

A REVIEW ON QUALITY CONTROL TEST OF TABLETS

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ABSTRACT:

Quality of pharmaceutical product is very significant because drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. The evaluation of the physical characteristics of the pharmaceutical products can ensure their quality as well as bioavailability and impart optimum therapeutic activity. The maintenance of quality with continuous improvement in facilities is very important in pharmaceutical industries because it is directly related to healthcare system. Various quality control tests are done with a view to remove error from every stage in production and maintain the quality of the final product with the compendial standards as specified in the pharmacopoeias. These include criteria for weight variation, disintegration, dissolution, content uniformity, hardness, friability and uniformity of thickness. The purpose of this article is to provide concise information on the various quality control tests for pharmaceutical tablets.

KEY WORDS: Pharmaceutical tablets, Quality control, Pharmacopoeia, Weight variation, Hardness, Friability, Dissolution, Disintegration time Etc.

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 drug 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 quantitative evaluation and assessment of a tablet's chemical, physical and bioavailability properties are important in the design of tablets 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. There are various standards that have been set in the various pharmacopoeias regarding the quality of pharmaceutical tablets. These include the diameter, size, shape, thickness, weight, hardness, disintegration and dissolution characters. The diameter and shape depend on the die and punches selected for the compression of tablets. The remaining specifications assure that tablets do not vary from one production lot to another. The manufacturer must give his assurance that the final product is of suitable quality. The clinical effectiveness exerted by tablet formulation depends on at least two factors such as; the medicament must be present in the labeled amount and its availability to the body¹. The principle target of an oral tablet is to convey the medication to the human body at certain and defined amount through the gastro-intestinal system for producing therapeutic effect². The formulation of the API (active pharmaceutical ingredient) can have a significant effect on the quality parameters such as weight variation, hardness, friability, disintegration time, dissolution profile etc. This also includes the physicochemical properties of the active ingredients and excipients as well as the procedures used in the manufacturing process^{3,4}. Moreover, physical properties of tablets or quality control parameters are useful tools for maintaining consistency in batch-to-batch

manufacturing and it should be performed for every drug product. All of these parameters are closely related to each other and have effect on drug absorption, bioavailability etc^{5,6}.

These tests categorized as following:

A. Official (Pharmacopoeial) Tests:

- Uniformity of Drug Content
- Uniformity of Weight
- Disintegration Test
- Dissolution Rate

B. Non-Official (Non-Pharmacopoeial) Tests:

- Hardness (Crushing Strength)
- Friability
- Uniformity of Thickness
- General appearance.

A. Official methods: Official quality control tests are described as below

Weight variation: The weight of a tablet is determined by quantity of fill in the die of a tablet press. The volume of fill is adjusted with the first few tablets to yield the desired weight and content. The variation of the weight of individual tablets is a valid indication of the corresponding variation in the drug content⁷. Controlling tablet weights within a tight range will contribute to better tablet hardness and friability⁸. Take 20 tablets and weigh individually. Calculate average weight and compare the individual tablet weight to the average. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in table below and none deviates by more than twice that percentage. The weight variation tolerance for tablets differs depending on average tablet weight according to table 1.

Table 1: Weight Variation Tolerance for tablets

Average weight of tablet (According to IP/BP)	Limit	Average weight of tablet (According to USP)
80mg or less	±10%	130mg or less
More than 80mg or Less than 250mg	±7.5%	130mg to 324mg
250mg or more	±5%	More than 324mg

For all tablet following mathematical equation was used for calculation of highest and lowest weight variation⁴.

$$\text{Highest weight variation (\%)} = \frac{\text{Highest weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

$$\text{Lowest weight variation (\%)} = \frac{\text{Lowest weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

This test is done on 20 tablets that will later be used in the friability test.

Significance: The objective of the weight variation test is to ensure - good manufacturing practices (GMP), appropriate size of the tablets and the content uniformity of the formulation⁹.

