to become responsible individuals and as a community, take steps to preserve nature. Participants took an oath to save nature. The webinar promoted a clear insight on providing green resources and a clean environment. A poster design contest was also conducted based on this year's theme, whose winners were announced during the virtual celebration. Dean, HoD's, faculty and students participated in the celebration. The event ended with a Vote of Thanks by Mr. P.N. Chakravarthy, HoD I/C, Dept. of Science and Humanities.

IPA Bengal State Branch

Relief and Health Camp

Indian Pharmaceutical Association, Bengal Branch and IPA Pharma & Health care trust jointly organised a relief and health camp for the people of Kumirmari village of Sunderban affected by devastating YAAS cyclone and tidal wave. On 15th June, 2021 a team of IPA Bengal Branch and IPA Pharma & Health care trust along with relief materials and healthcare personnel reached the Kumirmari village. Relief materials such as clothing, water purifiers, disinfectant liquids, masks, sanitisers and medicines for the affected people were distributed to about 250 families. Doctors and pharmacists served about 150 patients with several ailments.

IPA Delhi State Branch

Online Conference on 'Mucormycosis (Black Fungus) prevention, treatment and effect on post-COVID 19 patients'

A panel discussion on 'Mucormycosis (Black Fungus) prevention, treatment and effect on post-COVID 19 patients' was organized by

the Faculty of Pharmacy, Dehradun Institute of Technology (DIT) University, Dehradun, Uttarakhand in collaboration with the Indian Pharmaceutical Association, Delhi State Branch (IPADSB) virtually on 9th June, 2021. The half-day programme was chaired by Prof (Dr) Jagannath Sahoo, Director, Faculty of Pharmacy, School of Pharmacy & Population Health Informatics (SoPPHI), DIT University. The event began with the customary Saraswati Vandana which was followed by DIT University's Kulgeet. Prof Sahoo gave the welcome address and N. Ravi Shanker, honourable Chancellor of DIT University graced the occasion with his commendable remarks. Kalhan Bazaz, President of IPADSB and Editor & Publisher of The Indian Pharmacist gave a brief glimpse about the activities of IPA. The first scientific talk was delivered by Dr Mathew Varghese, Head, Department of Orthopaedics, St. Stephen's Hospital, Delhi on the topic 'Origin of mucormycosis and its treatment'. He highlighted that 'the use of antibiotics and immunomodulators make human beings more vulnerable to mucormycosis'. The second speaker, Dr Shailesh Kothalkar, Consultant, ENT, Head & Neck Surgeon, Seven Star Hospital, Nagpur, Maharashtra gave an overview of the 'Allopathic aspect of treatment in mucormycosis' and shared endoscopic features of mucormycosis. In his presentation, Dr. Kothalkar suggested early diagnosis and treatment is the best way to treat mucormycosis. The last virtual talk was given by Dr. Piyush Juneja, Ayurvedic Consultant who spoke on the topic 'Ayurveda and its importance in the treatment of black fungus'. He discussed the various aspects of Ayurveda for the treatment and management of COVID-19 and mucormycosis. He also suggested the pharma fraternity take up the ideas from Ayurveda for future research of POC (proof-of-concept). In his concluding remarks, Dr. Juneja explained the work of his team during the COVID-19 situation with Ayurvedic medicines. Lastly, Dr. Neeraj Kumar, Secretary, IPADSB gave the closing remarks and Prof. (Dr.) H.R. Chitme proposed the Vote of Thanks. The program was convened by Prof. Havagiray Chitme, HoD, Faculty of Pharmacy, DIT University; coordinated by Samir Bhargava, Assistant Professor, Faculty of Pharmacy, DIT University and moderated by Dr. Bhavna, Associate Professor, Faculty of Pharmacy, DIT University. The online gathering attracted more than 100 professionals across the country working in the pharma sector and was attended by leading organizations, associations, and prominent government policymakers of the country, along with students.

Awareness Program on 'Body Oxygen Crisis Management and Oxygen Concentrators'

An online session on 'Body Oxygen Crisis Management and Oxygen Concentrators' was organized by Sheffield MediLife along with the US-based, India Association of Virginia (IAVA) community members

in collaboration with the Indian Pharmaceutical Association, Delhi State Branch (IPADSB) on 8th May, 2021. IAVA is a non-profit organization committed to facilitating different events to cater for the individual and professional development of the members of the Indian community from the Metro Richmond & tri-cities area of Virginia, USA. Ms. Aekta Chawla, President of IAVA for 2021-22 gave the welcome address and introduced the speakers of the session. After the inaugural session, various speakers gave informative talks on Oxygen Concentrators (OCs), their relevance with the ongoing COVID-19 pandemic and how to select an appropriate OC in case someone needs one. Kalhan Bazaz, President of IPADSB talked about the current situation and shared important COVID-19 statistics with the audience. Dr. Prashant Kaushik, Chief Operating Officer (COO), Irvine Healthcare; and Dr. Pratibha Vats, medical officer & frontline medical warrior with Uttarakhand Government discussed the importance of exercise, yoga and physical activity during the pandemic to regulate the oxygen levels in the body. The final speaker of the day, Dr. Naresh Sharma, Immediate Past President of IPADSB & Vice Chairman—Industrial Pharmacy Division of IPA, Mumbai gave a walkthrough about the purpose of OCs, their working and how to select the right OC depending on one's needs. He also discussed the problems, maintenance and unknown areas of OCs. In the end, a Q&A session was conducted. Finally, the webinar ended with a Vote of Thanks proposed by Ms. Chawla. Around 50 participants drawn from India as well as from the US attended the informative webinar. The digital conference was conceptualized and coordinated by Ms. Tanishqa Gautam from Sheffield MediLife who fostered the idea of making the public aware of the topic.

IPA Hospital Pharmacy Division - Dr Suresh Saravdekar

Talk on 'Role of Counselling by Community Pharmacists during the current COVID-19 Pandemic'

A talk on 'Role of Counselling by Community Pharmacists during the current COVID-19 pandemic' was organised on 14th May, 2021 by J. B. Chemicals and Pharmaceuticals Ltd. Dr. Suresh Saravdekar spoke on various issues of irrational use and practices of different types of medications and how they should be avoided. Community pharmacists were made aware of the importance of patient counselling on various essential aspects. The lecture was attended by around 1500 community pharmacists from all across India and received encouraging feedback.

