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# ADVANTAGES OF PHARMACEUTICAL AIDS IN PHARMACEUTICAL FORMULATION

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**ABSTRACT**

The objective of a Pharmaceutical Aids development project is to deliver drug to the patient in the required amount, at the required rate, consistently within a batch, from batch to batch, and over the product's shelf life. To produce a drug substance in a final dosage form requires pharmaceutical ingredients.
Pharmaceutical Aid is all substances contained in a dosage form other than the active substance. They most commonly used dosage form because of the ease of manufacturing; convenience in administration, accurate dosing .*In addition, the review will highlight the Pharmaceutical Aid that can be substituted to ensure safety and efficacy of such products such as Excipients.*
The current review article is prepared to have a look over the recent development in excipients technology and the approaches involved in development of such excipients. The present review focus on such newer Excipients which have proved their potential in developing efficient solid dosage forms.

**Keywords:** Excipients, Impurities, ICH, Pharmaceutical substance, Pharmaceutical products, Standardization.



## INTRODUCTION

Many dosage forms formulated today are complex system containing many other components along with the active pharmaceutical ingredient (API) these compounds are generally added along with the active pharmaceutical ingredients in order to

**•Protect, support or enhance stability of the formulation:**

Most of the times it is observed that the active pharmaceutical ingredient in its pure form does not retain its stability for long which results in its denaturation or sticking to the container wall thus rendering it unfit, hence in order to stabilize the API excipients are added which aid in maintaining the stability of the product and ensures that API retains its stability for a considerable period of time thus improving the shelf life of dosage formulation.

•Bulk up the formulation in case of potent drug for assisting in formulation of an accurate dosage form

•Improve patient acceptance.

**•Help improve bioavailability of active drug:**

Excipients usually help in improving the bioavailability of the active pharmaceutical ingredient for e.g. In many cases an active substance (such as aspirin) is not absorbed easily by human body in such cases the active ingredient is dissolved in or mixed with an excipient which may either act as solvent or assist in absorption of the drug in human body.

•Enhance overall safety and effectiveness of the formulation during its storage and use.

The US pharmacopoeia National formulary (USP-NF) categorizes excipients according to the functions they perform in the formulations e.g.Binders, disintegrants etc.

Excipients can be classified on the basis of their origin, use in dosage form, and functions they perform as follow

**Excipient based on their origin:**

***Animal source*:** Lactose, Gelatin, Stearic acid, Bees wax, Honey, Musk, Lanolin etc.

***Vegetable source*:** Starch, Peppermint, Turmeric, Guargum, Arginates, Acacia etc.

***Mineral source*:** Calcium phosphate, Silica, Talc, Calamine, Asbestos, Kaolin, Paraffin, etc.

***Synthetic:*** Boric acid, Saccharin, Lactic acid, Polyethylene glycols, Polysorbates, Povidone etc.

**Classification of excipients based on their functions**

Excipients are classified on the basis of the functions they perform such as:-Various excipients used in solid dosage forms perform various functions like:-Binders, diluents, lubricants, disintegrating agent's plasticizers etc, e.g.: when 5% starch is used in formulation it acts as a binder for tablet formulations where as when it is used in dry form it can perform the function of a disintegrates.

Excipients that are used in Liquid dosage forms are:- Solvents co-solvents, buffers anti-microbial agents emulsifying agents sweetening agents, flavours, etc
Some excipients have therapeutic values which are classified as under:-Anesthetics10:-chloroform, etc
Laxatives: bentonite, psyllium, xanthan gum, guar-gum etc.
Ph modifiers: citric acid.
Astringent: cinnamon, alum, zinc sulphate.
Carminative: cinnamon, dill water, anise water.
Nutrient sources: agar, lactose, etc.

**Changing the dissolution rates of active species**

► Colours
► Flavours
► Sweeteners
► Preservative

**CHARACTERISTICS**:

The ideal characteristics of an excipients are given as under:

**Excipients must be:**

- Chemically stable
- Non reactive
- Low equipment and process sensitive
- Inert to human body
- Non toxic
- Acceptable with regards to organoleptic characteristics
- Economical
- Having efficiency in regards with the intended use excipients even though considered inert substance, have the tendency to react with drug components, other excipients, and also the packaging system.

Excipients may also contain various impurities which may result in decomposition of the active pharmaceutical ingredients in the formulation thus altering the shelf life of the formulation.

**QUALIFICATION OF PHARMACEUTICAL AIDS:**

Qualification is the process of acquiring and evaluating data that establishes the biological safety of an individual impurity or a given impurity profile at the level(s) being considered.
When appropriate, we recommend that applicants provide a rationale for establishing impurity acceptance criteria that includes safety considerations.
An impurity is considered qualified when it meets one or more of the following conditions:

• When the observed level and proposed acceptance criterion for the impurity do not exceed the level observed in an FDA approved human drug product.
• When the impurity is a significant metabolite of the drug substance.
• When the observed level and the proposed acceptance criterion for the impurity are adequately justified by the scientific literature.
• When the observed level and proposed acceptance criterion for the impurity do not exceed the level that has been adequately evaluated in comparative Invitro geno toxicity studies.

**STANDARIZATION OF PHARMACEUTICAL AIDS:**

Excipients quality plays a vital role in assuring safety, quality and efficacy of dosage forms.
Standardization of excipients usually assures the customers and manufacturers that the excipients quality will meet the international market, therefore the rules for regulation of bulk excipients are stringent and whenever a new excipients is to be introduced it is necessary for the applicant to submit safety and quality data and for an approved excipients the applicant has to provide literature reference data.
The various reasons for which excipients must be standardized are:-

- To assure the customer that the excipients used are safe and will not alter the formulation and cause undesirable effects.
- To assure the manufacture that he is using a standard quality material for formulating his dosage form.

**Storage conditions**:

Excipients are tested for the storage conditions for its thermal stability, moisture sensitivity or solvent loss.

**CONCLUSION**:

Excipients being an indispensible component of medicinal products must be evaluated for their safety and stability.
The safety assurance of excipients helps the formulator to design an effective and safe dosage form with the use of efficient and safe excipients.
Thus for an excipient to be in a formulation it must be highly stable, safe and efficacious, and above all it must comply with the expected performance in the formulation.

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