Disintegration: Disintegration is the first physical change observed for a drug when it enters into the body, thus to see simulate the disintegration of the tablet in the body the disintegration test is performed. It is the time required for the tablet to break into particles, the disintegration test is a measure only of the time required under a given set of conditions for a group of tablets to disintegrate into particles. In the present disintegration test the particles are those that will pass through a 10-mesh screen¹⁰. Complete disintegration occurs when no residue of the tablet still present on the screen except the insoluble ingredients as the shell or the coat of the tablet. This time was recorded. Mean disintegration time was calculated for each of the brand tablet¹¹.

Disintegration device (According to Indian Pharmacopoeia)¹²:

- a. A rigid basket-rack assembly supporting six cylindrical glass tubes, 77.5 ± 2.5 mm long, 21.5 mm internal diameter and with a wall thickness of about 2 mm (see Fig).
- b. The tubes are held vertically by two superimposed transparent plastic plates, 90 ± 2 mm in diameter and 6.75 ± 1.75 mm thick perforated by six holes having the same diameter as the tubes. The holes are equidistant from the centre of the plate and are equally spaced from one another. Attached to the underside of the lower plate is a piece of woven gauze made from stainless steel wire 0.615 ± 0.045 mm in diameter and having nominal mesh apertures of 2.00 mm. The upper plate is covered with a stainless steel disc perforated by six holes, each about 24 ± 2 mm in diameter, which fits over the tubes and holds them between the plastic plates. The holes coincide with those of the upper plastic plate and the upper open ends of the glass tubes.
- c. The plates are held rigidly in position and 77.5 mm apart by vertical metal rods at the periphery and a metal rod is also fixed to the centre of the upper plate to enable the assembly to be attached to a mechanical device capable of raising and lowering it smoothly at a constant frequency of between 28 and 32 cycles per minute through a distance of 50 to 60 mm. The design of the basket-rack assembly may be somewhat different provided specifications for the glass tubes and the screen mesh size are unchanged.
- d. A cylindrical disc for each tube, each 20.7 ± 0.15 mm thick in diameter and 9.5 ± 0.15 mm thick, made of transparent plastic with a relative density of 1.18 to 1.20, and pierced with five holes, each 2 mm in diameter, one in the centre and the other four spaced equally on a circle of radius 6 mm from the centre of the disc. Four equally-spaced grooves are cut in the lateral surface of the disc in such a way that the upper surface of the disc they are 9.5 mm wide and 2.55 mm deep and at the lower surface 1.6 mm square.
- e. The assembly is suspended in the liquid medium in a suitable vessel, preferably a 1000-ml beaker. The volume of liquid is such that the wire mesh at its highest point is at least 25 mm below the surface of the liquid, and at its lower point is at least 25 mm above the bottom of the beaker.
- f. A thermostatic arrangement for heating the liquid and maintaining the temperature at $37^\circ \pm 2^\circ$.

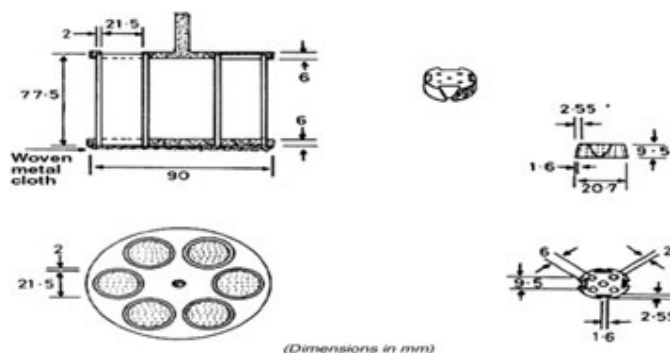


Fig: 1 Apparatus for disintegration of Tablets

Table 2: Disintegration test for tablets

Uncoated Tablet	NMT 15 min, in water with Disc $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$
Coated Tablet	NMT 30 min, In water with Disc for Film coated tablet, and NMT 60 min Other than Film coated tablet
Enteric Coated Tablet	Intact for 1 hr in 0.1N HCl & disintegrate within 2 hr in Mixed 6.8 Phosphate buffer. According to USP 1 hr in Simulated gastric fluid, then in Simulated Intestinal Fluid.
Dispersible/Soluble	Within 3 min in water at $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (IP) & $15-25^{\circ}\text{C}$ (BP)
Orodispersible	Within 1 min
Effervescent Tablet	5 min in 250 ml water at $20-30^{\circ}\text{C}$ (IP) & 5 min in 200 ml water at $15-25^{\circ}\text{C}$ (BP)
Buccal & Sublingual	Not Applicable but dissolve within 15-30 min.

