ejpmr, 2017,4(11), 526-530

SJIF Impact Factor 4.161

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

POST-COMPRESSION EVALUATION PARAMETERS FOR TABLETS-AN OVERVIEW

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Article Received on 17/09/2017 **Article Revised on 09/10/2017** **Article Accepted on 30/10/2017**

ABSTRACT

The quantitative evaluation and assessment of a tablet's chemical, physical and bioavailability properties are important in the design of tablet and to monitor product quality. These properties are important since chemical breakdown or interactions between tablet components may alter the physical tablet properties and greatly affect the bioavailability of the tablet system. These are various standards that have been set in the various pharmacopoeias tablets. These include the diameter, size, shape, thickness, weight, hardness, disintegration and dissolution character. The diameter and shape depends upon die and punches selected for the compression of tablets do not vary from one production lot to another.

KEYWORDS: Tablets, Limit, Pharmacopoeia, Post-Compression.

INTRODUCTION

Tablets are most widely used solid dosage form of medicament in which one usual dose of drug has been accurately include. They may be round, oblong, flat, convex, engraved or imprinted with an indentifying symbol. They are prepared in uncoated, coated, colored uncolored, one, two or three layered.

Evaluation of Tablet (Post-Compression Parameter)

Evaluation of tablet includes the assessment of tablets physical, chemical and biological properties. To studies them the following test are formulated.

General Appearance

General appearance is the physical appearance of the tablet it has two aspects to address:
First one is the patient compliance, if the tablet is appearance is legible and good, it improves the patient compliance.

The second one is for the manufacturer; it helps him in trouble free manufacturing if there is tablet to tablet, batch to batch uniformity of tablet.

General appearance would include a number of aspects like, size, shape, odor, taste, texture, legibility, and identifying marks.

Size and Shape

Tablet thickness should be controlled within a ±5% variation of standard value. The shape and size of a tablet would vary based on tooling used in the tablet manufacturing. The prime consideration here would be the crown size, because if the concavity is very high it many lead to capping, or chipping problem. The crown size is measured by using micrometer, and sliding caliper scale is used to measure the size of 5 to 10 tablets at a time.

Unique Identification Mark

Pharmaceutical manufacturers in order to differentiate their product from the other manufacturers emboss a special marking g on the tablet. The marking can be an embossing, engraving or printing. Apart from the company marking there can be imprints which include product code, product name, and product potency. But care must be taken that the letters that are embossed on the tablet are properly printed without double impression.

Organoleptic Properties

For rapid identification of the tablet and consumer acceptance the tablet are given a specific color, the color of the tablet will enable the manufacturer form differentiating the tablet lot. The uniformity of the color is important parameter here, the tablet should be free from mottling. The color uniformity and gloss of the tablet is evaluated by using reflectance spectrophotometer, tristimulus colorimetric measurement, micro-reflectance photometer. The odour of the tablet indicate the stability of the tablet, for example, the smell of acetic acid in aspirin tablet indicates that the tablet is degraded The taste of the tablet is also an important factor, every company has a taste panel which analyze the taste of the tablet, machines are

yet to be discovered which can provide the report of the taste.

Hardness (Crushing Strength)

"Hardness is defined as the resistance of the tablet against the applied force till it breaks"

Tablet hardness and strength are the essential to see that the tablet can with the shock and stress during manufacturing packing and transportation, and while handled by the patient. To test the hardness of the tablet Monsanto Hardness Tester or Stokes Hardness tester, Strong-Cobb Tester, the Pfizer Tester, the Erweka Tester, the Heberlain Hardness Tester or Schlesinger Hardness tester are used. Measure of the mechanical integrity of tablets is their breaking force, which is the force required to cause them to fail (i.e., break) in a specific plane. The tablets are generally placed between two platens, one of which moves to apply sufficient force to the tablet to cause fracture. For conventional, round (circular cross-section) tablets, loading occurs across their diameter (sometimes referred to as diametric loading), and fracture occurs in that plane.

Why do we measure hardness?

To determine the need for pressure adjustments on the tablet compression machine, hardness can affect the disintegration. If the tablet hardness is too high, we first check its disintegration time, if it is not within limit, we reject the batch. And if the disintegration is within limit, we accept the batch. And if the tablet is too soft, it will not withstand the handling during subsequent processing such as coating or packaging.