Talk on 'How to select a Quality Assured medicine from Quality assumed medicines'

A webinar on 'How to select a Quality Assured medicine from Quality assumed medicines' was organised on 11thJune, 2021 for the Thane Management forum and their members belonging from diverse faculties, mostly working in food, chemical and pharmaceutical industries or working in Drug Administration. The webinar highlighted the issue of lack of discovery of effective medicines made or available in the market for diseases prevalent in India such as malaria, leprosy, leptospirosis, tuberculosis, kala-azar (black fever), encephalitis along with several orphan diseases.

The webinar discussed the quality of medicine available in the Indian Market, stating that it is different for the same medicine and varies with various factors, e.g. WHO standards are needed for export but not for the domestic market. The quality also varies according to various types of licenses in India because when it is the case of Own license, the owner of the license is 100 % liable and can be prosecuted if the product is declared of substandard quality. However, if the product is manufactured by any third party license and declared of substandard quality, only the third party manufacturer is prosecuted and not necessarily, the owner of the license, who is merely a marketing firm. Similarly, in the case of generic medicines, the quality can be of three types—either chemically equivalent generic; bioequivalent generic or therapeutic equivalent generic.

The talk concluded with emphasis put on how the introduction of pre-qualification criteria in tenders, like Own license, WHO/GMP standards and bio-equivalent medicines, has helped the Ministry of Health and Family Welfare, Government of Maharashtra in getting quality-assured medicines for use in public healthcare hospitals by selecting only those firms who are quality-assured and filtering out quality assumed generic medicines.

PHARMASCENE

NEW DRUG APPROVALS

www.drugs.com

Rezurock (Belumosudil) Tablets

Company: Kadmon Holdings, Inc.

Date of Approval: 16th July, 2021

Treatment for: **Graft Versus Host Disease**

Rezurock (Belumosudil) is a kinase inhibitor for the treatment of patients with chronic graft-versus-host disease (cGVHD).

Vaxneuvance (Pneumococcal 15-valent conjugate vaccine) Injection

Company: Merck

Date of Approval: 16th July, 2021

Treatment for: **Pneumococcal Disease Prophylaxis**

Vaxneuvance (Pneumococcal 15-valent conjugate vaccine) is a vaccine indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.

Fexinidazole Tablets

Company: Drugs for Neglected Diseases Initiative

Date of Approval: 16th July, 2021

Treatment for: **Trypanosomiasis**

Fexinidazole is a nitroimidazole antibacterial indicated for the treatment of the *Trypanosoma brucei gambiense* form of sleeping sickness (Human African trypanosomiasis) in patients 6 years of age and older and weighing at least 20 kg.

Kerendia (Finerenone) Tablets

Company: Bayer HealthCare Pharmaceuticals Inc.

Date of Approval: 9th July, 2021

Treatment for: **Chronic Kidney Disease Associated with Type 2 Diabetes**

Kerendia (Finerenone) is a non-steroidal, selective mineralocorticoid receptor antagonist (MRA) for the treatment of patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

Rylaze (Asparaginase erwinia chrysanthemi (recombinant)-rywn) Injection

Company: Jazz Pharmaceuticals plc

Date of Approval: 30th June, 2021

Treatment for: **Acute Lymphoblastic Leukemia**

Rylaze (Asparaginase erwinia chrysanthemi (recombinant)-rywn) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL).

Verkazia (Cyclosporine) Ophthalmic Emulsion

Company: Santen Inc.

Date of Approval: 23rd June, 2021

Treatment for: **Vernal Keratoconjunctivitis**

Verkazia (Cyclosporine) is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

Astepro Allergy (Azelastine) Nasal Spray

Company: Bayer HealthCare Pharmaceuticals Inc.

Date of Approval: 17th June, 2021

Treatment for: **Allergic Rhinitis**

Astepro Allergy (Azelastine) is a nasal antihistamine for the treatment of seasonal allergic rhinitis.

Rezipres (Ephedrine hydrochloride) Injection

Company: Eton Pharmaceuticals, Inc.

Date of Approval: 14th June, 2021

Treatment for: **Hypotension**

Rezipres (Ephedrine hydrochloride) is an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

Soaanz (Torsemide) Tablets

Company: Sarfez Pharmaceuticals

Date of Approval: 14th June, 2021

Treatment for: **Edema**

Soaanz (Torsemide) is a loop diuretic indicated for the treatment of edema associated with heart failure or renal disease in adults.

Prevnar 20 (Pneumococcal 20-valent conjugate vaccine) Injection

Company: Pfizer Inc.

Date of Approval: 8th June, 2021

Treatment for: **Pneumococcal Disease Prophylaxis**

Prevnar 20 (Pneumococcal 20-valent conjugate vaccine) is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.

Aduhelm (Aducanumab-avwa) Injection

Company: Biogen

Date of Approval: 7th June, 2021

Treatment for: **Alzheimer's Disease**

Aduhelm (Aducanumab-avwa) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

VACCINES AND DRUG APPROVAL

Vir Biotechnology begins patient dosing in phase 2 MARCH study of combination of VIR-2218 & VIR-3434 as functional cure regimen for chronic HBV infection

www.pharmabiz.com; 17th July, 2021

Vir Biotechnology announced that the first patient has been dosed in the phase 2 MARCH (Monoclonal Antibody siRNA Combination against Hepatitis B) trial evaluating VIR-2218 together with VIR-3434 for the treatment of patients with chronic hepatitis B virus (HBV) infection – a combination designed to achieve a functional cure. VIR-2218 is an investigational small interfering ribonucleic acid (siRNA) designed to inhibit the production of all HBV proteins

(X, polymerase, S and core), which may be acting as immune tolerogens. VIR-3434 is an investigational HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes, as well as reduce the level of virions and subviral particles in the blood. It has also been Fc engineered to include the XX2 "vaccinal mutation," allowing it to potentially function as a therapeutic T cell vaccine against HBV.

Innovent begins patient dosing in phase 1 study of IBI319 to treat advanced malignant tumors

www.pharmabiz.com; 17th July, 2021

Innovent Biologics, a world-class biopharmaceutical company, announced that the first patient has been dosed in a phase 1a/1b study of IBI319, an anti-PD-1/CD137 bispecific antibody. The objective of this open-label, multi-center phase 1a/1b dose escalation and expansion study is to evaluate the safety, tolerability, potential optimal dosage and preliminary efficacy of IBI319 in patients with advanced malignant tumors whose cancer progressed on standard-of-care treatment. The trial is being conducted in China. In preclinical studies, IBI319 has demonstrated synergistically targeting both PD-1 and CD137 to simultaneously achieve anti-tumor activity and enhance efficacy. BI319 was discovered through collaboration between Innovent and Eli Lilly and Company and has been developed in China by Innovent. The IND for IBI319 has been approved by the NMPA in China, and a clinical trial in China is actively being conducted.

