



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Regulatory Affairs Division (RAD), IPA

Volume: 13

Number: 22

26th January 2020

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Editorial

Recent publication of the list of Reference Products for conduct of BE Study by the Drugs Controller General of India will clear the confusion of the manufacturers regarding the BCS classification and requirement of BE study for approval of a new drug.

Earlier Govt. of India has notified vide G.S.R. (E) dated 3rd April 2017(available at www.cdsc.nic.in), concept of “biopharmaceutical classification system” to classify drugs on the basis of solubility and permeability, classified as category I- high solubility and high permeability, category II- low solubility and high permeability, category III- high solubility and low permeability, and category IV- low solubility and low permeability.”; The applicant require to submit the result of bioequivalence study referred to in Schedule Y, along with the application for grant of a licence of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system.” This is a welcoming step in the process of approving solid dosage form.

This will also strengthen the concept of promoting generic version, because now BE study is require for both generic and brand products.



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F.No. 12-32/2019-DC(Pt-Misc-SND)
Government of India
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Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

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Dated: 22/11/2020

Notice

Sub: List of Reference Products for conduct of BE Study- regarding.

Drugs & Cosmetics Rules, 1945 have been amended vide G.S.R. 327(E) dated 03.04.2017, providing that the applicant shall submit the result of bioequivalence study along with the application for grant of a licence of oral dosage form of drugs specified under category II and IV of the biopharmaceutical classification system.

In order to have proper understanding about the BCS classification, requirement of BE study and reference product to be used in such studies, earlier CDSCO had issued guidelines vide letter dated 13.10.2017. Further the matter was also deliberated in meeting held on 02.06.2018 with State Drugs Controllers and various experts with CDSCO officers.

Further, 12 workshops for providing training on conduct of BA/BE studies for BCS Class II & BCS Class IV drugs were conducted in different parts of the country in collaboration with the State Drugs Controllers & the Indian Drugs/Pharmaceutical Association Forum between 03.08.2019 to 21.09.2019.

In order to streamline further, in respect of conduct of BE study, list of a number of drugs falling under BCS II & IV along with list of their reference products have been prepared taking information from various sources. The list will be expanded by including more drugs based on further available information in this regard.

It is expected that reference product for BA/BE studies should normally be the innovator's product, to which all generic versions should be shown to be bioequivalent. If, in case, innovator product is not available, applicant may use Indian product approved by CDSCO as Reference product.

A copy of the list of drug formulations along-with list of products that could be used as reference product in BE study is enclosed.

Discrepancies in the list, if any, may please be forwarded to this office for updating the list.



(Dr. V.G. Somani)
Drugs Controller General (India)

Detailed List is available at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTQ5Mg==

WHO warns 10M could die per year by 2050 without new antimicrobials

The World Health Organization warned that 10 million people per year could die by 2050 from drug-resistant infections if governments don't intervene and motivate pharmaceutical firms to develop new antimicrobials. Experts urged governments to incentivize development of therapies to combat drug-resistant infections, noting that most antimicrobial drugs in later stages of development are modifications of existing compounds, and few were designed to combat the most potent superbugs.

Ref.: [The New York Times \(tiered subscription model\)](#)

WHO to convene emergency meeting on coronavirus cases in China

Rising cases of a new coronavirus infection in China have prompted the World Health Organization to call for an emergency meeting to determine if the outbreak should be considered a public health emergency of international concern. Three deaths have been reported out of more than 200 cases, and a man who traveled home to Japan from China has tested positive.

Ref.: [Healio \(free registration\)/Infectious Disease News](#)

FDA approves cocaine nasal solution for local anesthesia

Lannett's new drug application for its investigational drug Numbrino, or cocaine hydrochloride nasal solution, was approved by the FDA as a local anesthetic of the mucous membranes for use during diagnostic procedures or surgeries in adults' nasal cavities.

Ref.: [eMPR](#)

IIT Kharagpur Researchers Develop Low-Cost Compact Disc For Blood Test In Rural Areas

Compact Discs may be outdated for our laptops but IIT Kharagpur researchers have redefined the use of these devices for low-cost medical diagnosis in rural areas.

