Solid Dosage Forms of Biopharmaceuticals in Drug Delivery Systems Using Sustainable Strategies

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Abstract:
Solid dosage forms, which were being used since ancient days, have been made modifications in terms of theirdrug delivery systems. As there are many adverse effects caused by solid dosage forms, recent advanced techniques were developed to minimize the adverse effects. These techniques are encapsulating the drug withmatrix, and polymer micelles. These two techniques have a good significant use in the recent era. They optimize the bioavailability, pharmacokinetic and Pharmodynamic properties of the drug. Further advance intheir drug delivery system is by applying nanotechnology in their drug delivery system. Applications of Nanotechnology in drug delivery would further minimize the adverse reaction.

Keywords: biopharmaceuticals, solid dosage forms, drying technologies, sustainable engineering, supercritical carbon dioxide, supercritical carbon dioxide-assisted spray-drying.

INTRODUCTION:

Solid dosage forms were been considered to be easiest forms of drug delivery systems. Among all the solid dosage forms, tablets, and capsules are commonly employed. They can be produced in a nonsterile environment. The main goal of pharmaceutical formulation is to achieve better therapeutic activity by using smallest quantity of drug administered by the most suitable route. Usually, solid oral drug products are produced, to give an immediate result upon administration. Oral route of drug administration has wide acceptable and of the drugs administered orally in solid dosage forms represents the preferred class of products. The reasons are tablets and capsules represent unit dosage forms in which one usual dose of drug has been accurately placed. Commonly, Tablet is preferable than capsules, because, tablets have an advantageof being tamper resistant. And any adulterant of the tablet after its manufacture is almost certain to be observed. As there are many advantages of tablets and capsules, there are few disadvantages as well, which may delay the absorption and also decrease the efficacy of the drug. Some of the disadvantages are, they delaythe onset of action, are not suitable in emergency and for unconscious patients. The drug content of the tabletmust be
bioavailability. Accurate bioavailability can be obtained from the drug levels of the drug after its administration. Tablets must be elegant in appearance and must have characteristic shape, colour, and other markings necessary to identify the product. Tablets must retain all these functional attributes, which include drug stability and efficacy 1.

Definitions: Solid dosage forms

Powders: Solid dosage forms containing finely divided particles in micron size.

Tablets: Solid dosage form containing medicaments with or without excipients.

Granules: Aggregate of particles – Capsules: Drug enclosed with gelatine capsule – Cachets: Drugs enclosedwith wafer sheet of rice – Pills: Small tablet containing excipients.

Lozenges: Solid preparations containing sugar and gum used to medicate mouth and throat.

Suppositories: Solid dosage containing medicaments with suitable suppository base that inserted in to thebody cavities other than mouth, like rectum, nose, ear.

Poultices: Solid dosage form converted to paste like preparation used externally in the skin to reduceinflammation.

Tablets: Tablets are unit solid dosage forms in which one usual dose of the drug has been accurately placed.

ADVANTAGES:

- Tablets are unit dosage forms and they offer the greatest capabilities of the all-oral dosage forms for thegreatest dose precision and the least content variability.
- Their cost is lowest of all oral dosage forms.
- They are the lightest and most compact of all oral dosage forms.
- They are in general easiest and cheapest to package and ship of all oral dosage forms.
- They are better suited to large scale production than other unit oral dosage forms2.

DISADVANTAGES:

- Some drugs resist compression into dense compacts
- Drugs with poor wetting, slow dissolution, intermediate to large dosages may be difficult or impossible toformulate and manufacture as a tablet that provide adequate or full drug bioavailability.
- Bitter taste drugs, drugs with an objectionable odour, or sensitive to oxygen or moisture may requireencapsulation or entrapment prior to compression or the tablets may require coating4.

TYPES OF TABLETS

Ingested orally: -Used in oral cavity

- Compressed tablet
- Buccal tablet
- Multiple compressed tablet
- Sublingual tablets

- Modified release tablets
- Lozenges Enteric coated tablets
- Dental cone Sugar coated tablets
- Film coated tablet
- Chewable tablets
- Targeted tablets

