Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

2.5.1. Disintegration Test

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Change **to**:

2.5.1. Disintegration Test

This General Chapter has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia.

Portions of the IP text that and are not part of the PDG harmonized text, are marked with symbols (♦♦).

This test is provided to determine whether tablets or capsules, ♦boluses, pessaries and suppositories♦ disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions presented below.

For the purpose of this test, disintegration does not imply complete dissolution of the unit or even of its active constituent. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the disc, if used, is a soft mass having no palpably firm core.

♦For tablets or capsules up to 18 mm longest dimension, test A is used. Test B is intended for tablets or capsules larger than 18 mm unless otherwise specified. ♦

Test A – Tablets and Capsules up to 18 mm

Apparatus

The apparatus consists of a basket-rack assembly, a 1000-ml low-form beaker, 138 to 160 mm in height and having an inside diameter of 97 to 115 mm for the immersion fluid, a thermostatic arrangement for heating the fluid at 37° ± 2°, and a ♦ mechanical♦ device for raising and lowering the basket in the immersion fluid at a constant frequency rate of 29 to 32 cycles per minute, through a distance of 53 mm to 57 mm. The volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid, and descends to not less than 25 mm from the bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition, rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

Basket-rack assembly. The basket-rack assembly consists of six open-ended transparent tubes, each 75.0 to 80.0 mm long and having an inside diameter of 20.7 to 23.0 mm and a wall 1.0 to 2.8 mm thick; the tubes are held in a vertical position by two plates, each 88 to 92 mm in diameter and 5.0 to 8.5 mm in thickness, with six holes, each 22 to 26 mm in diameter, equidistant from the center of the plate and equally spaced from one another. Attached to the under surface of the lower plate is a woven stainless steel wire cloth, which has a plain square weave with 1.8 to 2.2 mm mesh apertures and with a wire diameter of 0.57 to 0.66 mm. The parts of the apparatus are assembled and rigidly held by means of three bolts passing through the two plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis.

The design of the basket-rack assembly may be varied somewhat, provided the specifications for the glass tubes and the screen mesh size are maintained. The basket-rack assembly conforms to the dimensions found in Fig. 2.5.1-1.

Disc. The use of disc is permitted only where specified or allowed. Each tube is provided with a cylindrical disc 9.35 to 9.65 mm thick and 20.55 to 20.85 in diameter. The disc is made of a suitable, transparent plastic material having a specific gravity of 1.18 to 1.20. Five parallel 1.9 to 2.1 mm holes extend between the ends of the cylinder. One of the holes is centered on the cylindrical axis. The other holes are parallel to the cylindrical axis and centered 5.8 to 6.2 mm from the axis on imaginary lines perpendicular to the axis and to each other, as defined in Fig. 2.5.1-1. Four identical trapezoidal-shaped planes are cut into the wall of the cylinder, nearly perpendicular to the ends of the cylinder. The trapezoidal shape is symmetrical; its parallel sides coincide with the ends of the cylinder and are parallel to an imaginary line connecting the centers of two adjacent holes 6 mm from the cylindrical axis. The parallel side of the trapezoid on the bottom of the cylinder has a length of 1.5 to 1.7 mm, and its bottom edges lie at a depth of 1.5 to 1.8 mm from the cylinder's circumference. The parallel side of the trapezoid on the top of the cylinder has a length of 9.2

to 9.6 mm, and its center lies at a depth of 2.5 to 2.7 mm from the cylinder's circumference. All surfaces of the disk are smooth.

