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A REVIEW ON FORMULATIONS AND EVALUATION OF FILM COATED IMMEDIATE RELEASE TABLETS OF PIRACETAM

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ABSTRACT

Tablets are solid preparations each containing a single dose of one or more active substances with or without excipients usually obtained by compressing uniform volumes of particles. An immediate release dosage form allows a manufacturer to extend market exclusivity, while offering patients a convenient dosage form or dosage regimen. Immediate Release Tablets are those tablets which are designed to disintegrate and release their medication with no special rate controlling features, such as special coatings and other techniques. The term direct compression is used to define the process by which tablets are compressed directly from powder blends of the active ingredient and suitable Excipients which will flow uniformly into a die cavity and form into a firm compact. Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. Dry granulation processes create granules by light compaction of the powder blend under low pressures. After making a good tablet, coating is the next major step. Aqueous and solvent coating processes are extensively used in the pharmaceutical industry to apply functional and/or non functional coats to tablets. Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use. Packaging also refers to the process of design, evaluation, and production of packages.Blister pack is a term for several types of pre-formed plastic packaging used for small consumer goods.

KEY WORDS: Tablets, immediate release, Wet granulation, Dry granulation.

INTRODUCTION

An Oral Dosage Form is the physical form of a dose of a chemical compound used as a drug or medication intended for administration or consumption by oral route. Common oral dosage forms are tablets or capsules. Tablets are solid preparations each containing a single dose of one or more active substances with or without excipients usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated. The excipients can include binders, glidants and lubricants to ensure efficient tabletting; disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavors to enhance taste; and pigments to make the tablets visually attractive. These are included in the formulations to facilitate easy handling, enhance the physical appearance, and improve stability and aid in the delivery of the drug to the blood stream after administration. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance.

IMMEDIATE RELEASE TABLETS

The need for new oral drug delivery system continues, due to poor patient acceptance for invasive methods, need for exploration of new market for drugs and coupled with high cost of disease management. Developing new drug delivery techniques and utilizing them in product development is critical for pharma companies to survive this century. An immediate release dosage form allows a manufacturer to extend market exclusivity, while offering patients a convenient

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dosage form or dosage regimen. Immediate Release Tablets are those tablets which are designed to disintegrate and release their medication with no special rate controlling features, such as special coatings and other techniques. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer, has quick onset of action is economical and lead to better patient compliance. They are also a tool for expanding markets, extending product life cycles and generating opportunities.

Advantages of Immediate Release Tablets

- Economical and cost effective.
- Provides some advantages of liquid dosage forms.
- Improved stability and bioavailability.
- Suitable for industrial production
- Quick onset of action.
- Unique product differentiation
- Adaptable and amendable to existing processing and packaging machinery

Disadvantages of Immediate Release Tablets –

- Rapid drug therapy intervention is not possible.
- Sometimes may require more frequency of administration.
- Dose dumping may occur.
- Reduced potential for accurate dose adjustment.

METHODS OF FORMULATING IMMEDIATE RELEASE TABLETS-

In general, the choice of method for the manufacture of tablets is dependent on a number of factors like:-

a) The physical and chemical stability of the therapeutic agent during the manufacturing process.

b) The availability of the necessary processing equipment.

c) The cost of the manufacturing process and

d) The excipients used toformulate the product.

Direct Compression:-

The term direct compression is used to define the process by which tablets are compressed directly from powder blends of the active ingredient and suitable excipients which will flow uniformly into a die cavity and form into a firm compact.

Procedure:-

Step 1: Premilling of formulation components.
Step 2: Mixing of the therapeutic agent with the powdered excipients (including the lubricant).
Step 3: Compression of the mixed powders into tablets.

Wet granulation:-

Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. The amount of liquid has to be properly controlled, as over-wetting will cause the granules to be too hard and under-wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with than solvent-based systems.

Procedure:-

Step 1: The active ingredient and excipients are weighed and mixed.

Step 2: A wet granulate is prepared by adding the liquid binder to the powder blend and mixing thoroughly.

Step 3: Screening the damp mass through a mesh to form pellets or granules.

Step 4: Drying the granulation.

Step 5: After the granules are dried, they are passed through a screen of smaller size than the one used earlier.

Step 6: After granulation a final lubrication step is used to ensure that the tableting blend does not stick to the equipment during the tableting process.

Dry Granulation:-

Dry granulation processes create granules by light compaction of the powder blend under low pressures. The compacts so-formed are broken up gently to produce granules (agglomerates). This process is often used when the product to be granulated is sensitive to moisture and heat. Dry granulation can be conducted on a tablet press using slugging tooling or on a roll press called a roller compactor. Dry granulation equipment offers a wide range of pressures to attain proper densification and granule formation. It is simpler than wet granulation, therefore the cost is reduced. However, this method often produces a higher percentage of fine granules, which can compromise the quality or create yield problems for the tablet. Dry granulation requires drugs or excipients with cohesive properties, and a 'dry binder' may need to be added to the formulation to facilitate the

formation of granules. At last powdered lubricants are added.