Celltrion's monoclonal antibody treatment for COVID-19 works against Delta variant

www.expresspharma.in; 16th July, 2021

Celltrion Group announced new results from an in vivo efficacy study showing that regdanvimab (CT-P59) has a strong neutralising effect against the rapidly spreading Delta variant (B.1.617.2, first identified in India). According to the World Health Organization (WHO), the Delta variant has been reported in 96 countries becoming the most common variant. The pre- clinical in vivo study assessed the neutralisation effect of CT-P59 against the Delta variant, using a clinically relevant dose. The study demonstrated that CT-P59 treatment results in a 100 percent survival rate from COVID-19 compared to 0 percent for the placebo group, with significant protection against body weight loss shown after viral challenge also seen. In addition, a therapeutic dosage of CT-P59 significantly reduced the viral load of SARS-CoV-2 and inflammation in the lungs compared to non-treated controls with virus eradication from all animals treated with CT-P59.

Heat-tolerant COVID-19 vaccine from IISc effective against all major SARS-CoV-2 variants

www.expresspharma.in; 16th July, 2021

A heat-tolerant COVID-19 vaccine formulation developed by the Indian Institute of Science (IISc) Bengaluru has proven effective against all current SARS-CoV-2 variants of concern, according to a study in animals. The research, published in the ACS Infectious Diseases journal, showed that vaccine formulations by IISc-incubated biotech start-up Mynvax triggered a strong immune response in mice. The formulation also protected hamsters from the virus and remained stable at 37 degrees Celsius up to a month, and at 100 degrees Celsius for up to 90 minutes. The team, including researchers from Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO), noted that most vaccines require refrigeration to remain effective. For example, the Oxford-AstraZeneca vaccine, known as Covishield in India, must be kept between 2-8° Celsius and the Pfizer preventive requires specialised cold storage at minus 70° Celsius.

Venus Remedies forays into consumer healthcare, launches R3SET for pain management

www.expresspharma.in; 16th July, 2021

Foraying into the Rs 30,000-crore Indian consumer healthcare market, Venus Remedies launched its full-fledged Consumer Healthcare Division. The company's Consumer Healthcare Division will come up with a wide range of products covering the crucial pain management, gastroenterology, hygiene, stress management and vitamins and supplements segments. Stating that the newly launched business division would introduce disruptive products in these segments in India over the next five years. Focused on everyday healthcare solutions, the product line under this segment will help people deal with lifestyle-associated pains more effectively through a 360° self-care approach that blends latest technologies with time-tested natural remedies.

FDC launches Favipiravir oral suspension to treat mild to moderate cases of COVID-19

www.buisnesstoday.in; 12th July, 2021

Pharma firm FDC Ltd has launched oral suspension of Favipiravir to treat mild to moderate cases of COVID-19 in the country. This prescription-only Favenza oral suspension is currently available at all retail medical outlets and hospital pharmacies across India. Convenient loading dosage of the oral suspension helps reduce dosage frequency. In order to combat COVID-19, they believe offering best efficacy along with convenience to the patients is the key and as such their focus now is in making the process of COVID-19 treatment hassle-free.

Positive new data for Johnson & Johnson single-shot COVID-19 vaccine on activity against Delta variant and long-lasting durability of response

www.worldpharmanews.com; 7th July, 2021

Johnson & Johnson announced data that demonstrated its single-shot COVID-19 vaccine generated strong, persistent activity against the rapidly spreading Delta variant and other highly prevalent SARS-CoV-2 viral variants. In addition, the data showed that the durability of the immune response lasted through at least eight months, the length of time evaluated to date. The two preprint study summaries have been submitted to bioRxiv. Current data for the eight months studied so far show that the single-shot Johnson & Johnson COVID-19 vaccine generates a strong neutralizing antibody response that does not wane; rather, they observe an improvement over time.

REGULATORY AFFAIRS

USFDA to review full approval of Pfizer/BioNTech's COVID-19 vaccine by January

www.expresspharma.in; 17th July, 2021

The USFDA will review Pfizer and German partner BioNTech SE's application for full approval of their COVID-19 vaccine in people 16 years and older by January. The vaccine is among the three being used in the US under the FDA's emergency use authorization, alongside shots from Johnson & Johnson and Moderna Inc. If approved, it would be the first shot to get the agency's full approval based on longer-term data on safety and effectiveness, potentially helping ease vaccine hesitancy as the country witness's new outbreaks in some parts, mainly due to the highly infectious Delta coronavirus variant. Over 85 million Americans have been fully vaccinated with Pfizer's vaccine, according to latest government data. The companies said they intend to submit an application to support approval of the vaccine in this age group once the required data is available six months after the second dose. Moderna filed for full US approval of its COVID-19 vaccine for adults early in June.

Ocugen seeks approval for Covaxin in Canada

www.expresspharma.in; 16th July, 2021

Ocugen, Bharat Biotech's partner for US and Canada for COVID-19 vaccine Covaxin, has initiated a rolling submission to Health Canada for the jab. The move follows the release by Bharat Biotech of Phase 3 clinical trial results, which demonstrated efficacy and safety in nearly 25,800 adults. Often referred to as a rolling review, this allows Health Canada to start its review right away, as information continues to come in, to accelerate the overall review process. Ocugen initiated the rolling submission through its affiliate, Vaccigen. Health Canada will make a decision upon review of the evidence submitted that supports its safety, efficacy and quality.

Abbott gets CDSCO approval for marketing of estradiol, dydrogesterone FDC

www.pharmabiz.com; 15th July, 2021

Abbott, the global healthcare company, has received approval from the Subject Expert Committee (SEC) at Central Drugs Standard Control Organisation (CDSCO) for importing and marketing of the fixed dose combination of dydrogesterone+estradiol (2.5 mg + 0.5mg) tablets. The firm presented the trial data with respect to Asian population as per the recommendation of earlier SEC held on September 23, 2020. After detailed deliberation, the committee considered phase III CT waiver and recommended grant of permission for import and market of the subject FDC subject to the condition that the firm should submit the phase IV clinical trial protocol within 3 months of approval of the FDC. Estradiol/dydrogesterone (E2/DYD), sold under the brand name Femoston among others, is a combination of estradiol (E2), an estrogen, and dydrogesterone (DYD), a progestin, which is used in menopausal hormone therapy, specifically to treat and prevent hot flashes and osteoporosis, in postmenopausal women.

