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Review Article on Inprocess Problems and Evaluation Tests of Tablets Manufacturing

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ABSTRACT

Tablets are the traditional over all medicinal dosage forms for solid dosages. A tablet is a solid pharmaceutical dosage form that is typically manufactured by compressing or moldings the medicinal component with appropriate diluents. They are easier to create than any other dosage form, but during manufacturing, a number of issues may occur that force the batch to be discarded. Post compression studies are also crucial before the dosage forms are put on the market. Modern standards and concepts that emphasize bioavailability, bioequivalence, and validation, among other things, have an impact on formulation design and production. In this article, we discussed the issues (Picking, Sticking, Mottling, etc.) that will arise during the production of tablets, their solutions, as well as the pre- and post- Compression qualities (such as hardness, thickness, and weight variation) and the upper limitations of their use in commercial dosage forms.

Keywords- tablet, dissolution, problems.

I. INTRODUCTION

A compressed solid dosage form called a tablet that contains drugs with or without excipients is referred to as this. Pharmaceutical coated tablets are solid, flat or biconvex dishes, unit dose forms made by compressing a drug or medicine combination, with or without diluents, according to the Indian Pharmacopoeia. Depending on the dosage of medications and the intended method of administration, they vary greatly in size, weight, and shape. It is the most often used dose form, and 70% of all medications are given out as tablets. All medications, with the exception of those that are difficult to prepare or deliver, are available in tablet form.

1.1 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.
- ❖ Cost is cheapest of all oral dosage form.
- ❖ Lighter and compact.
- ❖ Easiest and lowest to package and strip.
- ❖ Easy to swallowing with least tendency for hangup.
- ❖ Sustained release product is possible by enteric coating.
- ❖ Objectionable odor and bitter taste style can be masked by coating technique.
- ❖ Suitable for massive scale production.
- ❖ Greatest chemical and microbial balance over all oral dosage form.

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

1.2 Disadvantages of Tablet Dosage Form

❖ Difficult to swallow in case of youngsters and unconscious patients.

❖ Some capsules resist compression into dense compacts, owing to amorphous nature, low density character.

❖ 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.

❖ 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

II. GENERAL APPEARNCE [1,2]

The typical appearance, identity, and general elegance of a tablet are crucial for the consumer, the manipulation of lot-to-lot uniformity, and the manipulation of tablet-to-tablet uniformity. The measuring of size, form, color, the presence or absence of odor, taste, etc. is used to govern popular look.

2.1 Size and Shape

It may be regulated and characterized in terms of dimensions. Only variables can affect a pill's thickness. Tablet thickness can be determined using a micrometer or another measuring tool. Tablet thickness should be kept to an average variation of 5% or less. distinctive identification marks These markings make use of printing, engraving, or embossing in some way. These markings include the name or symbol of the corporation, the product code, the product name, etc.

2.2 Organoleptic Properties [3,4]

There must be no mottling and a uniform color dispersion. Compare the sample's color to a standard color to make a visual color comparison.

2.3 Hardness and Friability

Tablet require certain amount of strength or hardness during transportation and handling. Hardness generally measures tablet crushing strength. Hardness is roughly measured by placing tablets in between fingers of the hand and throwing it lightly on floor. A tablet will shoe proper hardness if it does not break. Too hard tablet will not disintegrate in required period of time while too soft tablet will cause problem during handling or packing. Hardness is measured to determine the need for adjustment of pressure on tablet machine. The tablet to be tested is placed between jaws as seen in figure. The reading on pressure dial will be zero. Then press the pliers-like handle with hands. The reading on pressure dial is noted which indicates the force required in kilogram or pounds to break the tablets.

2.4 Friability

This test is applicable for compressed uncoated tablet. This test is done to determine physical strength of tablets especially during handling and transportation The instrument used to perform this test is known as "Roche's Friabilator. The instrument consists of a drum or plastic chamber having diameter 283-291 mm and depth is 36-40 mm. A central ring is present whose outer diameter is 24.5 to 25.5 mm. The rotation speed of drum is 25 rpm. Carefully dedust the 10 tablets and weighed them. Placed them in plastic chamber and rotate it for 4 minutes or set 100 number of counts. During each revolution tablets falls from a distance of 6 inches. After 4 minute or 100. counts removed tablets from chamber and again weighed the tablets. Loss in weight indicates friability. It is expressed in percentage A good quality tablet will show loss in weight is less than 0.8%.

Formula

$$\% F = (Wo - W) / Wo \times 100$$

Where, F = friability Wo = initial weight of the ten tablets W = final weight of the ten tablets**.**

III. DRUG CONTENT AND RELEASE

3.1 Weight Variation Test (U.S.P.)

To calculate uniformity of weight, 20 tablets are randomly select and weighed. The average weight is determined and individual weight of each tablet is also calculated. Then the individual weight of each tablet is compared with average weight. Not more than two of individual weight may deviate from average weight.

Formula

$$\text{Weight variation} = \frac{IW - AW}{AW} \times 100\%$$

3.2 Content Unifoemity Test

According to USP, 10 tablets are assayed individually. Out of this 9 should contain not less than 85% or more than 115% of the labelled drug content. The 10 tablets should contain not less than 75% or more than 125% of the labelled content. If this condition is not fulfilled then other tablets are assayed individually and not of any tablet may fall outside the range of 85-115%.