Researchers from IIT Kharagpur led by Professor Suman Chakraborty from the Department of Mechanical Engineering have recently innovated

a simple low-cost motorized spinning disc based kit to perform Complete Blood Count (CBC).

"We have proposed a unique low-cost kit comprising a motorized device as a blood cell counting platform," said Dr. Chakraborty.

CBC are a collection of the most commonly required blood tests, which can detect a wide range of diseases, ranging from a common fever to cancer. It is the basic blood test that any doctor runs to make a diagnosis.

Currently, these tests cost around Rs. 200 due to the requirement of sophisticated instruments and trained medical professionals, which makes it expensive for the underprivileged population.

"The device is a simple spinning disc running on a small motor which is capable of performing the test whereby the parameters such as haematocrit (packed volume of red blood cells), haemoglobin, red blood cell (RBC), white blood cell (WBC), and platelet counts are estimated with an accuracy higher than 95 % as compared to an automated haematology analyser," Dr. Chakraborty added.

How was this unique innovation developed?

Ph.D students Rahul Agarwal and Devdeep Mukherjee, and Post Doctoral Fellows Arnab Sarkar and Arka Bhowmik were a part of the research team for this project, which was also mentioned in Biosensors and Bioelectronics, which is a notable journal from Elsevier.

While explaining the mechanism behind this innovation, Ph.D students Rahul Agarwal and Devdeep Mukherjee said, "The method essentially exploits the difference in densities of cells for separation in a rotating disc due to centrifugal force and implements label-free imaging method for counting the separated cells within the spinning disc."

This method is not only cost efficient but also biodegradable, as per the researchers.

According to Post Doctoral Fellows Arnab Sarkar and Arka Bhowmik, the design and techniques involved in the process are fairly simple which makes the device portable and easy to use. It also eliminates the need for downstream processing of the separated blood.

CBC test cost brought down drastically

As per the researchers, a normal CBC test costs about Rs. 200 but this innovation will help bring down the cost of the test to nearly Rs. 10.

Director V K Tivari feels that such an innovation of medical device might bring a paradigm shift in providing diagnostic services to the underserved rural population at large.

He said, "The upcoming superspecialty hospital of IIT Kharagpur would operate in a hub and spoke model, and would use several of such devices to ensure improved reach of telemedicine and mobile healthcare to the last man of the society."

Dr. Chakraborty remarked that the CBC kit will be a key product which could be licensed and made market ready by MSMEs.

"The Common Research & Technology Development Hub on Technologies for Affordable Healthcare supported by the Government of India's DSIR aims to support growth & development of precision manufacturing of innovative technologies through MSMEs to reduce India's massive import in healthcare technologies and their affordability and accessibility," he added.

Chakraborty also confirmed that more such healthcare technology commercialization is in the process.

Source: India today

Tiny Organs Grown In Lab Can Produce Real Snake Venom

Scientists have created small organs in the laboratory which can be used to mass produce natural snake venom.

In the study published in the journal Cell, the researchers described how they created organoids of the venom glands of the Cape coral snake, which is endemic to parts of southern Africa.

If the method could be commercialised, it would be much more efficient than the way venom is currently produced — by raising snakes on farms and milking their glands, the researchers said.

"More than 100,000 people die from snake bites every year, mostly in developing countries. Yet the methods for manufacturing anti-venom haven't changed since the 19th century," said Hans Clevers from Utrecht University in the Netherlands.

"It's clear there is a huge unmet medical need for new treatments," Clevers said.

Every snake has dozens of different components in their venom. These are extremely potent molecules that are designed to stop prey from running away.

"They affect systems as varied as the brain, neuromuscular junctions, blood coagulation, and more. Many of them have potential bioprospecting applications for new drugs," said Clevers.

However, some of his students decided to study stem cells and develop organoids from reptiles.

For details: Daily Excelsior



IPA National President-Dr. T.V.Narayana is at IPA, Bengal Branch office along with members and executives of IPA, Bengal Branch



IPA National President-Dr. T.V.Narayana with other dignitaries during inaugural programme of an International seminar at JHIP, West Bengal

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