- However, the result of Strong cob hardness tester is 1.6 times accurate than the Heberlain hardness tester and 1.4 times more accurate than the Pfizer hardness tester. Most commonly used apparatus for hardness is electronically operated hardness tester i.e. Heberlain Hardness Tester.

- Thickness and diameter of the tablets can also be checked by this Heberlain hardness tester. The mode of the apparatus is set according to the test (hardness, thickness or diameter),

Unit- kg/cm^2 or Newton

Criteria: Tablet hardness should lies between 5 to 10 kg/cm^2.

Result limit: ± 5%.

Factors Affecting the Hardness

- Compression of the tablet and compressive force.
- Amount of binder. (More binder a more hardness)
- Method of granulation in preparing the tablet (wet method gives more hardness than direct method; Slugging method gives the best hardness).

Friability: *FRIABILITY* is the phenomenon where the surface of the tablet is damage or shown a site of damage due to mechanical shock. It is tested by using Roche friabilator. This is made up of a plastic drum fixed with a machine which rotated at 25 rpm for 100 revolutions (25X4=100). Tablet falls from 6 inches height in each turn within the apparatus.

"Roche Friabilator" specification
Internal diameter -283mm-291mm
Depth -36mm-40mm
Inside radius -75.5mm-85.5mm
Outer diameter of central ring -24.5mm-25.5mm

Procedure

For tablets with a unit weight equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5 g. For tablets with a unit weight of more than 650 mg, take a sample of 10 whole tablets.
Percentage Friability = $W_1 – W_2/W_1 \times 100$
W_1 = weight of tablets before testing.
W_2 = weight of tablets after testing.

Limits: According to B.P/I.P = Percentage of friability should be not more than 0.8% - 1.0% According to U.S.P = Percentage of friability should be not more than 4%.

The tablets should be carefully de-dusted prior to testing. Accurately weigh the tablet sample, and place the tablets in the drum. Rotate the drum 100 times, and remove the tablets. Remove any loose dust from the tablets as before, and accurately weigh.

Generally, the test is run once. If obviously cracked, cleaved, or broken tablets are present in the tablet sample after tumbling, the sample fails the test. If the results are difficult to interpret or if the weight loss is greater than the targeted value, the test should be repeated twice and the mean of the three tests determined. A maximum mean weight loss from the three samples of not more than 1.0% is considered acceptable for most products.

Effervescent tablets and chewable tablets may have different specifications as far as friability is concerned. In the case of hygroscopic tablets, an appropriate humidity-controlled environment is required for testing.

Weight Variation

Weight variation test is performed to check that the manufactured tablets have a uniform weight.

Procedure: Weigh individually 20 units selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage given in the pharmacopoeia and none deviates by more than twice that percentage. IP/BP & USP limits for tablet weight variation is given below.

S. No	USP	Max % difference allowed	IP/BP
1.	130mg > or less	±10%	80mg > or less
2.	130mg-324 mg	±7.5%	80mg-250mg
3.	324mg < or more	±5%	250mg < or more

Disintegration

Disintegration is the first physical change observed for a drug when it enters into the body, Disintegration test helps in knowing the API solubility in the gastric fluids of the digestive system. As per USP the disintegration apparatus consist of 6 glass tubes (77.5mm±2.5mm long & 21.5mm internal diameter) with a 10 number mesh (1.8-2.2mm) at the bottom. This arrangement of 6 tubes is placed in a medium simulated to the disintegration environment which is maintained at $37^{o}C \pm 2^{o}C$, in 1 liter vessel. This system is made to move up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. Tablet remains 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. The disintegration time of the tablet is compared with the values in the monograph.