*NMT=Not more than

Factors affect Disintegration Time:

It has been recognized that one should not expect a correlation between Disintegration & Dissolution. However, since the dissolution of a drug from the fragmented tablet appears to partially or completely control the appearance of the drug in the blood, disintegration is still used as a guide to the formulator in the preparation of an optimum tablet formula and as in-process control test to ensure lot-to-lot uniformity.

The formulator should be aware that the medium used, the temperature of the medium, and the operator recording the results can have a significant effect on disintegration time. In addition many factors involved with a tablet's formula and method of manufacture can affect the disintegration such factors are: the diluents used, the binder, the nature of the drug, the type and amount of disintegrating agent, the type and amount of lubricant, as well as the method of incorporation for all of these additives. The compaction pressure used to make the tablets also influences the disintegration, in general disintegration time's increase with an increase in pressure.

Dissolution: The definition of dissolution is deceptively simple. It is defined as the rate of mass transfer from a solid surface into the dissolution medium under standardized conditions of liquid/solid interface, temperature and solvent composition. It is a dynamic

property that changes with time and describes the process by which a homogenous mixture of a solid or a liquid can be obtained in a solvent.

Significance of dissolution test:

- Disintegration test simply identifies the time required for the tablet to break up under the condition of the test but it does not ensure the drug release in the bulk of the fluid.
- Rate of dissolution is directly related to the efficacy of the drug.
- Rate of dissolution is a good index for comparing the bioavailability of two tablet products of the same drug.

Dissolution Apparatus according to USP¹⁴:

Apparatus 1 (Basket Apparatus): It consists of a vessel, which is made up of glass or other inert transparent material, a motor, a metallic drive shaft and a cylindrical basket. The vessel is partially immersed in a suitable water bath or heated by a suitable device such as a heating jacket. The water bath or heating device maintains the temperature inside the vessel at $37 \pm 0.5^\circ \text{C}$ during the test and keeps the bath fluid in a constant and smooth motion. The cylindrical vessel has a hemispherical base with the following dimensions and capacities: for a nominal capacity of 1 L, the height is 160 mm to 210 mm and its inside diameter is 98 mm to 106 mm; for a nominal capacity of 2 L, the height is 280 mm to 300 mm and its inside diameter is 98 mm to 106 mm; and for a nominal capacity of 4 L, the height is 280 mm to 300 mm and its inside diameter is 145 mm to 155 mm. Its sides are flanged at the top and a fitted cover may be used to retard evaporation. The shaft is positioned so that its axis is not more than 2 mm at any point from the vertical axis of the vessel and rotates smoothly and without significant wobble that could affect the results. The total height of the basket is 37 ± 3.0 mm. A motor with a speed regulator capable of maintaining the speed of rotation within $\pm 4\%$ of that specified in the individual monograph. The vent hole is 2.0 ± 0.5 mm. The clear opening is 20.2 ± 0.1 mm. Shaft and basket components of the stirring element are fabricated of stainless steel, type 316, or other inert material. A dosage unit is placed in a dry basket at the beginning of each test. The distance between the inside bottom of the vessel and the bottom of the basket is maintained at 25 ± 2 mm during the test.

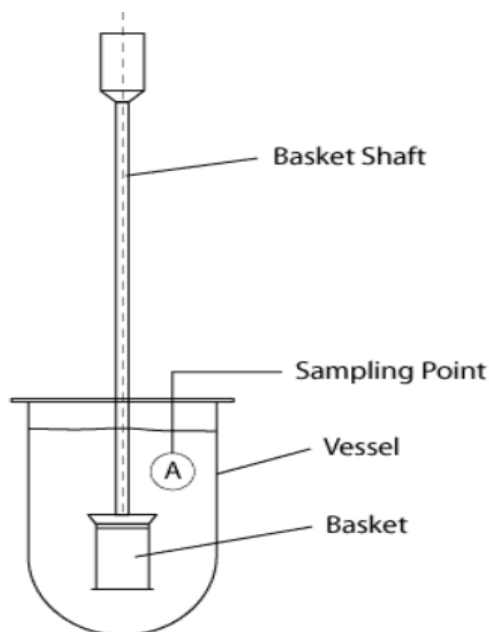


Fig:2 Schematic view of Rotating Basket Designed

Apparatus 2 (Paddle type):

