R.N.I. No. MAHENG/2000/05366

Thursday ◆ February 24, 2022 ◆ ₹60

South Asia's No.1 Pharma News Weekly

CHRONICLE PHARMABIZ

A Saffron Media Publication ◆ Mumbai ◆ Vol. 22 No. 13 ◆ Visit us at: www.pharmabiz.com

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NMC to frame module on AMR containment

Laxmi Yadav, Mumbai

In an effort to operationalise national action plan on antimicrobial resistance (AMR) aiming to curtail spread of AMR in the country, the National Medical Commission has decided to frame common module on AMR containment which will improve awareness and understanding of AMR among undergraduate, postgraduate medical students, and teaching professionals of medical colleges.

The Union ministry of health and family welfare came out with the National Action Plan (NAP) for curtailing AMR in April 2017 which needs to be launched across the country so as to bring about an alignment with the Global Action plan on AMR with a "one health" approach.

The NAP outlined certain strategic intervention activities which need to be carried out by the NMC. This include reviewing and revising curricula of professionals in human and animal health as well as reviewing and developing curriculum and resources for in-service training of different professionals and allied services.

In a bid to improve knowledge and skills of prescribers, dispensers and medical trainees on optimal antimicrobial use, NAP stressed the need for collaboration with regulatory bodies including health ministry, NMC, Pharmacy Council of India, Dental Council of India etc to mandate periodic training to optimise antibiotic use through pre-service and in-service trainings. ◆

Centre to bring processing charges of blood components under DPCO

Gireesh Babu, New Delhi

The Central government is taking up a proposal to bring the processing charges of blood and blood components under the drug price regulations and the same is under the consideration of the drug price regulator, said the ministry of health and family welfare (MoHFW).

Dr Bharati Pravin Pawar, the minister of state in the MoHFW recently informed Lok Sabha, "The matter regarding processing charges of blood and blood components has been taken up with the NPPA for bringing the same under DPCO."

The Minister has recently said that during a meeting with the State Blood Transfusion Councils (SBTCs) of all States and Union Territories (UTs) held on January 3, 2022, it has been recommended to take up a review of the National Blood Policy. Further, the National Blood Transfusion Council (NBTC)/Blood Transfusion Services (BTS) Division is under transition from National AIDS Control Organization (NACO) to Directorate General of Health Services (Dte.GHS).

The Ministry has earlier notified the Drugs and Cosmetics (Second Amendment) Rules, 2020, pertaining to the functioning of blood banks, blood processing and related matters, to support the National Blood Policy. There are 3,807 licensed blood banks (blood centres) in the country.

Government of India through Blood Transfusion Services, also supports 1,131 Blood banks in the Public and Charitable sector in respect of manpower, procurement of Blood Bags and testing kits, conducting Voluntary Blood Donation (VBD) camps and Information Education Communication (IEC) activities etc. In addition, Mobile vans for Blood collection and blood transportation vans are provided to the States/UTs. ◆

Regulatory aspect of pharmaceutical excipients

Dr. Sanjay Agarwal

The regulatory element of pharmaceutical excipients plays a role in dosage forms. Excipients were once thought to be inactive substances. However, with time, pharmaceutical scientists discovered that they are not inactive and impact the manufacture, quality, safety, and efficacy of the drug(s) in a dosage form. The active ingredient cannot be given alone, and the number of excipients in a formulation is more than the number of active ingredients. As a result, excipients play a crucial role in a dosage form, influencing attributes such as absorption efficacy, safety, bioavailability, solubility, stability, and dissolution.

Earlier excipients might cause substantial side effects, but the regulatory debate over their usage is still unclear compared to active pharmaceutical ingredients (APIs). Excipients require strict regulation and laws to avoid unwanted side effects and interactions with the medicine. Excipients must be evaluated for toxicity, preclinical trials, compatibility tests, and other factors before being used in a formulation.

Excipients alter a formulation's numerous qualities, including absorption, efficacy, safety, bioavailability, solubility, stability, dissolution, and so on. They are increasingly being used as a significant component in boosting product branding and the design of more patient-friendly dosage forms. They are in charge of product performance and ensure that the medicine has the appropriate pharmacological effect. According to regulatory guidelines, all ingredients of a medication formulation must be compliant and tested according to current cGMP criteria for drug safety and efficacy.

Brief on excipients

Without a proper delivery mechanism, even the best new therapeutic substance in the world is worthless. Tablets, capsules, oral liquids, topical creams and gels, transdermal patches, injectable treatments, implants, eye products, nasal products, inhalers, and suppositories are among the many dose forms available today.

Pharmaceutical excipients are compounds added to a pharmaceutical dosage form to help with the manufacturing process, protect, support, enhance stability, or improve bioavailability or patient acceptability. They may also help with product identification and improve its overall safety or function during storage or use.

Several different excipients are utilized in pharmaceuticals, accounting for over 90% of each product on average. According to industry experts, they have a market worth of €3 billion (almost $4 billion) and account for 0.5 per cent of the whole pharmaceutical market.

Origin and sources of excipients

Excipients come from a variety of places:

- Mineral sources, such as talc, calcium silicate, and silica
- Shellac, gelatine, Magnesium stearate, Lactose, and other animal sources
- Plant-based sources, such as starches, cellulose, sugar, alginates, and so on.
- Origins are semi-synthetic, such as cellulose derivatives such as Hydroxypropylmethylcellulose (HPMC), etc.
- Polyvinylpyrrolidone, polyethylene glycol, Cross povidone, and other synthetic materials

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Drug - excipient compatibility study maximizes stability

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Various advanced analytical techniques such as thermal methods, thermomicroscopy, isothermal microcalorimetry, isothermal titration calorimetry, high sensitivity differential scanning calorimetric, isothermal stress testing, optical microscopy and chromatography are also used to detect potential drug-excipient incompatibilities.