Sputnik V may get WHO approval by October, says RDIF CEO

www.buisnesstoday.in; 14th July, 2021

The Russian COVID-19 vaccine Sputnik V is expected to get World Health Organization's (WHO) approval in September-October this year. The vaccine is developed by Russia's Gamaleya National Research Institute of Epidemiology and Microbiology, while RDIF is marketing it globally. The RDIF CEO added that the first batch of Sputnik V is likely to be manufactured at Serum Institute's facilities in September. The parties intend to produce over 300 million doses of the vaccine in India per year. They noted that the tie-up is going to be a "great contribution to the Indian vaccine making effort" and after Indian demand has been met, the rest of the doses, produced by the Serum Institute, will be supplied to other nations. Besides SII, RDIF has signed deals with six other producers in India - Gland Pharma, Hetero Biopharma, Panacea Biotec, Stelis Biopharma, Virchow Biotech, and Morepen.

USFDA adds rare reaction risk warning to J&J COVID-19 vaccine

www.buisnesstoday.in; 14th July, 2021

US regulators added a new warning to Johnson & Johnson's COVID-19 vaccine about links to a rare and potentially dangerous neurological reaction, but not entirely clear the shot caused the problem. The Food and Drug Administration announced the new warning, flagging reports of Guillain-Barre syndrome, an immune system disorder that can cause muscle weakness and occasionally paralysis. Health officials described the side effect as a small possible risk" for those getting the shot. The action comes after the FDA and the Centers for Disease Control and Prevention reviewed reports of about 100 people developing the syndrome after receiving the one-dose vaccine. Almost all of them required hospitalization and one person died. Guillain-Barre syndrome occurs when the body's immune system mistakenly attacks some of its nerve cells, causing muscle weakness and sometimes paralysis that typically is temporary. An estimated 3,000 to 6,000 people develop the syndrome each year, according to the CDC.

CDSCO notifies 10 more medical devices testing laboratories for quality assurance

www.pharmabiz.com; 12th July, 2021

In a bid to regulate all medical devices under Drugs and Cosmetics (D&C) Act in an effective way, the Central Drugs Standard Control Organization (CDSCO) has notified ten more medical devices testing laboratories (MDTL) for carrying out evaluation of medical devices under the new Medical Devices (MD) Rules 2017 on behalf of manufacturers in the country. With this, the total number of MDTLs notified for conducting evaluation of medical devices reached 14. The new MD rules were notified on January 31, 2017 under D&C Act to regulate manufacture, import, sale and distribution of medical devices which were effective from January 1, 2018. The recently notified MDTLs are Tamil Nadu based GLR Laboratories & Trustin Analytical Solutions, Telangana based Palamur Biosciences, Bangalore based Eurofins Advinus, West Delhi based Devansh Testing & Research Laboratory, ITL Labs, Conformity Testing Labs, Rajasthan based Jagdamba Laboratories & Brothers Laboratories and Gujarat based Accuprec Research Labs.

MSN Labs enters into licence deal with DRDE for Covid-19 drug 2-DG

www.buisness-standard.com; 10th July, 2021

Drug firm MSN Laboratories has entered into a license agreement with the Defense Research & Development Establishment (DRDE) for the manufacturing, distribution and marketing of 2-Deoxy-D-Glucose (2-DG), used for the treatment of COVID-19. Developed by DRDO, 2-DG has been granted permission by the Drug Controller General of India (DCGI) for emergency use as adjunct therapy in moderate to severe COVID-19 patients. The company has entered into a license agreement with DRDE and the Institute of Nuclear Medicine and Allied Sciences (INMAS) establishments of DRDO for the manufacturing, distribution and marketing of 2-Deoxy-D-Glucose (2-DG) in India, it added. MSN labs will be launching the 2-DG as a twice-a-day product in sachet form under the brand name MSN 2D in strength of 2.34 g.

Lupin receives CDSCO committee approval for marketing ranibizumab

www.pharmabiz.com; 09th July, 2021

Lupin Ltd has received marketing approval from the Subject Expert Committee (SEC) at Central Drugs Standard Control Organisation (CDSCO) for ranibizumab. Ranibizumab (trade name Lucentis among others) is a monoclonal antibody fragment (Fab) created from the same parent mouse antibody as bevacizumab. It is an anti-angiogenic that has been approved to treat the "wet" type of age-related macular degeneration (AMD, also ARMD), diabetic retinopathy, and macular edema due to branch retinal vein occlusion or central retinal vein occlusion. The firm presented the proposal for marketing authorization based on the results of phase III multicentre clinical trial conducted in the country. After detailed deliberation, the committee recommended grant of approval for marketing, subject to the following condition such as the specifications of the drug should be equivalent to the reference product. The firm shall submit phase IV clinical trial protocol within three months of the grant of marketing authorization.

MERGERS, ACQUISITION AND COLLABORATION

Ipsen and IRLAB ink pact to develop & commercialise Mesdopetam to treat Parkinson's disease

www.pharmabiz.com; 17th July, 2021

Ipsen and IRLAB announced the signing of a licensing agreement, providing Ipsen exclusive worldwide development and commercial rights to mesdopetam, a novel dopamine D3-receptor antagonist. Mesdopetam is being assessed in phase IIb clinical trials as a potential treatment option for people living with Parkinson's disease experiencing levodopa-induced dyskinesia. It is estimated that approximately 40-50 percent of people living with PD will experience LID after five years of initiating dopamine replacement therapy. LID currently has limited treatment options. Mesdopetam is also in early development for Parkinson's disease Psychosis (PDP), which is a common symptom of PD; around 50 per cent of people with PD eventually develop such symptoms over the course of their disease. PD is a common, progressive neurodegenerative condition affecting more than 10 million people worldwide. PD affects nerve cells in the brain that control movement and affects patients differently; the most common motor symptoms however are tremor, muscle rigidity and slowness of movement. People living with PD also experience other problems not related to movement including anxiety, pain and depression. Symptoms of PD are most managed by medicines, such as levodopa that aim to compensate for the loss of dopaminergic neurons. A common side effect of levodopa is dyskinesia, involuntary and erratic movements of the face, arms, legs, or trunk. For many people, dyskinesias can be so severe that they interfere with normal functioning. Mesdopetam has also shown antipsychotic properties in preclinical studies.