The assembly is same as Apparatus 1, except that in the stirring element the basket is replaced by a paddle. The shaft is situated so that its axis is not more than 2 mm from the vertical axis of the vessel and turns easily without a wobble that could influence the results. The vertical centre line of the blade passes through the axis of the shaft so that the bottom of the blade is flush with the bottom of the shaft. The distance of 25 ± 2 mm between the bottom of the blade and the inside bottom of the vessel is maintained during the test. The height and thickness of the blade is 19.0 ± 0.5 and 4.0 ± 1 mm. The radius of the disk of the paddle is 41.5 ± 0.5 mm. The dosage unit is allowed to sink to the bottom of the vessel before rotation of the blade is started. A small, loose piece of nonreactive material having few turns of wire helix may be attached to dosage units that would otherwise float.

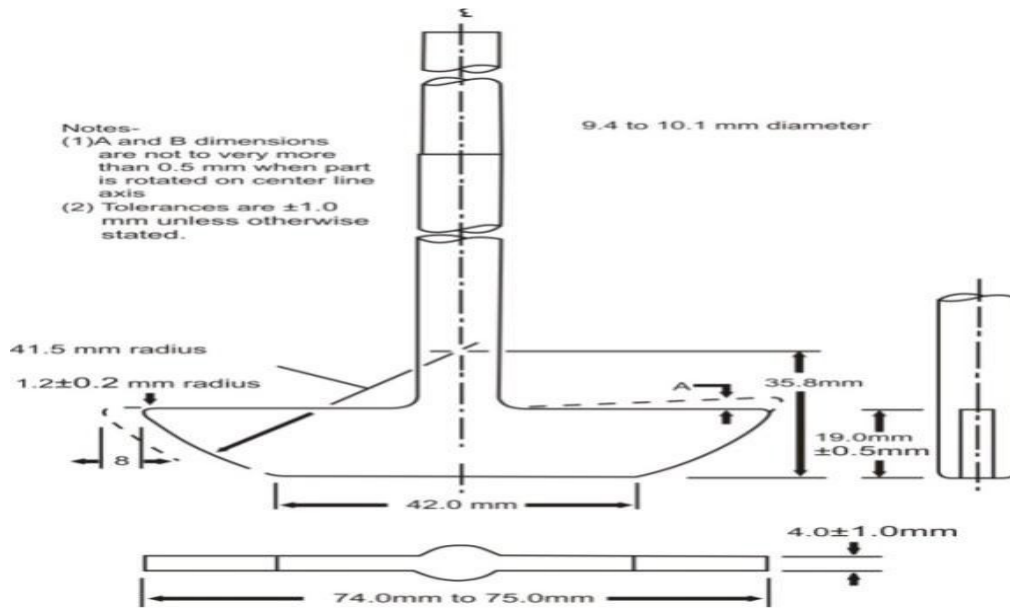


Fig: 3 Schematic view of Rotating Paddle Designed

Various Dissolution Apparatus according to I.P.

- 1) **Apparatus 1 (Paddle type):** The design and measurements of this apparatus is same as USP Apparatus 2 (Paddle type) except the height of the vessel and blade is 168 ± 8 mm and 19.0 mm and the radius of the paddle is 41.5 mm.
- 2) **Apparatus 2 (Basket type):** The design and measurements of this apparatus is same as USP apparatus 1 (Basket type) except the height of the basket is 36.8 ± 3.0 mm, the clear opening is 22.2 ± 1.0 mm and the vent hole which is attached to shaft is 2.0 mm.