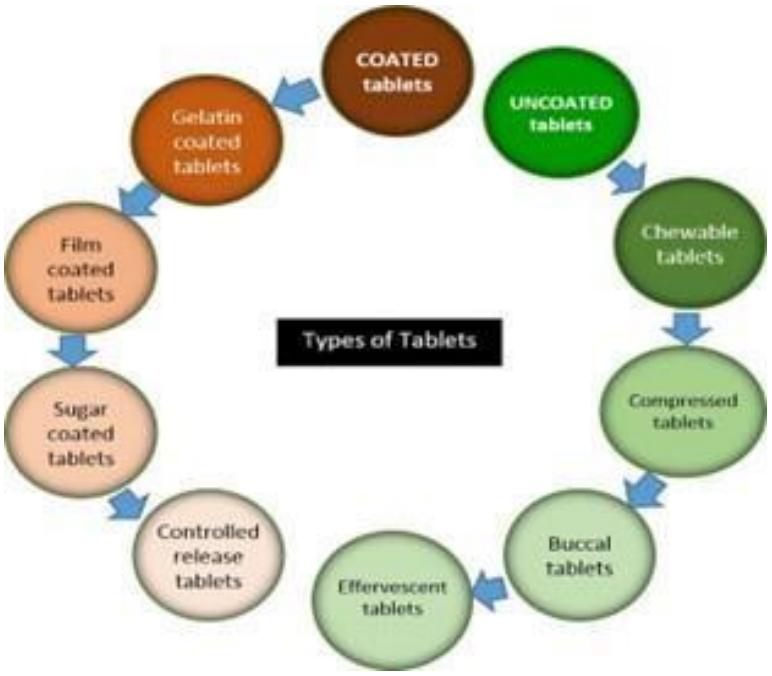

Figure: Classification of Tablets based On Coating

Multiple compressed tablets

- To separate physically or chemically incompatible ingredients &
- To produce repeat action/ prolonged action tablet.

Layered tablets: - two to three component systems. **Compression coated tablets:** – tablet within a tablet.**Modified release tablet:**

- Modified-released tablet is either uncoated or coated5.

METHODOLOGY:

Process Validation of the manufacture of solid dosage form, process should be carried out for threeconsecutive batches as per protocol. During the process validation following steps should be followed.

- Preparation of PV protocol
- Preparation of batch manufacturing record (BMR)
- Identification of critical process parameters (CPP) for critical steps in the manufacturing process.
- In process quality control test at every stage of manufacturing Sampling plan. Quality control test for tablets
- Acceptance criteria.
- Stability studies
- Recording and analysing results of critical control variables and response variables as per process parameters considered.
- Identify the productivity of tablets and prepare a validation report 6.

1. PREPARATION OF PV PROTOCOL:

- Make sure that PV protocol must be prepared then approved by Quality assurance personnel as it will guide on how the PV should be performed.

2. Preparation of BMR:

- It is an important document which covers the overall records of the production history of a particular batchof product. It also assures that the quality and regulatory requirements are attained. BMR contains the following:
- Product name
- Batch number
- Dispensing of raw and packaging material details
- Raw and packaging materials verification details
- The process involved in manufacturing
- Exactly date for starting and finishing of manufacturing process
- Signatures of the operators and reviewers
- All test carried out, the results should be recorded

- Name of the equipment used, cleanliness, line clearances etc.

3. PV of solid dosage form to be carried out for three consecutive batches as per protocol:

PV should be conducted for three consecutive batches to confirm that process consistently will produce a product meeting predetermined specifications along with its quality attributes. Three consecutive batches means in sequence such as 1, 2, 3 (correct) and not by skipping one batch example 1, 3, 4 (incorrect).

4. Manufacturing process:

Step 1: Sifting: - The accurately weighed amount of the raw materials should be sifted by using sieve shakermachine with the specified sieve number for example sieve number 20, 40, 60 etc.

Step 2: Dry granulation: - The sifted raw materials should be mixed at a particular blender for the specifiedperiod of time. Examples of blender used for mixing dry powder and granules are; double cone blender, v cone blender etc.

Step 3: Paste preparation: - The mixed raw materials are taken and forming paste with the help of bindingagent. Equipment used for this process is paste preparation kettle.

Step 4: Wet granulation: - The formed paste is going to be mixed by using specific granulator to achieve optimized mixing and consistent granules at higher productivity and lower operating cost.

Step 5: Drying: - After wet mixing process, drying process follows in which Fluid bed dryer is going to be used by following the specified set parameters.

Step 6: Dry milling: - The obtained dried granules should be milled by using multi mill equipment to get uniform particle size.

Step 7: Blending: - The obtained uniformly sized powder or granules should be mixed by using double coneblender by following the specified set parameters in order to obtain the uniformity of the blended material.

Step 8: Compression: - Then the blended material should be compressed using tablet compression machineto get tablets by following all the standard set parameters so that to achieve the product of high quality7.

Step 9: Tablet coating: - This step should be applied to in case of coated tablets. Its major importance is tomask the taste or odour of the drug. It also protects the drug from physical and chemical degradation. Equipment's used for tablet coating such as standard coating pan, perforated coating pan, fluidized bed coater
etc need to be qualified before processing8.

Step 10: Packaging: - Last is packaging of the product, in which the tablets are going to be packed in different packaging material such as blisters, strips, bottles etc. Packaging step it is important as it protects the product during storage9.

CONCLUSION:

The physicochemical property is most important factor in solid dosage form Coues it's occurring or chances to difficulties in formulation. The quality and curative effect of solid drugs, polymorphism of drug substances has been investigated in the pharmaceutical field for over 50 years. BCS relies on black and white definitions of solubility and permeability, are these definitions reliable or realistic, and There may be a risk of misclassification. The study of preformulation, characterization is important in solid dosage form.

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