Collaboration between AbbVie, Biogen and Pfizer creates the world's largest browsable resource.

www.worldpharmanews.com; 15th July, 2021

The access to the world's largest browsable resource linking rare protein-coding genetic variants to human health and disease was launched through a genetic exome sequence analysis collaboration between AbbVie, Biogen Inc., and Pfizer. Managed by the Broad Institute of MIT and Harvard, the browser gives access to results from analyses of whole exome sequencing data from 300,000 UK Biobank research participants. These genetic data have been paired with detailed health information to create this browsable resource. The collaboration between AbbVie, Biogen and Pfizer to make these data available highlights the importance of working together to advance science. The companies engaged with the Broad Institute for data processing and to conduct single variant and gene-based association testing with nearly 4,000 UK Biobank phenotypes to identify associations between distinct genes or genetic variants and disease. In line with the collaboration members' commitment to openness, these results can now be accessed freely via the new browser. This browser will enable scientists worldwide to explore and utilize the data for their respective areas of interest in accordance with UK Biobank's terms of use. The UK Biobank whole exome sequencing data has been generated as part of the UK Biobank Exome Sequencing Consortium, formed in 2018, which, in addition to AbbVie, Biogen and Pfizer, includes additional industry partners, supporting a trend across the industry to collaborate in a pre-competitive manner for generating the source data for an improved understanding of human biology and disease.

Ionis Pharma inks licensing agreement with Bicycle Therapeutics to increase delivery capabilities of advanced LICA medicines

www.pharmabiz.com; 15th July, 2021

Ionis Pharmaceuticals announced that it has entered into an exclusive licensing agreement with Bicycle Therapeutics to increase the delivery capabilities of Ionis' advanced Ligand Conjugated Antisense (LICA) medicines. The agreement provides Ionis exclusive access to Bicycle's proprietary macrocyclic peptides, referred to as Bicycles, to design LICAs that target transferrin receptor 1 for use with oligonucleotides. This LICA strategy has demonstrated both the improved delivery of antisense medicines to muscle tissue, including cardiac muscle, as well as the potential to cross the blood brain barrier. Bicycles are fully synthetic short peptides constrained with small molecule scaffolds to form two loops that stabilize their structural geometry. This constraint facilitates target binding with high affinity and selectivity, making Bicycles attractive candidates for drug development. Under terms of the agreement, Ionis obtained an exclusive license to Bicycle's technology covering the entire class of transferrin receptor 1 Bicycles for use in targeted delivery of oligonucleotide drugs.

Vor Biopharma collaborates with Janssen to develop eHSC transplants combined with bi-specific antibody therapy for AML

www.pharmabiz.com; 12th July, 2021

Vor Biopharma, a cell therapy company, announced the formation of a collaboration with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson. The agreement was facilitated by Johnson & Johnson Innovation. Under the terms of the collaboration, Vor Biopharma will investigate the combination of these two technologies into a treatment solution, pairing Vor's invisible eHSC transplant platform with one of Janssen's bi-specific antibodies in development for acute myeloid leukaemia. Vor Biopharma is a cell therapy company that aims to transform the lives of cancer patients by pioneering engineered hematopoietic stem cell therapies to create next-generation, treatment-resistant transplants that unlock the potential of targeted therapies.

Philips collaborates with Cognizant to introduce digital health solutions to providers, researchers, and patients

www.pharmabiz.com; 10th July, 2021

Royal Philips, a global leader in health technology, and Cognizant, a world-leading professional services firm, announced a new collaboration to develop end-to-end digital health solutions that will enable healthcare organizations and life sciences companies to improve patient care and accelerate clinical trials. The strategic alliance brings together Philips HealthSuite, a cloud-based platform and Cognizant's digital engineering expertise to deliver and maintain leading-edge digital health solutions at scale, providing advanced connectivity and using big data to create actionable insights. Philips HealthSuite, built on Amazon Web Services, is an integrated, modular set of standards-based capabilities that support the development of digital health propositions. The platform securely stores critical healthcare data and provides both advanced data analytics and AI capabilities, while delivering industry-leading interoperability, connectivity, and regulatory compliance.

GSK and Alector announce global collaboration in immuno-neurology

www.worldpharmanews.com; 2nd July, 2021

GlaxoSmithKline and Alector announced a strategic global collaboration for the development and commercialisation of two clinical-stage, potential first-in-class monoclonal antibodies (AL001 and AL101) designed to elevate progranulin (PGRN) levels. PGRN is a key regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders, making it one of the most attractive genetically validated targets for the development of new immuno-neurology treatments. The collaboration brings together Alector's leading immuno-neurology expertise with GSK's R&D focus on the science of the immune system and human genetics, proven late-stage drug development capabilities and global

footprint. Enrolment is currently underway for a pivotal Phase 3 trial for AL001 in people at risk for or with frontotemporal dementia due to a progranulin gene mutation (FTD-GRN). FTD-GRN is a rapidly progressing and severe form of dementia found most frequently in people less than 65 years old at the time of diagnosis and has no approved treatments. AL001 is also currently in a Phase 2 study in symptomatic FTD patients with a mutation in the C9orf72 gene and is planned to enter Phase 2 development for amyotrophic lateral sclerosis (ALS) in the second half of 2021.

RESEARCH

Cytena Bioprocess introduces S.NEST, a high throughput microbioreactor with real-time monitoring to ensure maximum cell growth and streamlined workflows

www.pharmabiz.com; 20th July, 2021

Cytena Bioprocess Solutions, a CELLINK company, has launched the S. NEST, a state-of-the art microbioreactor that maximizes cell growth while monitoring and analyzing cell conditions from start to finish. Well-known for combining innovative bioscience technologies with best-in-class software development, Cytena Bioprocess Solutions has developed their new microbioreactor to disrupt the field of cell line development (CLD). Microbioreactors have been instrumental in a string of research breakthroughs in CLD for a range of downstream applications, but with the addition of real-time monitoring, the S. NEST is at the forefront of those advances. Furthermore, it boasts an impressive merger of enhanced features, including patented technology for reciprocating mixing, incubation chambers with individual environmental controls, a camera module for real-time pH and dissolved oxygen monitoring, powerful analytical software to crunch data, compatibility with 96-well or 24-well culture plates, and four chambers for the high-throughput culturing of as many as 384 wells at once. CLD researchers looking to streamline upscaling and expansion workflows, which previously required weeks to complete, are sure to embrace the S.NEST's unique suspension culturing nourished by a continuous supply of oxygen. As part of Cytena's extensive portfolio of single-cell instruments, the S. NEST will make highly efficient cell culturing results accessible to laboratories around the world.