Table: 2 List of official dissolution apparatus

Various Official Dissolution Test apparatus					
	IP	USP	BP	EP	JP
Type 1	Paddle Apparatus	Basket Apparatus	Basket Apparatus	Basket Apparatus	Basket Apparatus
Type 2	Basket Apparatus	Paddle Apparatus	Paddle Apparatus	Paddle Apparatus	Paddle Apparatus
Type 3		Reciprocating cylinder	Flowthrough cell Apparatus	Flowthrough cell Apparatus	Flowthrough cell Apparatus

Type4		Flowthroughcell Apparatus			
Type5		Paddle over Disk			
Type6		Rotating cylinder			
Type7		Reciprocating Holder			

USP Apparatus (non-official)

- Rotating bottle method
- Diffusion cell
- Peristalsis cell
- Intrinsic dissolution method

When Apparatus 1 is used, allow the tablet to sink to the bottom of the vessel prior to the rotation of the paddle. A suitable device such as a wire of glass helix may be used to keep horizontal at the bottom of the vessel tablets or capsules that would otherwise float. Care should be taken to ensure that air bubbles are excluded from the surface of the tablet. When Apparatus 2 is used, place the tablet in a dry basket at the beginning of each test. Lower the basket into position before rotation. Operate the apparatus immediately at the speed of rotation specified in the individual monograph. Within the time interval specified, or at each of the times stated, withdraw a specimen from a zone midway between the surface of the dissolution medium and the top of the rotating blade or basket, not less than 10 mm from the wall of the vessel. Except in the case of single sampling, add a volume of dissolution medium equal to the volume of the samples withdrawn. Perform the analysis as directed in the individual monograph. Repeat the whole operation five times. Where two or more tablets are directed to be placed together in the apparatus, carry out six replicate tests.

For each of the tablets tested, calculate the amount of dissolved active ingredient in solution as a percentage of the stated amount where two or more tablets are placed together, determine for each test the amount of active ingredient in solution per tablet and calculate as a percentage of the stated amount. If the results do not conform to the requirements at stage S1 given in the accompanying acceptance table (Table 1), continue testing with additional tablets through stages S2 and S3 unless the result conforms at stage S2. Correction factors should not be greater than 25% of the stated amount. In the given table below *D is the amount of active ingredient specified in the individual monograph, expressed as a percentage of the labelled content.

TABLE3-AcceptanceTable

Stage	Number Tested	Acceptance
S1	6	Each unit is not less than $D \pm 5\%$.
S2	6	Average of 12 units (S1+S2) is equal to or greater than D , and no unit is less than $D \pm 15\%$.
S3	12	Average of 24 units (S1+S2+S3), is equal to or greater than D , not more than 2 units are less than $D \pm 15\%$ and no unit is less than $D \pm 25\%$.

Content uniformity: The content uniformity test is used to ensure that every tablet contains the amount of drug substance intended with little variation among tablets within a batch. Due to increased awareness of physiological availability, the content uniformity test has been included in the monographs of all coated and uncoated tablets where the ranges of size of the dosage form available include 50mg or smaller sizes. Tablet monographs with a content uniformity requirement do not have weight variation requirements.

According to USP: For content uniformity test, representative samples of 30 tablets are selected and 10 are assayed individually. At least 9 must assay within $\pm 15\%$ of the declared potency and none may exceed $\pm 25\%$.

According to Indian Pharmacopoeia: This test is applicable to tablets that contain less than 10 mg or less than 10% w/w of active ingredient. For tablets containing more than one active ingredient carry out the test for each active ingredient that corresponds to the aforementioned conditions. Determine the content of active ingredient(s) in each of 10 tablets taken at random using the method given in the monograph or by any other suitable analytical method. The tablets comply with the test if not more than one of the individual values thus obtained is outside the limits 85 to 115% of the average value and none is outside the limits 75 to 125% of the average value. If two or three of the individual values are outside the limits 85 to 115% of the average value and none is outside the limits 75 to 125%, repeat the determination using another 20 tablets. The tablets comply with the test if in the total sample of 30 tablets not more than three of the individual values are outside the limits 85 to 115% and none is outside the limits 75 to 125% of the average value.

