A Review on Evaluation of Tablets

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Abstract

Tablets are defined as solid unit dosage form of medicaments intended for oral use. They became most popular as they were easy in preparation compared to any other type of dosage forms. But the major drawback exists in its manufacturing. If any minor problem occurs during their manufacturing then the whole batch of the unit should be discarded. It is necessary to avoid any sort of errors during its manufacturing and as a result evaluation of tablets is very important before dispatching of a batch. In the present study, we discussed about the evaluation tests for tablets.

Keywords: Solid unit dosage; Compression method; Indian pharmacopoeia; Organoleptic properties

Introduction

Tablets are a solid dosage form of medicaments with or without excipients which are prepared by compression method. According to the Indian Pharmacopoeia tablets are solid, flat or biconvex unit dosage form of a medicament alone or medicament along with excipients prepared by compressing technique. They may vary in its size shape and weight depending on the medicament and its mode of administration. Tablets are said to be most widely used conventional dosage forms due to its variety of advantages and 70% of the medicaments were dispensed in tablet forms. Most of the medicaments can be processed into tablets but there are some exceptions like medicaments with low density characters, hygroscopic and the medicaments which were not possible to administer. Post-compression studies (Evaluation parameters) plays a major role to release any dosage form into the market [1-25].

Advantages

- Unit dosage forms with dose precision,
- Least content variability,
- Administration of accurate amounts of minute doses of a drug is possible,
- Economical of all oral dosage forms as its production doesn’t requires additional processing steps,
- Easy transportation,
- Sustain release of a drug can be achieved through enteric coating,
- Medicaments with bitter taste can be masked with coating technique (Sugar coating),
- Tablet dosage form is stable when compared to all oral dosage forms.

Disadvantages

Administration of drugs is not easy in case of children,

Drugs with slow dissolution is not acceptable for tableting with good bioavailability,

Medicaments with low density characters and amorphous in nature are difficult to compress,

Hygroscopic nature of drugs is not acceptable for tablet compression.

Evaluation of Tablets

- Appearance,
- Size and Shape,
- Organoleptic properties,
- Uniformity of thickness,
- Hardness,
- Friability,
- Drug Content Uniformity,
- Weight Variation Test,
- Wetting time,
- Water Absorption Ratio,
- In vitro Dispersion Time,
- In vitro Disintegration Test,
- In vitro Dissolution Studies,
- Two set of apparatus,
- Apparatus-1,
- Apparatus-2.

Appearance

Appearance is the first most required quality for the acceptance of tablet. General elegance and its identity play a major role for the consumer acceptance. Acceptance of the appearance of batches of the tablet has been done based on the measurement of the following factors like size, color, shape, presence or absence of odor, taste etc. [26-50].

Size and shape

Size and shape of a tablet has been determined by its thickness.

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Size and shape of a tablets plays an important role in its patient compliance as the size of the tablet increases it is not much easier for its administration. Micrometer is the devise which is used to determine the thickness of a tablet. It can be acceptable if the batch falls within the ±5% of standard deviation.

**Organoleptic properties**

Color should be distributed uniformly without appearance of any signs of mottling. Colour of the tablet should be compared with the standard colour for comparison.

**Uniformity of thickness**

To determine the uniformity of thickness random selection of tablets has to be done from each and every batch and need to measure its thickness independently. If the thickness of any single tablet varies then the batch containing that batch will not be dispatched into market (Figure 1).

**Hardness**

The ability of a tablet to withstand for mechanical shocks is known as hardness. Pfizer hardness tester is the instrument which is used to determine the hardness of tablet. It is expressed in kg/cm². Take three tablets from each batch and hardness should be determined and the selection of tablet should be done randomly. Then the mean and standard deviation values should be determined.

**Friability**

Roche friabilator is the equipment which is used for the determination of friability.

It is expressed in percentage.

Note down the initial weight of the tablets individually (W initial).

Tablets are placed in a plastic chamber which revolves at 25 rpm and they are subjected to fall from a height of 6 inches in the friabilator for about 100 revolutions. Then measure the weight of the tablet (W final) and observe any weight difference before tablet and after the friabilator processing (Figure 2).

Limits: loss in weight less than 0.5 to 1% of the initial weight of the tablet should be considered as acceptable limits.

Percentage of friability is calculated as:

\[ F = \frac{(W \text{ initial}) - (W \text{ final})}{(W \text{ initial})} \times 100. \]

**Drug content uniformity**

Initially weigh the tablet and then powder it. Now the powdered tablet is transferred into a 100 ml volumetric flask and add 0.1 N HCl upto mark. Now filter the solution and discard first few ml of filtrate. Take 10 ml of filtrate should be taken into a 50 ml volumetric flask and add 0.1 N HCl up to the mark and analysed spectrophotometrically at 274 nm and 234.5 nm. The concentration of the content of the drug (μg/ml) was calculated by using the standard calibration curve of the respective drug [51-75].

Drug content is calculated by using the below formula

Concentration of the drug in (μg/ml) × 100 × 50/10 × 1000

**Weight variation test**

Random selection of 20 tablets from each batch should be done and note down the weight of the tablet individually and check for any variation in its weight. According to US Pharmacopies small variations in the weight is negligible and can be accepted. Below is the acceptable limit of percentage deviation in weight variation (Table 1).

**Wetting time**

This method was performed to determine the wetting time of a tablet. A piece of tissue paper which is folded twice is kept in a petridish containing 6 ml of water and place the tablet on the tissue paper. Observe the time taken for complete wetting of the tablet. Following procedure should follow three times (three trial) for each batch and standard deviation is also calculated from the obtained results.

**Water absorption ratio**

A piece of tissue paper which is folded twice is kept in a petridish (i.d.=6.5 cm) containing 6 ml of water and place the tablet on the tissue paper. Observe the time taken for complete wetting of the tablet. Thus wetted tablet was weighed. Now the water absorption ratio R is calculated using the formula

\[ R = 100 \times \frac{Wa - Wb}{Wb} \]

Wb is the weight of the tablet before absorption,

Wa is the weight of the tablet after absorption,

Following procedure should follow three times (three trial) for each batch and standard deviation is also calculated from the obtained results.

**In vitro dispersion time**

Dispersion time of a tablet is determined by placing a tablet in 6 ml
Figure 3: in vitro disintegration test.

of 6.8 pH phosphate buffer and note down the time taken for complete dispersion of tablet.

Following procedure should be done for three tablets from each batch and in vitro dispersion time is calculated. Standard deviation time is also determined from the obtained results. It is expressed in seconds [76-102].

In vitro disintegration test

Disintegration is defined as the process of breakdown of tablet into small particles. Disintegration time of a tablet is determined by using disintegration test apparatus as per IP specifications. Place each tablet in each 6 tubes of the disintegration apparatus a then add a disc to each tube containing 6.8 pH phosphate buffer. The temperature of the buffer should maintain at 37 ± 2°C and run the apparatus raised and lowered for 30 cycles per minute. Note down the time taken for the complete disintegration of the tablet without any remittants (Figure 3).

Two set of apparatus

Conclusion

Tablets are the conventional dosage forms compared to any other oral dosage forms. It is necessary for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form with a good bioavailability. Every batch of the tablets should undergo the above-mentioned evaluation tests before dispatching in to markets.

References


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