Role of bacterial motility in differential resistance mechanisms of silver nanoparticles and silver ions

www.worldpharmanews.com; 14th July, 2021

Antimicrobials are used to kill or slow the growth of bacteria, viruses and other microorganisms. They can be in the form of antibiotics, used to treat bodily infections, or as an additive or coating on commercial products used to keep germs at bay. These life-saving tools are essential to preventing and treating infections in humans, animals and plants, but they also pose a global threat to public health when microorganisms develop resistance to them, a concept known as antimicrobial resistance. One of the main drivers of antimicrobial resistance is the misuse and overuse of antimicrobial agents, which includes silver nanoparticles, an advanced material with well-documented antimicrobial properties. It is increasingly used in commercial products that boast enhanced germ-killing performance - it has been woven into textiles, coated onto toothbrushes, and even mixed into cosmetics as a preservative. The Gilbertson Group at the University of Pittsburgh Swanson School of Engineering used laboratory strains of E. coli to better understand bacterial resistance to silver nanoparticles and attempt to get ahead of the potential misuse of this material. The team recently published their results in Nature Nanotechnology.

Artificial intelligence could be new blueprint for precision drug discovery

www.worldpharmanews.com; 12th July, 2021

University of California San Diego School of Medicine described a new approach that uses machine learning to hunt for disease targets and then predicts whether a drug is likely to receive FDA approval. The study findings could measurably change how researchers sift through big data to find meaningful information with significant benefit to patients, the pharmaceutical industry and the nation's health care systems. The researchers used the disease model for inflammatory bowel disease (IBD), which is a complex, multifaceted, relapsing autoimmune disorder characterized by inflammation of the gut lining. Because it impacts all ages and reduces the quality of life in patients, IBD is a priority disease area for drug discovery and is a challenging condition to treat because no two patients behave similarly.

Microbial short-chain fatty acids modulate CD8+ T cell responses and improve adoptive immunotherapy for cancer

www.worldpharmanews.com; 09th July, 2021

Scientists at the Universities of Würzburg and Marburg have now succeeded for the first time in experimentally demonstrating that bacterial metabolites are able to increase the cytotoxic activity of certain immune cells and thus positively influence the efficiency of tumor therapies. Ideally, the composition of the bacterial species in the microbiome could be used to control its influence on the success of the therapy. Short-chain fatty acids belong to the most dominant class of metabolites of the gut microbiome. On the one hand, they can boost the metabolism of T cells by inducing central regulators of energy metabolism. On the other hand, they can inhibit specific enzymes that regulate the accessibility to the genetic material and thus the gene expression in the T cells. In doing so, they induce epigenetic changes. CAR-T cells are written out as chimeric antigen receptor T cells. While normal T cells are largely blind to tumor cells, CAR T cells can recognize specific target antigens on the tumor surface and destroy the cancer cells thanks to a genetic modification.

Roche announces positive results from of Hemlibra to treat people with haemophilia A

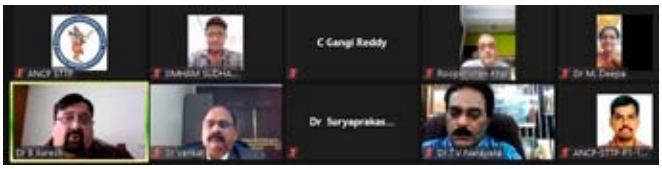
www.pharmabiz.com; 20th June, 2021

Roche announced results from the final analysis of the STASEY study, which confirm the favorable safety profile of Hemlibra, consistent with the phase III HAVEN clinical programmed. In the analysis, no new safety signals were identified with longer-term Hemlibra treatment in adults and adolescents with hemophilia A with inhibitors to factor VIII, the clotting protein that is missing or defective in people with hemophilia A. The data were presented at the virtual International Society on Thrombosis and Hemostasis (ISTH) 2021 Congress. Nearly one in three people with hemophilia A develop factor VIII inhibitors, antibodies that bind to and block the efficacy of replacement factor VIII. People with hemophilia A with inhibitors are at greater risk of more frequent bleeding, including life-threatening bleeds, and may face greater challenges in their day-to-day lives than people with hemophilia A who do not have inhibitors. Hemlibra has been approved in more than 100 countries worldwide for the treatment of people with hemophilia A with factor VIII inhibitors. Hemlibra is approved to treat people with hemophilia A with factor VIII inhibitors in more than 100 countries worldwide and people with hemophilia A without factor VIII inhibitors in more than 80 countries worldwide, including the US, EU and Japan. Hemlibra has been studied in one of the largest clinical trial programs in hemophilia A with and without factor VIII inhibitors, including eight phase III studies.

CAMPUS NEWS

Annamacharya College of Pharmacy, Rajampet

Short Term Training Program (STTP)



A six-day Short Term Training Program (STTP) on 'Application of Quality by Design and other Computational Tools in Pharmaceutical Product Development: Current Trends and Future Prospective', sponsored by AICTE (All India Council for Technical Education) was conducted through online mode in the campus of Rajampet, Andhra Pradesh. Prof. B. Suresh, Chief Guest, President, Pharmacy Council of India, recalled all the participants to educate this learning to the students. Prof. G. Ranga Janardhana, Guest of Honour, Honorable Vice-Chancellor, JNTU, Anantapur, suggested utilizing the online tools for best teaching to students. Col. B. Venkat, Guest of Honour, Director-FDC, All India Council for Technical Education, appreciated the ANCP team for conducting the AICTE sponsored program. Dr. T. V. Narayana, Guest of Honour, President, Indian Pharmaceutical Association, advised the staff to equip themselves with all concerns of the online modes for justifying the students. Sri. C. Gangi Reddy, Guest of Honour, Secretary, AET, encouraged the staff for conducting this program in Covid situation. Dr. V. Venkateswarlu, Managing Director, Neuheit Pharma Technologies Pvt. Ltd. Hyderabad gave the keynote address on 'QBD- An Overview'. Dr. C.V.S. Subrahmanyam, PG Coordinator, Gokaraju Rangaraju College of Pharmacy, Hyderabad, delivered his session on 'QBD Principles and Applications in Formulations'. Dr. Roop K. Khar, Professor and H.O.D, B. S. Anangpuria Educational Institutes, Faridabad explained the topic 'Fundamentals of QBD for Professional Development'. Dr. D. Swarnalatha, Principal, Annamacharya College of Pharmacy, expressed her gratitude to the commendable personalities, participants and Coordinator. Dr. P. Dwarakanadha Reddy, Coordinator, Prof. and HOD, Dept. of Pharmaceutics, and Co-Coordinators Dr. C. Surya Prakash Reddy and Dr. N. Raghavendra Naveen and staff team participated in this program. Dr. C. Ramachandra Reddy, Chairman; Sri. C. Yella Reddy, Vice Chairman; Sri. C. Abhishek Reddy, Treasurer addressed the audience.