B. Non-official: Non-official quality control tests are described as below

Hardness: Tablet requires a certain amount of strength or hardness and resistance to friability with mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures the tablet crushing strength. The strength of a tablet was determined by following ways;

- By cracking the tablet between 2nd and 3rd fingers with the thumb acting as a fulcrum. If there is a sharp snap, the tablet is an acceptable strength.
- Tablet hardness can be defined as the force required breaking a tablet in a diametric compression. In this test the tablet is placed between two anvils, force is applied to the anvils, and the crushing strength that just causes the tablet to break is recorded. Generally used Hardness testers are:

Instruments used:

1. Monsanto Hardness Tester
2. Strong Cobb Hardness Tester.
3. Pfizer Hardness Tester
4. Heberlein Schleuniger Hardness Tester
5. Erweka Hardness Tester
6. Casburt Hardness Testers.

Hardness for compressed tablet is 5 to 8 kg.

Factors affecting hardness:

- Hardness is a function of the applied pressure and is therefore the factors which contribute the force to vary also affect it. As additional pressure is applied to make a tablet, the hardness values increase, this relationship holds up to the maximum value beyond which increase in pressure causes the tablet to laminate or cap, thus destroying the integrity of the tablet.
- Tablets generally are harder several hours after compression than they are immediately after compression. Lubricant can affect the tablet hardness when mixed for too long period or used in too high concentration. The lubricant will coat the granules and interfere with tablet bonding.
- Larger tablets require a greater force to cause fractures (harder) than small tablets. An appropriate balance between a minimally acceptable tablet hardness to produce an adequate friability value and a maximum acceptable tablet hardness to achieve adequate tablet dissolution may be required.

Significance of Hardness measurement:

- Hardness determinations are made throughout the tablet runs to determine the need for pressure adjustments on the tableting machine.
- Hardness can affect the disintegration. So if the tablet is too hard, it may not disintegrate in the required period of time. And if the tablet is too soft, it will not withstand the handling during subsequent processes such as coating or packaging.

In general, if the tablet hardness is too high, we first check its disintegration before rejecting the batch. And if the disintegration is within limit, we accept the batch.

Friability Test¹⁵: Tablet hardness is not an absolute indicator of strength since some formulations, when compressed into very hard tablets may produce chipping, capping and lamination problems. Therefore another measure of tablet strength i.e. friability is often measured, i.e. the friability. A friability test is performed to determine the ability of tablets to withstand abrasion during packaging, handling, and shipping processes. A maximum weight loss of not more than 1% is generally considered acceptable.

Roche Friabilator: Subjects a number of tablets to abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm, dropping the tablets a distance of 6 inches with each revolution. After a given number of rotations the tablets are weighed and the loss in weight indicates the ability of the tablets to withstand this type of wear.

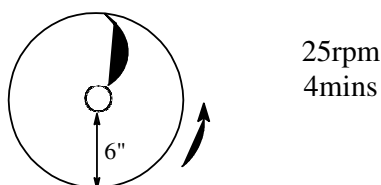
Procedure:

1. Weigh 20 tablets together = W_1
2. Put these tablets in the friabilator and adjust the instrument at 100 rpm (i.e. = 25 rpm for 4 min)

3. Weight of 20 tablets (only the intact ones) = W_2

$$\text{Friability (\% loss)} = \frac{\text{Weight before test (W}_1\text{)} - \text{Weight after test (W}_2\text{)}}{\text{Weight before test (W}_1\text{)}} \times 100$$

Factors affecting tablet friability: Tablets friability may also be influenced by the moisture content of the tablets granulation in the finished tablets. A low but acceptable moisture level frequently serves to act as a binder. Very dry granulation that contains only fractional percentages of moisture will often produce more friable tablets than will granules containing 2 to 4% moisture.



Roche Friabilator

Fig:4 Friability test apparatus

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.

- a. **Size & Shape:** It can be dimensionally described & controlled. The thickness of a tablet is only variable. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a $\pm 5\%$ variation of standard value.
- b. **Unique identification marking:** These markings utilize some form of embossing, engraving or printing. These markings include company name or symbol, product code, product name etc.
- c. **Organoleptic properties:** Color distribution must be uniform with no mottling. For visual color comparison compare the color of sample against standard color.