TABLET COATING:

After making a good tablet, coating is the next major step. Aqueous and solvent coating processes are extensively used in the pharmaceutical industry to apply functional and/or nonfunctional coats to tablets. Final product performance, including coating uniformity and drug release, is a strong function of these coatings. In addition to functionality, the texture and opacity of the coatings also affect bulk flow characteristics as well as overall aesthetics of the finished product. Coating is performed for the following reasons:

I. Therapy

i) Avoid irritation of esophagus and stomach

ii) Avoid bad taste

iii) Avoid inactivation of drug in the stomach

iv) Improve drug effectiveness

v) Prolong dosing interval

vi) Improve patient compliance

II. Technology

i) Reduce influence of moisture

ii) Avoid dust formation

iii) Reduce influence of atmosphere

iv) Improve drug stability

v) Prolong shelf life.

vi) Reduces the need of specialized packing.

III. Marketing.

i) Avoid bad taste

ii) Improve product identity

iii) Improve appearance and acceptability

vi) Reduces tablet breakage during transportation and packing.

v) Helps in effective anti counterfeiting protection and trade marking opportunity.

Film coating:-

It involves the deposition, usually by spraying method, of a thin uniform film of a polymer formulation surrounding a tablet.

Film coating liquid contains-
1) Polymer
2) Plasticizer
3) Colorants
4) Solvent (vehicle)

1) Polymer: A film former capable of producing smooth thin films reproducible under the prescribed coating conditions.eg- Cellulose acetate pthalate.

2) Plasticizer: Affords flexibility and elasticity to the coat and thus provide durability. Examples; Polyethylene glycol (PEG), Polypropylene glycol and castor oil.

3**) Colorants and Opaquants:** Provides an elegant appearance. Ex. Iron oxide pigment, Titanium dioxide and Aluminium lakes.

4) Solvent (vehicle): Volatile organic solvents may be used to allow good spread ability of the coat components over the tablet and allowing rapid evaporation, but they are expensive and show environmental hazards and solvent residue in the formulation must be investigated (certain limit). Aqueous vehicles are safer, but they show slower evaporation and may affect drug stability.

Compression coating:-

Although less popular, it gained increased interest in the recent years for creating modified-released products. It involves the compaction of granular materials around a preformed tablet core using specially designed tableting equipment. Compression coating is a dry process.

It is done to separate incompatible materials (one in the core and the other in the coat). There is an interface between the two layers and thus compromise product stability. It is possible to apply an inert placebo coating layer first, to separate the core from the final coat more effectively.

Enteric coating:

They are given for those dosage forms which are intended to pass through the stomach intact to disintegrate and release their drug content in the intestine for absorption. Usually an enteric coating is based on factors like pH, resisting dissolution in the highly acid environment of the stomach but yielding to the less acidic environment of the intestine.

PACKAGING OF IMMEDIATE RELESE TABLETS

Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use. Packaging also refers to the process of design, evaluation, and production of packages.

Packaging and package labelling have several objectives like

Physical protection - The objects enclosed in the package may require protection from things like shock, vibration, compression, temperature etc. Barrier protection - A barrier from oxygen, water vapour, dust, etc., is often required to keep the contents clean, fresh, sterile and safe for the intended shelf life is a primary function.

Agglomeration protection - Small objects are typically grouped together in one package for efficient transportation and handling.

Information transmission - Packages and labels communicate how to use, transport, recycle, or dispose of the package or product. Some packages and labels also are used for track and trace purposes.

Marketing - The packaging and labels can be used by marketers to encourage potential buyers to purchase the product.

Security - Packaging can play an important role in reducing the security risks of shipment. Packages can be made with improved tamper resistance to deter tampering and also can have tamper-evident features to help indicate tampering. Packages can be engineered to help reduce the risks of package pilferage.

Convenience - Packages can have features that add convenience in distribution, handling, stacking, display, sale, opening, reclosing, use, dispensing, and reuse.

Portion control - Single serving or single dosage packaging has a precise amount of contents to control usage.

SCALE UP

It is defined as a process in pharmaceutical industry where a lab scale formula is transformed into a viable product by operating at relatively small scale to produce experimental data or trial lot quantities or both of the compounds under investigation.

It enables experimenters to evaluate the effect on the process of a large change in the scale up operations and to gather other data so that a good design of a large unit may be made with a high probability of commercial success. Here a close examination of the formula is done to determine its ability to withstand batch scale and process modification. Scale up helps in providing short term and long term efficiencies, guidelines for production and process controls and also evaluation and validation for process and production controls.

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