Delhi Pharmaceutical Sciences Research University, Delhi

Inauguration of DPSRU Yoga and Meditation Center by Honorable Chief Minister of Delhi

The Yoga Fitness center was started in 2016 by Delhi Pharmaceutical Sciences Research University to provide 3 credit Yoga courses for students of Pharmacy and Physiotherapy in the University. Further, a certificate course was started for the general public. On the day before International Day of Yoga, the center was inaugurated by Shri Arvind Kejriwal, Honorable Chief Minister of Delhi. Initiated in collaboration with the government of NCT of Delhi, this center will conduct the course on Diploma in Meditation and Yoga Sciences. 464 students have been enrolled for the course, while 20 yoga teachers have been appointed. On 21st June, 2021 International Yoga Day was celebrated where students and staff members practiced yoga and meditation following all COVID protocols. Overall 200 staff and faculty members and 400 students joined and participated in the celebration, online as well as offline. This initiative has been brought to a successful implementation under the aegis of the Honorable Vice-Chancellor of DPSRU. Prof. (Dr.) Ramesh K. Goyal.

Inauguration of Community Health Facility of School of Allied Health Sciences

The Community Health Facility of School of Allied Health Sciences (SAHS), Delhi Pharmaceutical Sciences and Research University was inaugurated by Shri K.J. Alphons, former Union Minister of State for Culture and Tourism and Member of Parliament. The Distress Management Collective India (DMCI) in association with the India Canada Association of Kingston, the voluntary service organization, donated five oxygen concentrators of 10 liters capacity and pulse oximeters. The team DMCI donated the masks made by the rehabilitated inmates of GB Road promoted by Kat-katha and DMCI to the Community Health Facility of the University. The inaugural function was chaired by Prof. Ramesh K. Goyal, Vice-Chancellor DPSRU in the presence of Shri O.P. Shukla, Registrar; Prof. Harvinder Popli, Director, SPS; Prof. P.K. Sahoo, Director DIPSAR; Prof. Geeta Aggarwal, Dean Academics; Prof. Rajiv Tonk, Dean Students Welfare; Dr. Jaseela Majeed, Head SAHS; Dr. Priyanka Sonam, Medical Officer; Dr. Shilpa Jain, Head Physiotherapist and senior faculty of the University. Shri K.J. Alphons gave the inaugural speech and congratulated the team. Prof. Goyal addressed the gathering and said that the Community Health Facility in collaboration with like-minded organizations will facilitate the responsibilities towards the society. The inaugural function was attended by Shri. Babu Panicker, Delhi Coordinator. The executive members of DMCI- Dr. K.C. George, Dr. Sakhi John, Shri. Jobi Joseph, Shri Joseph Koovachal and Shri. Sudheernath acknowledged the student volunteers who are working for Prana Vayu Project which has saved the lives of hundreds of people during the second wave of the pandemic, with certificates of appreciation and momentos.

PES's Rajaram and Tarabai Bandekar College of Pharmacy

Vanamahotsav 2021- Tree Plantation Drive

Ponda Education Society, Farmagudi-Ponda, Goa in association with the Department of Forest, Government of Goa, organized Van Mahotsav 2021, a tree plantation drive on 16th June, 2021. Shri Ravi S. Naik, Hon. MLA Ponda Constituency, President of Ponda Education Society, explained the motto of the Society to have a clean and green campus. Accordingly, Van Mahotsav is celebrated every year with an emphasis on planting all types of fruit-bearing and medicinal plants so as to ensure a conducive environment for the health and wellbeing of mankind. Dr. S.N. Mamle Desai, Principal of PES's Rajaram and Tarabai Bandekar College of Pharmacy highlighted the importance of growing trees and their benefits to society. The program was attended by Shri. Santosh Phadte, the Deputy Director of Forests and other forest officials who have taken up this initiative of tree plantation drive across the state. Staff and the Principals of other PES institutions graced the occasion.

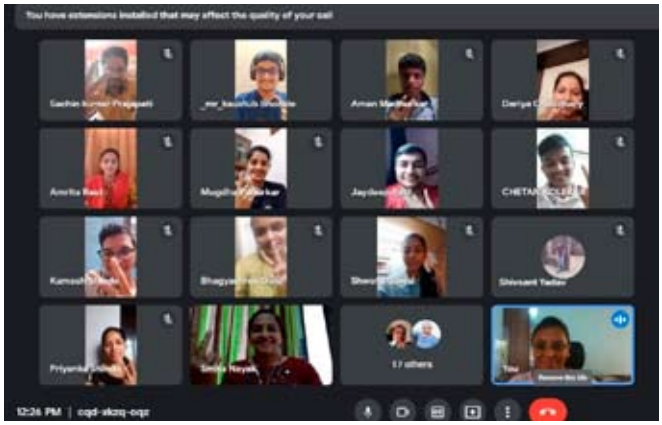
Sri Ramachandra Institute of Higher Education and Research, Chennai

XIIIth Faculty Development Program (Focused Workshop)

Pharmacy Education Unit, Sri Ramachandra Faculty of Pharmacy (DST-FIST-sponsored Department), Sri Ramachandra Institute of Higher Education and Research (DU), Chennai in association with Anchrom Enterprises (I) Pvt. Ltd., Mumbai organized virtual XIIIth Faculty Development Program (Focused Workshop) with the Theme: 'HPTLC Method Development, Trick or Treat? – Learn, Relax and Stress out – Tech model' on 8th June, 2021. Dr. K. Chitra, Principal i/c, Sri Ramachandra Faculty of Pharmacy, SRIHER (DU) welcomed the virtual gathering. Dr. Latha Ravichandran, Dean (Education), SRIHER (DU), Chennai graced the occasion with her inaugural address. Dr. Saikat Mallick, Asst. Manager, Anchrom Enterprises (I) Pvt. Ltd., Mumbai, delivered a lecture on 'HPTLC Techniques and Applications'. Mr. Abhijeet Khale, Application Chemist, Anchrom Enterprises (I) Pvt. Ltd., Mumbai, delivered a lecture on 'HPTLC Demonstration (with Q&A)'. Dr. Archana B., Faculty, Department of Pathology, SRIHER (DU), Chennai, delivered a lecture on 'Breathe in Oxygen and Breathe out Stress: Immune Enhancement in COVID times'. Dr. K. Mangathayaru, Additional Vice Principal, Sri Ramachandra Faculty of Pharmacy, SRIHER (DU) concluded the meeting by extending a Vote of Thanks.

