

Process of problems and evaluation test of tablet manufacturing

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ABSTRACT

Tablets are the solid dosage forms which are conventional over all pharmaceutical dosage forms. They are easy to prepare than any other dosage forms but during their manufacturing many problems will arise which will cause discarding of the entire batch and also post compression studies also very important to release the dosage forms in to the market. In this article we mentioned what are the problems (Picking, Sticking, mottling etc...) will arise during the tablet manufacturing and their remedies and also what are the Pre and post compression properties (Hardness, Thickness and Weight variation etc...) and their limits to release the dosage form in to the market.

KEYWORDS: Tablet, Pharmaceutical dosage form, Picking, Sticking and Hardness

I. INTRODUCTION

Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of Tablet.

All medicaments are available in the Tablet form except where it is difficult to formulate or administer.

The Advantages of the Tablet Dosage Form^{1,2}

1. They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
2. Cost is lowest of all oral dosage form.
3. Lighter and compact.
4. Easiest and cheapest to package and strip.
5. Easy to swallowing with least tendency for hang-up.
6. Sustained release product is possible by enteric coating.

7. Objectionable odour and bitter taste can be masked by coating technique.

8. Suitable for large scale production.

9. Greatest chemical and microbial stability over all oral dosage form.

10. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face.

Disadvantages of Tablet Dosage Form

1. Difficult to swallow in case of children and unconscious patients.

2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.

3. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.

4. Bitter tasting drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.

Evaluation of Tablet¹⁻⁴

General Appearance The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste etc.

Size and Shape

It can be dimensionally described and controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a $\pm 5\%$ variation of standard value.

Unique identification marking

These marking utilize some form of embossing, engraving or printing. These markings include company name or symbol, product code, product name etc.

Organoleptic properties

Color distribution must be uniform with no mottling. For visual color comparison compare the color of sample against standard color.

Hardness and Friability

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures the tablet crushing strength. The apparatus showed in the Figure No.1.

Friability

Friability of a tablet can determine in laboratory by Roche friabilator. This consist of a plastic chamber that revolves at 25 rpm, dropping the tablets through a Distance of six inches in the friabilator, which is then operate for 100 revolutions. The tablets are reweighed. Compress tablet that lose less than 0.5 to 1.0 % of the Tablet weigh are consider acceptable. Friabilator showed in the Figure No.2.

Drug Content and Release

Weight Variation test (U.S.P.)

Take 20 tablets and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Content Uniformity Test

Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablets assayed individually and none may fall outside of the 85 to 115% range.

Disintegration Test (U.S.P.)

The U.S.P. device to test disintegration uses 6 glass tubes that are 3" long; open at the top and 10 mesh screens at the bottom end. To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at 37 ± 20 C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm

from the bottom of the beaker in their downward movement. Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet. Apparatus showed in the Figure No.3. According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified. If any residue remains, it must have a soft mass. Disintegration time: Uncoated tablet: 5-30 minutes Coated tablet: 1-2 hours.

Dissolution Test (U.S.P.)

Two set of apparatus

Apparatus-1

A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor. The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100 ml flask. The flask is cylindrical with a hemispherical bottom. The flask is maintained at 37 ± 0.50 C by a constant temperature bath. The motor is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Apparatus-2

It is same as apparatus-1, except the basket is replaced by a paddle. The dosage form is allowed to sink to the bottom of the flask before stirring. For dissolution test U.S.P. specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft, time limit of the test and assay procedure for. The test tolerance is expressed as a % of the labeled amount of drug dissolved in the time limit. Apparatus showed in the FigureNo.4. Inprocess Problems in tableting:

- Capping and Lamination
- Picking and Sticking
- Mottling
- Double impression

Capping and Lamination

Capping is a term used to describe the partial or complete separation of the top or bottom crowns of a tablet from the main body of the tablet. Lamination is the separation of a tablet in to two or more distinct layers.

Picking and Sticking

Picking is a term used to describe the surface material from a tablet that is sticking to and being removed from the tablet's surface by a punch.

Mottling Mottling is an unequal distribution of colour on a tablet, with light or dark areas standing out in an otherwise uniform surface.

Double impression

This involves only punches that have monogram or other engraving on them. At the

moment of compression the tablet receives the imprint of the punch. Sometimes it will receive double impression due to improper movement of lower punch. Preventive methods:

- By proper mixing
- By improving the flow properties of granules
- By using proper camtracks which are responsible for punches movements.



Figure No.1: Hardness Tester



Figure No.2: Friabilator



FIG: 3



Figure No.4: Dissolution Apparatus

II. CONCLUSION

Tablets are the conventional dosage forms and they are also widely using dosage forms due to many advantages over other dosage forms. During their manufacturing many inprocess problems and



also after formulation also problems will arise. By using proper preventive methods we can reduce those problems or we can make them in standard limits.

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