Thickness Uniformity:

Tablet thickness should be controlled with 5% or less of a standard value. Any variation in tablet thickness should not be apparent to the unaided eye to maintain product acceptance by consumer as well as to facilitate packaging. At constant compressive load, tablet thickness varies with changes in die fill and tablet weight. Whereas, with a

constant die fill, thickness varies in variation in compressive load.

Three set of factors influence tablet thickness and tablet thickness control:

- The physical properties of raw materials including true bulk density and crystal form.
- Control of flower and punch lengths, which should be standardized.
- The granulation prosperities including tapped density, bulk density, particle size, and particle size distribution.

Conclusion: From the above review it can be concluded that Indian Pharmacopoeia and United States Pharmacopoeia included the most of quality control tests. These quality control tests are essential to maintain the quality of the dosage forms.

REFERENCES:

1. Jabeen S, Ali A, Hassan F, Fatima, N, (2006), Studies on the effects of cyclodextrin polymer as a tableting aid on some selected analgesics. *Pakistan Journal of Pharmacology*, 23(1), 67-71.
2. Islam SMA, Islam S, Shahriar M, Dewan I, (2011), Comparative in vitro dissolution study of aceclofenac marketed tablets in two different dissolution media by validated analytical method. *Journal of Applied Pharmaceutical Science*, 1(9), 87-92.
3. Ofori-Kwakye K, Osei-Yeboah F, Kipo SL, (2010), Formulation and quality evaluation of two conventional release tablet formulations. *International Journal of Pharmaceutical Sciences Review and Research*, 4(1), 94-99.
4. Kalakuntla, R, Veerlapati U, Chepuri M, Raparla R, (2010), Effect of various superdisintegrants on hardness, disintegration and dissolution of drug from dosage form. *J. Adv. Sci. Res*, 1(1), 15-19.
5. Awofisayo SO, Awofisayo OA, Eyen N, Udoh IE, (2010), Comparative assessment of the quality control measurements of multi source ofloxacin tablets marketed in Nigeria. *Dissolution technologies*, 17(2), 20-25.
6. Jain N, Mandal S, Banweer J, Jain S, (2012), Effect of superdisintegrants on formulation of fast masked fast disintegrating ciprofloxacin tablets. *International Current Pharmaceutical Journal*, 1(4), 62-67.
7. Rawlins EA, (1977), Bentley's text book of pharmaceuticals (8th ed., pp. 289-290), Bailliere Tindal publisher.

8. Tousey,MD,(2011).Tabletpro:Atabletmakingtrainingresourcefortabletmakingprofessionals. Techceuticals, 4(1),1-15. www.dipharma.com/TP_V4.pdf
[Accesseson:09.03.2012]
9. Yoshida I and Sakai Y, (1999), The applications of the content uniformity test and the weight variation test on process validation tests of multiple ingredient preparations. *ChemPharmBull*,47(5),678-83.
10. Banker GS and Anderson NR, (2009). Tablets. In Lachman, L. and Lieberman, H.A, *The theory and practice of industrial pharmacy (Special Indian ed., pp 229-345)*, CBS Publishers and Distributors Pvt. Ltd., India
11. Gangwar S, Singh S, Garg G, Garg V, Sharma PK, (2010). To compare the disintegrating property of papaya starch and sago starch in paracetamol tablets. *Int J Pharmacy Pharm Sci*,2(Suppl2),148-151.
12. *Indian Pharmacopoeia*,(2010),Disintegration Test. Volume 1, page no.187-189.
13. Kishore BH, Venkateswararao T, Sankar KR, Rao BS, (2011), Studies on dissolution rate of paracetamol tablets by using different polymers. *Journal of Global Trends in Pharmaceutical Sciences*,2(1),1-10.
14. *Dissolution(711), United States Pharmacopoeia and National Formulary USP32-NF27*,(2009), Vol.1.
15. Banker, G.S. and Anderson, N.R. (2009). Tablets. In Lachman, L. and Lieberman, H.A, *The theory and practice of industrial pharmacy (Special Indian ed., pp 229-345)*, CBS Publishers and Distributors Pvt. Ltd., India.