3.3 Disintegration Test (U.S.P.)

Disintegration testing determines the time required to the breaking of tablets when placed in a liquid medium. The apparatus used to perform the test is known as disintegration test apparatus. The apparatus consists of a water bath which is filled with water upto mark mentioned. Place 1000 ml beakers into water bath. A basket rack holding six plastic tubes open at the top. The bottom is covered with a 10mesh screen. The basket rack assembly is suspended in liquid medium in 1000 ml beakers. The temperature of liquid is maintained at 37°C. One tablet is placed into each tube. The assembly

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moves up and down at a specified rate (30 times per minute). A cylindrical disk made of transparent plastic is also placed over the tablet. The disc should impart little pressure on tablet. The time to disintegrate of tablet and fall through the screen is noted. The beaker is filled in such a way that highest point of wire mesh remains about 2.5 cm below the surface of liquid while its lowest point remains about 2.5 cm above the bottom of beaker. The rate of disintegration varies from tablet to tablet.

3.4 Dissolution Test (U.S.P.)

3.4.1 Two set of apparatus

a. Apparatus-1

A single tablet is placed in a tiny wire mesh basket that is attached to the very cheap of the shaft of a variable speed motor, and the basket is submerged in a dissolution medium (as described in the monograph) contained in a cylindrical, subfigure-bottomed flask with a 100 metric capacity. The temperature of the flask is kept constant at 370.5 °C by a constant temperature tub.

b. Apparatus-2

Similar to apparatus 1, but with a paddle in place of the basket. Before stirring, the dose type is allowed to reach the flask's solid bottom. U.S.P. specifies the dissolution check medium and volume, range of equipment to be utilized, rate of the shaft, cut-off date of the check, and assay technique for the dissolution check. The labelled medication quantity dissolved within the cut-off date is how the check tolerance is expressed.

IV. COMPRESSION AND PROCESSING PROBLEMS [5,6]

An ideal tablet should be free from any visual defect or functional defect. During the processing of tablets, an industrial pharmacist faces various problems. Few defects may occur during the compression of granules in tablet.

4.1. Capping

Capping happens when a fracture occurs at the top of the tablet and there is partial or complete detachment of top or bottom part of tablet.

4.1.1 Causes and remedies

- Air entrapment is one of the causes of capping. Air entrapment can be reduced by pre compression or by increasing dwell time and by increasing punch tip-die clearance.
- Too much of fines in granules is also responsible for capping. The defect can be overcome by reducing the number of fines in granules
- Over drying of granules also cause capping. If the granules are too dry, they tend to cap or laminate. This problem can be overcome by adding sufficient amount of moisture to granules. It is necessary to moisten the granules suitably by adding hygroscopic substance.
- e.g.: sorbitol, methyl- cellulose or PEG-4000.
- Capping occurs if granules are not thoroughly dried. So, dry the granules properly.

4.2. Lamination

It is the segregation of a tablet into two or more layers.

4.2.1 Causes and remedies

- Higher speed of turret cause air-entrapment during compression which cause Lamination. This problem can be overcome by carry out precompression and by increasing dwell time and also by increasing punch die clearance.
- Oily or waxy materials in granules also cause lamination. So, modify the mixing process by adding adsorbent or absorbent.
- The large amount of hydrophobic lubricant cause lamination. Therefore, use less amount of lubricant or change the type of lubricant.

4.3. Chipping

This is the defect where the film on the edges of the tablet is chipped or dented.

4.3.1 Causes and remedies

- Too dry granules cause chipping. So, moisten the granules by adding hygroscopic substance.
- Large amount of also cause chipping. Therefore, use dry binder or binder in appropriate amount.
- If the edge of punch face turned inside it cause chipping. This problem is resolved by polishing the punch edges.

4.4. Cracking

This is the defect where upper and lower central surface of tablets get cracked.

4.4.1 Causes and Remedies

- If the size of the granules is large. Because of this air get entrapped between the created cavities and during compression cause cracking. This can be overcome by reducing the granule size or by adding fines.
- Too dry granules also cause cracking. Therefore, Moisten the granules properly proper amount of binder.
- Always compress granules at room temperature to avoid cracking.
- Deep concave punches also cause cracking during the ejection of tablets. Therefore, replace them.

4.5. Sticking and Picking

Sticking is the defect where the tablet material gets adhere to the die wall while Picking is the defect where small amount of material from a tablet surface gets removed off by a punch face. Picking occurs when punch tips have engraving or embossing letters and when the granular material is improperly dried.

4.5.1 Causes and remedies

- Sticking occur due to Improperly dried or improperly lubricated granules which c improved by drying the granules properly or by changing the lubricant.
- Addition of colloidal silica as polishing agent avoid sticking.
- Fast Compressing process also cause sticking. Therefore, reduce speed of compression machine.
- Rough punch faces cause picking. Plate the punch faces with chromium to produce a smooth and non-adherent face.

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4. 6. Mottling

It refers to uneven distribution of the color on the surface of the colored tablet.

4.6.1 Causes and remedies

- This defect occurs due to Migration of dye to the surface during the process of drying This can be overcome by changing solvent system, and by decreasing drying temperature.
- Variation in the colors of medicament and excipients. This can be overcome by selecting appropriate colorants
- Improper mixing of a colored binder solution. This problem can be overcome by incorporating dry color excipients during powder blending step, then add fine powdered adhesives such as acacia and tragacanth and mix well and finally add granulating liquid.

V. CONCLUSION

Tablets are the conventional indefinite quantity forms and they come in many different varieties. During their production, a number of in-process problems as well as formulation-related problems can occur. By employing proper preventive measures, we may either reduce these issues or, to a certain extent, increase them. Due to a number of benefits, there is widespread victimization indefinite quantity forms.

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