



PHARMSOL NEWS

EXCIPIENTS: FROM AN AUXILIARY SUBSTANCE TO GAME CHANGER IN DRUG DELIVERY

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“An excipient is any component, other than the active substance, present in medicinal product or used in the manufacturing process”. Excipient plays a central role in the drug development process and contribute such as stability, biopharmaceutical profile, appearance, patient acceptability and to the ease with which the product can be manufactured.

An inappropriate choice of excipient can lead to severe implications on therapeutical results of the product. However right choice of excipient can lead the desired outcome w.r.t. compatibility, stability, clinical outcome as well as to overcome the manufacturing hurdles.

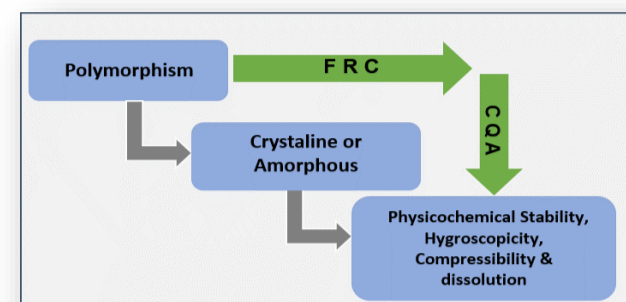
The intended function of an excipient is to guarantee the required physicochemical and biopharmaceutical properties of the pharmaceutical preparations. Since excipients are key parts of the formulation of medicine, it is compendial requirement to test their functionality and control the properties that may influence their suitability of dosage form prepared from them.

Functions of Excipients

Each excipient has their unique function to guarantee the desired critical quality attribute of product. Excipients are categorized based on their functionality in the formulation recipe, e.g., diluent, disintegrant, binder, lubricant, plasticizer, glidant etc. Since excipients can frame the critical quality attributes of final finished product, now a days it has been mandatory from various regulatory body to keep stringent check over selection and use of excipient

Functionality Related Characteristics (FRC)

Functionality of excipient is determined by its physicochemical properties, its molecular structure, and some cases by its content of byproduct or of additives, thus additives may contribute to the functionality of an excipients. Functionality of given excipient is controlled with setting specified acceptance criterion using monographs or In-house standards. Scientifically driven specifications for functionality related characteristics of input material define critical quality attribute (CQA) of final product. Example of some of the FRCs depicted in figure and their impact on CQA.



Development of New Excipient: The new chemical compound proposed and targeted to be used as excipient requires detailed safety testing procedure similar to that of new drugs. The safety aspect evaluation of new drug requires considerable investment in terms of time and money. However, significant progress happened on development of different grade of same excipient without changing inherent property of original excipient.

Oral absorption enhancement: Such excipients are used as an auxiliary with molecules with limited solubility and permeability to enhance solubility and permeability.

Excipient for localized delivery of drug: Active pharmaceutical ingredient (API) with defined absorption window is suitable candidate for localized drug delivery. e.g., the molecules which degraded in acidic stomach environment can be delivered in lower GI by using gastro-resistant polymer.

Excipient as stabilizer: API with known stability issue will be great challenge to formulate in suitable dosage forms. Such scenario excipient plays a significant role creating microenvironment to the API throughout the shelf life.

Excipient as process Aid: Excipients as a manufacturing process aid can help to make the manufacturing process smooth and speedy.

Novel excipients: Some of the novel excipients are Gelucire, Myvacet 9-45k, Avicel SMCC, Methacrylic Acid and Ethyl Acrylate Copolymer, tartaric acid, sodium lauryl sulphate.

Conclusion: Excipient plays a crucial role in development of robust, stable, efficacious, and commercially successful product.

How PharmSol can help you?

- ◆ **Development and tech transfer of finished dosage forms**
- ◆ **Reformulation of approved products to improvise product economics & cost effectiveness**
- ◆ **Product re-engineering**

Get in touch with our experts
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