

Review Article on Inprocess Problems and Evaluation Tests of Tablet Manufacturing

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ABSTRACT

Tablets are the solid dosage forms which are traditional over all pharmaceutical dosage forms. Tablet is a solid pharmaceutical dosage form containing drug substance generally with suitable diluents and prepared by either compression or molding methods.

They are handy 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.

Latest standard and concept focus on bioavailability, bioequivalence and validation etc. impact formulation designing and manufacture. In this article we mentioned what are the problems (Picking, Sticking, mottling etc...) will occur during the tablet manufacturing and their treatments 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 described as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical coated 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 fluctuate in shape and differ extensively 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 reachable in the Tablet form except where it is difficult to formulate or administer.

The Advantages of the Tablet Dosage Form

1. They are unit dosage form and offer the biggest competencies of all oral dosage form for the greatest dose precision and the least content variability.
2. Cost is cheapest of all oral dosage form.
3. Lighter and compact.
4. Easiest and lowest 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 odor and bitter taste style can be masked by coating technique.
8. Suitable for massive scale production.
9. Greatest chemical and microbial balance over all oral dosage form.
10. Product identification is effortless 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 youngsters and unconscious patients.
2. Some capsules resist compression into dense compacts, owing to amorphous nature, low density character.
3. Drugs with negative wetting, slow dissolution properties, top-quality absorption high in GIT may be challenging to formulate or manufacture as a pill that will nevertheless provide sufficient or full drug bioavailability.
4. Bitter testing drugs, drugs with an objectionable scent or drugs that are touchy to oxygen may require encapsulation or coating. In such cases, tablet may additionally offer the nice and lowest cost. Evaluation of Tablet

General Appearance

The usual appearance of a tablet, its identity and general magnificence is essential for consumer

acceptance, for manipulate of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of popular 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 pill is solely variables. Tablet thickness can be measured by means of micrometer or by means of other device. Tablet thickness should be controlled

within a $\pm 5\%$ variant of popular 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 sure amount of energy or hardness and resistance to friability to withstand mechanical shakes of managing in manufacture, packaging and shipping. Hardness generally measures the pill crushing strength.

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.

Drug Content and Release

Weight Variation test (U.S.P.)

Take twenty tablets and weighed one by one. Calculate average weight and compare the individual pill weight to the typical. The pill pass the U.S.P. check if no quite a pair of pills are outside the share limit and if no tablet differs by quite a pair of times the share limit.

Content Uniformity Test

Randomly choose thirty tablets. Ten of those assayed severally. The pill pass the check if nine of the ten tablets should contain not but eighty fifth and no more than one hundred and fifteenth of the

labeled drug content and therefore the tenth pill might not contain but seventy fifth and over one hundred and twenty fifth of the labeled content. If these conditions aren't met, remaining twenty tablets assayed severally and none might fall outside of the eighty five to one hundred and fifteenth vary.

Disintegration Test (U.S.P.)

The U.S.P. device to check disintegration uses vi glass tubes that ar 3" long; open at the highest and ten mesh screens at rock bottom finish. to check for disintegration time, one pill is placed in every tube and also the basket rack is positioned in a very 1-L beaker of water, simulated stomachic fluid or simulated enteral fluid at thirty seven \pm twenty C such the pill stay a pair of.5 cm below the surface of liquid on their upward movement and not nearer than a pair of.5 cm from rock 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 twenty eight to thirty two cycles per minute. Floating of the pills is often prevented by putting perforated plastic discs on every tablet.

According to the check the pill should disintegrate and every one particles should withstand the ten mesh screen within the time such that. If any residue remains, it should 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 pill is placed during a tiny wire mesh basket connected to very cheap of the shaft connected to a variable speed motor. The basket is immersed during a dissolution medium (as laid out in monograph) contained during a one hundred metric capacity unit flask. The flask is cylindrical with a subfigure bottom. The flask is maintained at $37\pm 0.50C$ by a relentless temperature tub. The motor is adjusted to point out at the required speed and sample of the fluid unit withdrawn at intervals to ascertain the amount of drug in solutions.