Type of Tablet	Disintegration Time (D.T.)
Uncoated Tablet	15 Minute (B.P/I.P)
Film Coated	30 Minute (B.P/I.P)
Sugar Coated	60 Minute (B.P/I.P)
Enteric Coated/ Gastric Resistant Tablet	0.1M HCl for 2 hrs and phosphate buffer 6.8 for 1 hr. (B.P/I.P) OR The test is carried out first in distilled water (at room temperature for 5 min. Than stimulated gastric fluid 1 hour. Then, stimulated intestinal fluid without enzymes 1 hour (USP)
Effervescent Tablet	3 Minute (B.P/I.P)
Dispersible Tablet	5 Minute (B.P/I.P)
Sublingual Tablet	3 Minute

- D.T. is not applicable for Sustain Release or Modified Tab.& Chewable Tablet
- Recommended temperature for D.T. of Dispersible tablet is $25^{0}c \pm 1^{0}c$ (IP) & $15^{0}c$ - $25^{0}c$ (BP)

CONTENT UNIFORMITY

Content Uniformity Testing is useful for assessing the consistency of Powder blends before filling or compressing, semi-solid and liquid bulk batches before filling, filling during manufacturing (such as powders into capsules or liquids into vials or bottles) and active content within individual units post-manufacturing (such as individual tablets after compression).

Content uniformity testing involves using a content/potency assay to determine the content of active material contained in multiple different samples collected throughout the batch. Drug content or content uniformity is determined by U.V.

Procedure: Select 10 capsules or tablets at random. If using capsules empty contents of each capsule carefully in a suitable container. Using a suitable analytical method, assay the individual content of the active ingredient in each capsule or tablet.

The preparation complies if not more than one (all within limits) individual content is outside the limits of 85 to 115 % of the average content and none is outside the limits of 75 to 125 % of the average content. The preparation fails to comply with the test if more than 3 individual contents are outside the limits of 85 to 115 % of the average content or if one or more individual contents are outside the limits of 75 % to 125 % of the average content. According to Indian Pharmacopoiea Content of active ingredients. Determine the amount of active ingredient(s) by the method described in the Assay and calculate the amount of active ingredient(s) in each capsule. The result lies within the range for the content of active ingredient(s) stated in the monograph. This range is based on the requirement that 20 capsules, or such other number as may be indicated in the monograph, are used in the Assay. Where 20 capsules cannot be obtained, a smaller number, which must not be less than 5, may be used, but to allow for sampling errors the tolerances are widened in accordance with Table 1. The requirements of Table 1 apply when the stated limits are between 90 and 110 per cent. For limits other than 90 to 110 per cent, proportionately smaller or larger allowances should be made Weigh of Active Subtract Weigh of Active ingredients in each Capsules. The table is given in IP.

***IN-VITRO DRUG RELEASE* (Dissolution Apparatus)**

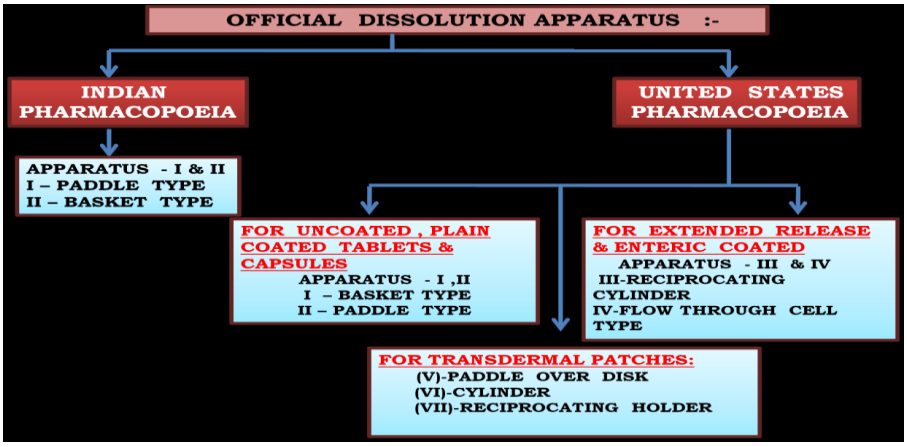
The rate and extent of drug release form the tablet (under standardized condition of temperature and solvent composition) is estimated by dissolution test. It is a dynamic property that changes with time and describes the process by which a homogeneous mixture of solid or a liquid can be obtained in a solvent. Dissolution testing is a critical preformulation solubility analysis research tool in the process of drug discovery. Drug Dissolution testing plays an important role as a routine quality control test, for characterization the quality of product