Gahlot Institute of Pharmacy, Koparkhairane

Workshop on 'Guidance on Psycho-social skills to helpers during pandemic'



Gahlot Institute of Pharmacy Koparkhairane in association with MGNCRE (Mahatma Gandhi National Council for Rural Education) India under the Ministry of India, Education Department organized an online workshop on 'Guidance on Psychosocial skills to helpers during pandemic' on 17th June, 2021. The resource person for this workshop was Ms. Jayshree Jani, Principal, Vishvaniketan Shanti Asiatic School, Gujarat. The workshop was organized by Dr. Smita Nayak, Professor and HOD under the guidance of Dr. V.H. Bhaskar, Principal and was attended by more than 100 students and faculty.

Poona College of Pharmacy, Pune

Celebration of 7th International Yoga Day 2021

Poona College of Pharmacy, Bharati Vidyapeeth, Pune, celebrated the International Yoga Day 2021 day 21st June, 2021 virtually, as part of a government initiative by performing yoga, encouraging yoga through Life Pledge, IDY 2021 Quiz and 'My life, My Yoga' video blogging under the guidance of I/C Principal Dr. Atmaram Pawar. The demonstrator of the program was Dr. Hemant K. Jain, Professor, QA-PCP. He trained the attendees in Chalan Kriyas, Asanas, Kapalbhati, Pranayamas, etc. to increase the immunity to fight against COVID-19 and other lifestyle disorders. The principal, dean, 87 staff members and students of the college actively attended this program.

Vignan Pharmacy College, Guntur

Workshop on 'Guidance on Psycho-social and Counseling Skills'

The inaugural ceremony of Psychosocial Support Service Cell and Workshop on 'Guidance on Psychosocial and Counselling Skills' was organized by Vignan Pharmacy College on 14th June, 2021. Students, faculty, Deans and HoD's participated in the ceremony

through digital mode. The inauguration ceremony was initiated with a prayer song and was followed through the introductory remarks by Dr. P. Sowjanya, the Coordinator of the cell. Dr. P. Srinivasababu, Principal gave the welcome address. An insightful thought process on how to get connected with people in these hard-hitting times and rendering moral support was delivered by Mr. Suresh Jampa, MGNCRE, Ministry of Education, and Govt. of India. Online exercises on instilling empathy and psychological support for the needy paved the way for enthusiastic learning and active participation. The session ended with the Plan of Action for the weeks to come by Dr. P. Srinivasa Babu. Many students volunteered themselves to work under various groups like medical support group, psycho-emotional group, family care group and social service support group as an outcome of the webinar.

Webinar on 'National Educational Policy 2020 – Reforms in Higher Education'

Vignan Pharmacy College organized a webinar on 'National Educational Policy 2020 – Reforms in Higher Education' on 4th May, 2021. Students, faculty, Deans and HoD's participated in the webinar through digital mode. The session began with introductory remarks by Dr. P. Sowjanya Dean, IQAC, Professor and Dept. Head of Pharmaceutical Biotechnology. Dr. P. Srinivasababu Professor and Principal proposed a warm welcome to the speaker and the participants. Dr. Sharmila Shamsu, Formerly OSD, Ministry of Education, Government of India, Secretary Committee to draft NEP was the speaker of the session. She explained about the NEP 2020 by giving some insights into its history. Participants were especially grateful for the discussion and for answering their questions. The session ended with a Vote of Thanks by Mrs. J. Srividya, Asst. Professor, Dept. of S&H.

G.Pulla Reddy College of Pharmacy, Hyderabad

International Yoga Day celebration

Seventh International Yoga Day was celebrated virtually on 21st June, 2021 in G. Pulla Reddy College of Pharmacy, Hyderabad. The program was initiated by Dr. B. Madhava Reddy, Principal, briefing about the importance of yoga during the corona pandemic. Dr. Veeresh B. introduced the speaker, Ms. M. Supraja Reddy, an International Yoga trainer and founder of 'The Yoga Hive', Hyderabad. The speaker explained the importance of yoga in management of management of COVID-19 and instructed yogasanas and breathing techniques to control COVID-19 complications. About 100 students and teaching staff members actively participated in the Yoga Day celebration. The program concluded with the Vote of Thanks presented by Dr. Veeresh B.

Ph.D. Award

Name: Dr. Nimrata Seth

Title: Design and Evaluation of Microspheres of Antihypertensive Drug

University: IKG- Punjab Technical University, Kapurthala, Punjab

Guide: Dr. Shailesh Sharma, Professor, Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial College of Pharmacy (An Autonomous College) BELA, Ropar, Punjab

American Association of Indian Pharmaceutical Scientists
AAiPS Distinguished Young Educator and Researcher Scholarship-2021

Eligibility: Pharmaceutical Faculty in a Recognized Indian Pharmacy Institute

Grant: Research scholarship of US$ 500

Criteria: Outstanding young faculty members in the pharmaceutical arena **under the age of 45 years as of April 1, 2021** and those who have made significant and consistent contribution to teaching and research in Pharmaceutical Sciences and Technology in a recognized academic institution in India are eligible to apply

Guidelines: This grant is fully funded by the AAiPS and facilitated by the Indian Pharmaceutical Association (IPA) in India.

a. The grant covers a Scholarship of US $500 to the awardee to be spent for a research purpose such as purchasing a research chemical or software or a database and IPA would release the fund upon submission of a supporting invoice

b. The nominations for this Grant shall be facilitated by IPA. The selection committee consists of Dr. Sampat Singhvi, Chair, Awards Committee (AAiPS), Mike Yelvigi (AAiPS), and Dr Rao Vadlamudi (IPA).

c. **Application should be submitted electronically to ipacentre@ipapharma.org by the end of August 2021.**

d. Application should include the following **(Total package not to exceed 10 pages – longer package will be rejected without consideration):**

   a. Outline of significant achievement in pharmaceutical sciences with full references. An updated CV with a recent Photograph

   b. Two letters of recommendation

   c. A brief abstract of recent original research

e. This award is available only once to selected candidates.

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