Using these techniques in preformulation stage, rationalized excipient selection can be performed. Although many analytical methods can be applied, hyphenated techniques such as differential scanning calorimetry, differential scanning calorimetry. Fourier transform infrared spectroscopy or mass spectrometry are more advantageous methods because they not only simulate the accelerated drug stability testing but also at the same time enable to detect and quantify the degradation products.

Differential scanning calorimetry is a thermo-analytical technique in which the difference in the amount of heat required to rise the temperature of a sample and reference is measured as a function of temperature. Both the sample and reference are maintained at nearly the same temperature throughout the experiment. Normally, the temperature programme for a differential scanning calorimetry analysis is designed such that the sample holder temperature rises linearly as a function of time. The reference sample should have a well- defined heat capacity over the range of temperatures to be scanned.

Conclusion

Excipients are non-toxic and does not interact with the active ingredients. But, practically only a few excipients are meeting these criteria. Many of the excipients have more than one use, which can be beneficial to manufacturers as it reduces the number of excipients needed and minimises the risk of drug-excipients interactions.

Pharmaceutical excipients of functional and non-functional are increasingly getting attention of global markets due to its importance in formulation process. Like active pharmaceutical ingredients, excipients also play important role in a finished pharmaceutical product. The false excipients can interact with active ingredients and hurt the consumers while the contaminated excipients can lead to adverse drug response to the consumers.

Standard and quality of excipients play vital role in efficacy, safety and effectiveness of a dosage form. Production processes of excipients must be controlled to ensure the excipients consistently meet the required specifications. In an ideal manner an excipient is pharmacologically inert, non-toxic, and does not interact with the active ingredients.

Generally, the excipients are pharmacologically inactive substance formulated alongside the active pharmaceutical ingredients of a dosage form, they provide bulk in to the formulation and facilitate drug absorption and help in to handle the active pharmaceutical ingredients during production processes of a dosage form and they have very important role in pharmaceutical sector. They are the most required constituents of a dosage form that enable enhanced drug efficacy.

Drug-excipient compatibility study targets to detect how compatible an excipient is with active pharmaceutical ingredient or candidate drug molecules. The study helps to find out the excipient that stabilizes an unstable active pharmaceutical ingredient and also helps to assign a relative risk level to each excipient. Drug-excipient compatibility study maximizes the stability of a dosage form. It bridges drug discovery and development. It is essential for investigational new drug submission.

A study on drug-excipient compatibility is an important stage in pre-formulation stage of a drug development. The potential interactions between drugs and excipients have effects on the chemical, physical, bioavailability and stability of the pharmaceutical products. ◆

(The author is a practicing chemical engineer)

Excipients can affect product safety and efficacy

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Requirement of excipient in drug formulations

Excipients such as mercurial preservatives, benzyl alcohol in parenteral medications for children, benzoic acid esters in injections, and sulfites and bisulfites are considered undesirable in formulations. A thorough justification will be necessary if some of them are to be used. Each excipient's function must be explained, and the inclusion of material must be justified.

There has been consistent data that is established with the combined excipients. Research shows that the excipients are chosen based on the dosage administration by the novel excipients. It is well supported by a new drug full of data compared to the other inclusions, compositions, and safety.

The novel excipient is combined with the matric in the prolonged release of the products, propellants, and permeability enhancers. The quality excipients need to be described adequately to give antimicrobial preservatives that have impacted the appropriate tests to demonstrate the anti-fungal and anti-bacterial activity.

Formulation functions of excipients

The total amount of excipients utilized in a dosage form is more than active drug components. Excipients, like pharmacological ingredients, are derived from natural sources or produced using chemical or other methods. Excipients were once thought to be inert components, but as time went on, pharmaceutical experts discovered that excipients are not inactive and have a significant impact on dosage forms. Excipient performance varies from batch to batch within the same producer and between sets from different manufacturers.

Excipients in pharmacological dosage forms are now known to have well-defined functional activities. Modulating API solubility and bioavailability, improving active ingredient stability in finished dosage forms, maintaining pH and osmolarity of liquid formulations, acting as an antioxidant, emulsifying agent, aerosols, tablet binders, disintegrates, lubricants and diluents are among their many functions.

Excipients also interact with the active ingredient in a prepared dosage form, forming a matrix that can impact essential quality features of the medicinal substance, such as stability and bioavailability. It can affect the finished dosage form and the product's safety and efficacy. Excipients must therefore be carefully considered by pharmaceutical companies when incorporating into a dosage form.

Quality standard and GMP for excipients

Tragedy due to lack of GMP has created a lot of unrest in society in the past. As per the records, the data has made a massive impact today! The excipients industry, which comprises hundreds of small businesses, is subjected to a stringent regulatory environment, increasingly stringent quality standards, and a consumer base that expects more but better services. No evaluation is required if the method of administration for the drug product comprising the main excipient requires high GMP. Otherwise, the nature of the excipient and its manufacturing procedure must be evaluated, as these aspects can raise the necessary GMP level. ◆

(The author is leading pharmaceutical consultant and Editor- in Chief of IJMToday)