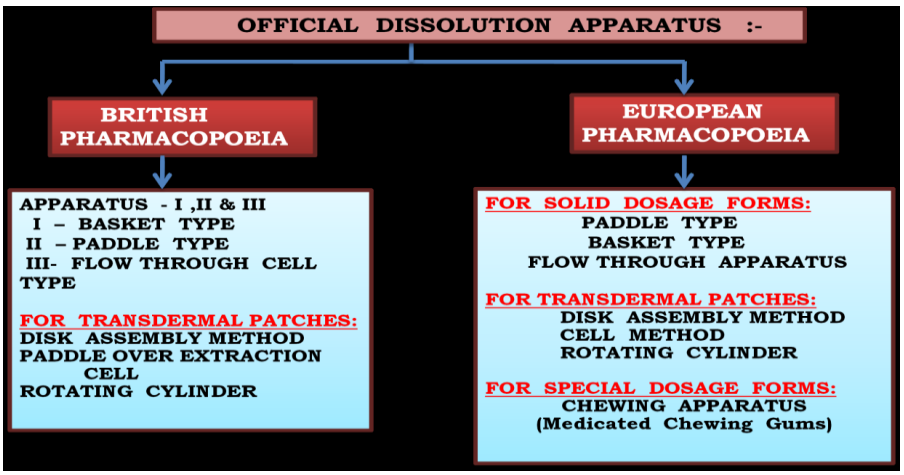
and also plays a major role in drug development. Different types of apparatus are used to study the dissolution test of the tablet. As per IP apparatus I (paddle) and apparatus II (basket) are used.

List of official dissolution apparatus.

Type	IP	USP	BP	EP	JP
Type 1	Paddle	Basket	Basket	Basket	Basket
Type 2	Basket	Paddle	Paddle	Paddle	Paddle
Type 3	-	Reciprocating Cylinder	Flow Through Cell	Flow Through Cell	Flow Through Cell
Type 4	-	Flow Through Cell	-	-	-
Type 5	-	Paddle Over Disk	-	-	-
Type 6	-	Rotating Cylinder	-	-	-
Type 7	-	Reciprocating Holder	-	-	-

Comparison of Various Disssolution Specification As Per IP/ BP/ USP/ EP





Common specification of various dissolution apparatus

CHARACTERISTIC	USP	IP	BP	EP	JP
Dissolution Vessel	Nominal Capacity 1L-4L	Nominal Capacity 1L	Nominal Capacity 1L	Nominal Capacity 1L	Nominal Capacity 1L
Shaft Position	NMT 2mm from vertical axis	NMT 2mm from vertical axis	NMT 2mm from vertical axis	NMT 2mm from vertical axis	NMT 2mm from vertical axis
Allowable Variation	±4%	±4%	±4%	±4%	±4%
Shaft rotation speed	50-100	50-100	50-100	50-100	----
Distance from bottom of apparatus (inside bottom of apparatus)	25±2mm	25±2mm	25±2mm	25±2mm	25±2mm
Apparatus suitability test	Specified	Not Specified	Not Specified	Not Specified	Not Specified
Temperature	37±0.5	37±0.5	37±0.5	37±0.5	37±0.5

APPARATUS SUITABILITY TEST (As Per U.S.P.)

➢USP REFERENCE STANDARDS FOR APPARATUS –I ,II ,IV & V

- USP Prednisone Tablet RS

(Dissolution Calibrator, Disintegrating)

- USP Salicylic acid Tablet RS

(Dissolution Calibrator, Non-disintegrating)

➢USP REFERENCE STANDARDS FOR APPARATUS –III

- USP Chlorpheniramine Extended-Release Tablets RS

(Drug Release Calibrator, Single Unit)

- USP Theophylline Extended-Release Beads RS

(Drug Release Calibrator, Multiple Unit)

CONCLUSION

Formerly, tablets were considered satisfactory if they were elegant and firm enough to withstand handling without damage. The realization that such criteria were inadequate for the scientific control of tablet quality led to the inclusion of suitable standard and tests in all national pharmacopoeia. Although corresponding procedures differ in detail or emphasis they serve an identical purpose which may, in general, be understood by a consideration of the requirement of the any pharmacopoeia and standards.

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