Apparatus-2

It is same as apparatus-1, except the basket is replaced by a paddle. The dose type is allowed to

sink to rock bottom of the flask before stirring. For dissolution check U.S.P. specifies the dissolution check medium and volume, variety of equipment to be used, rate of the shaft, cut-off date of the check

and assay procedure for. The check tolerance is expressed as a capturing of the labeled quantity of drug dissolved within the cut-off date.

Inprocess Problems in tableting:

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

Capping and Lamination

Capping could be a term accustomed describes the partial or complete separation of the highest or bottom crowns of a tablet from the most body of the pill. Lamination is that the separation of a pill in to 2 or more distinct layers.

Picking and projecting

Picking could be a term accustomed describes the surface material from a pill that's projecting to and being removed from the tablet's surface by a punch.

Mottling

Mottling is associate degree unequal distribution of color on a pill, with light-weight or dark areas standing enter associate degree otherwise uniform surface.

Double impression

This involves solely punches that have symbol or different engraving on them. At the instant of

Compression the pill receives the imprint of the punch. Typically it'll receive double impression thanks to improper movement of lower punch.

Preventive methods:

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

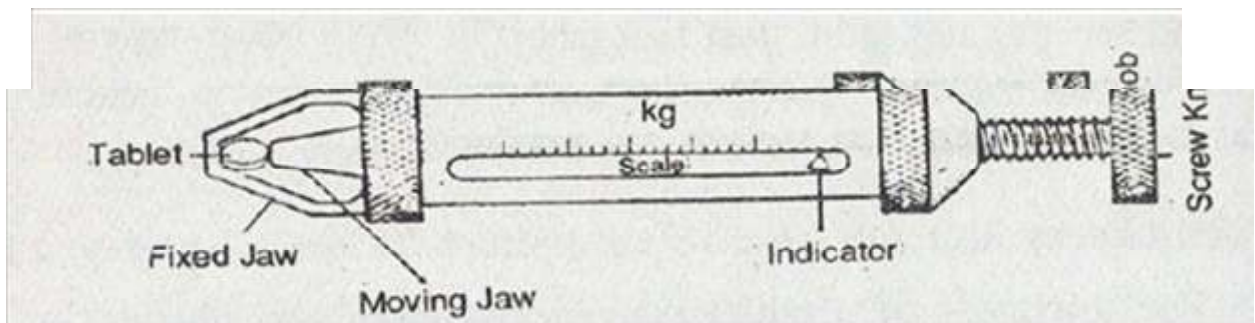


Figure: Hardness Tester

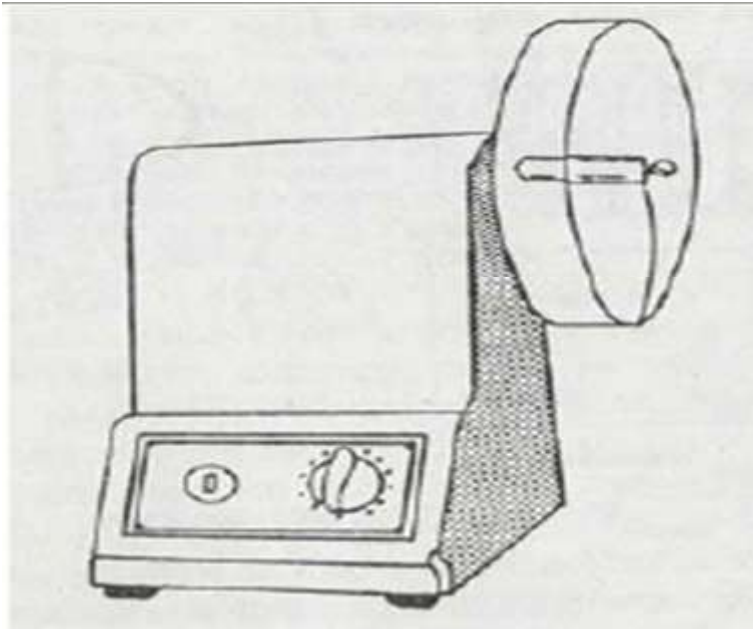


Figure: Friabilator

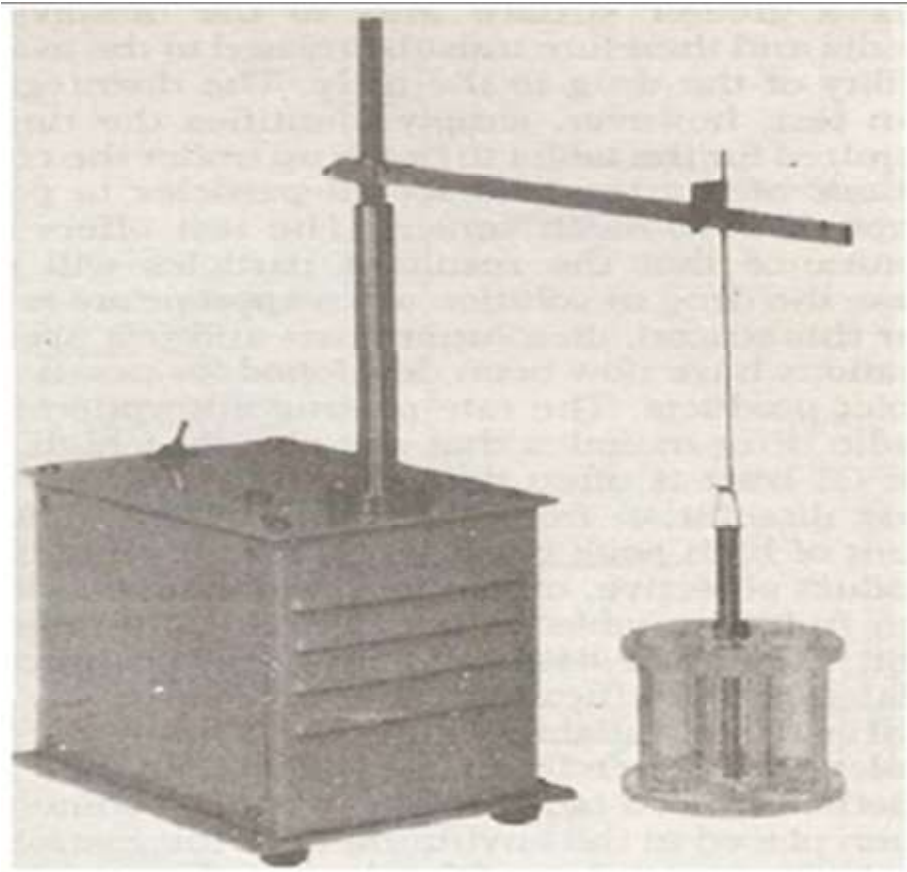


Figure: Disintegrating Apparatus



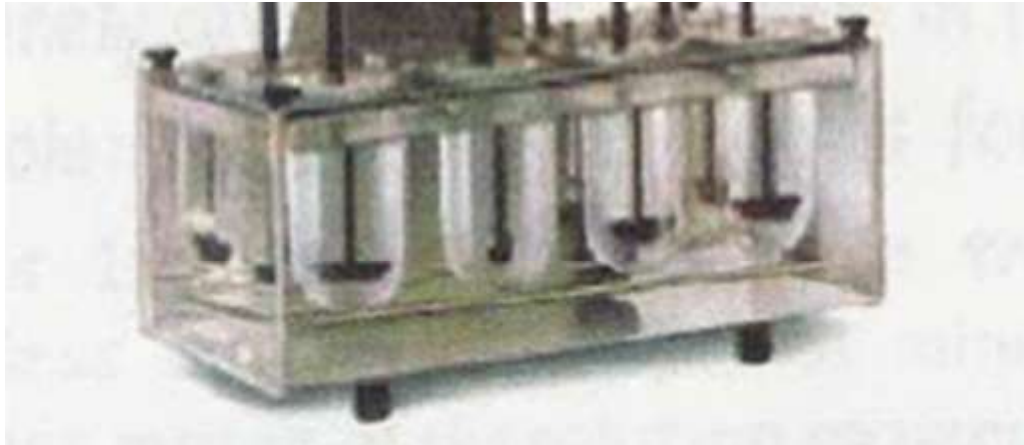


Figure: Dissolution Apparatus

II. CONCLUSION

Tablets square measure the traditional indefinite quantity forms and that they are wide victimisation indefinite quantity forms thanks to several advantages over different indefinite quantity forms. throughout their producing several inprocess issues and conjointly once formulation conjointly issues can arise. By victimisation correct preventive ways we are able to cut back those problems or we are able to create them in customary limits.

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