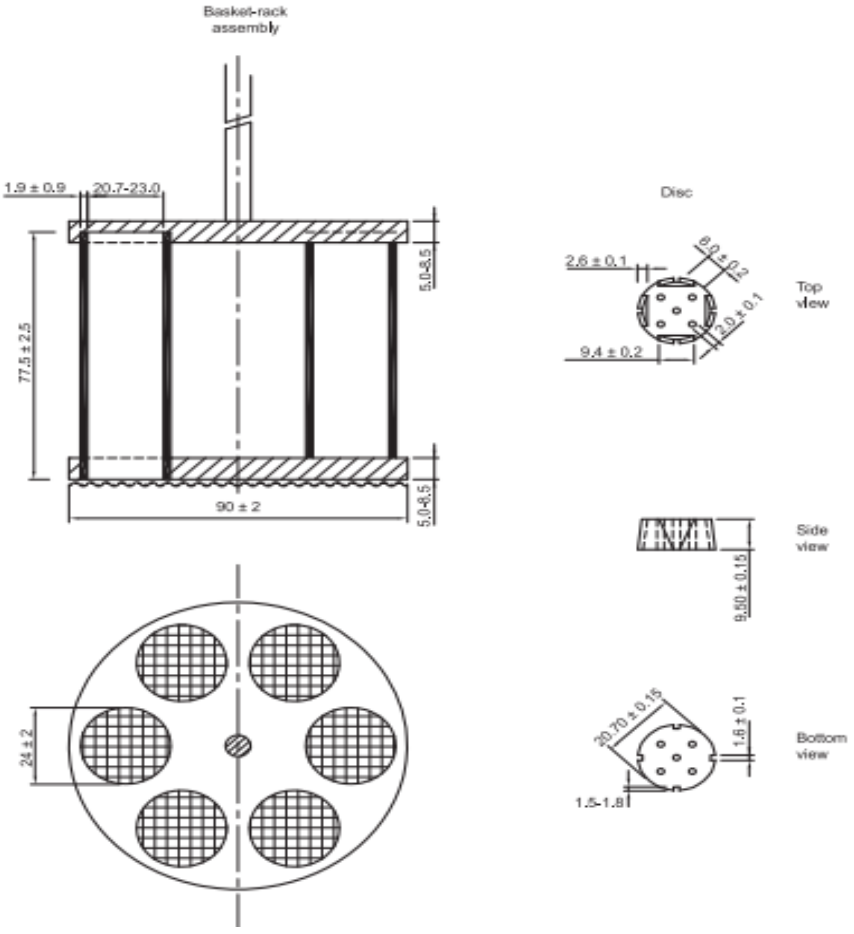
If the use of discs is specified, add a disc to each tube and operate the apparatus as directed under Procedure. The discs conform to the dimensions shown in Fig. 2.5.1-1.

The use of automatic detection employing modified discs is permitted where the use of discs is specified or allowed. Such discs must comply with the requirements of density and dimension given in this chapter.

Procedure. Place 1 dosage unit in each of the six tubes of the basket and, if prescribed, add a disc. Operate the apparatus, using the specified medium as the immersion fluid, maintained at 37° ± 2°. At the end of the specified time, lift the basket-rack assembly from the fluid, and observe the dosage units: all of the dosage units have disintegrated completely.

If 1 or 2 dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of the test are met if not fewer than 16 of the totals of 18 dosage units tested have disintegrated.

♦If the tablets or capsules adhere to the disc and the preparation under examination fails to comply, repeat the test omitting the disc. The preparation complies with the test if all the tablets or capsules in the repeat test disintegrate♦.



(Dimensions in mm)

Fig. 2.5.1-1: Apparatus for Disintegration Test A

♦***Test B. Tablets and Capsules larger than 18 mm***

Apparatus

The apparatus consists of a basket-rack assembly, a 1000 ml low-form beaker, 138 to 160 mm in height with an inside diameter of 97 to 115 mm for the immersion fluid, a thermostatic arrangement for heating the fluid at 37° ± 2°, and a device for raising and lowering the basket in the immersion fluid at a constant frequency rate of 29 to 32 cycles per minute, through a distance of 53 to 57 mm. The volume of the fluid in the beaker is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid, and descends to not less than 25 mm from the bottom of the beaker on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition, rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

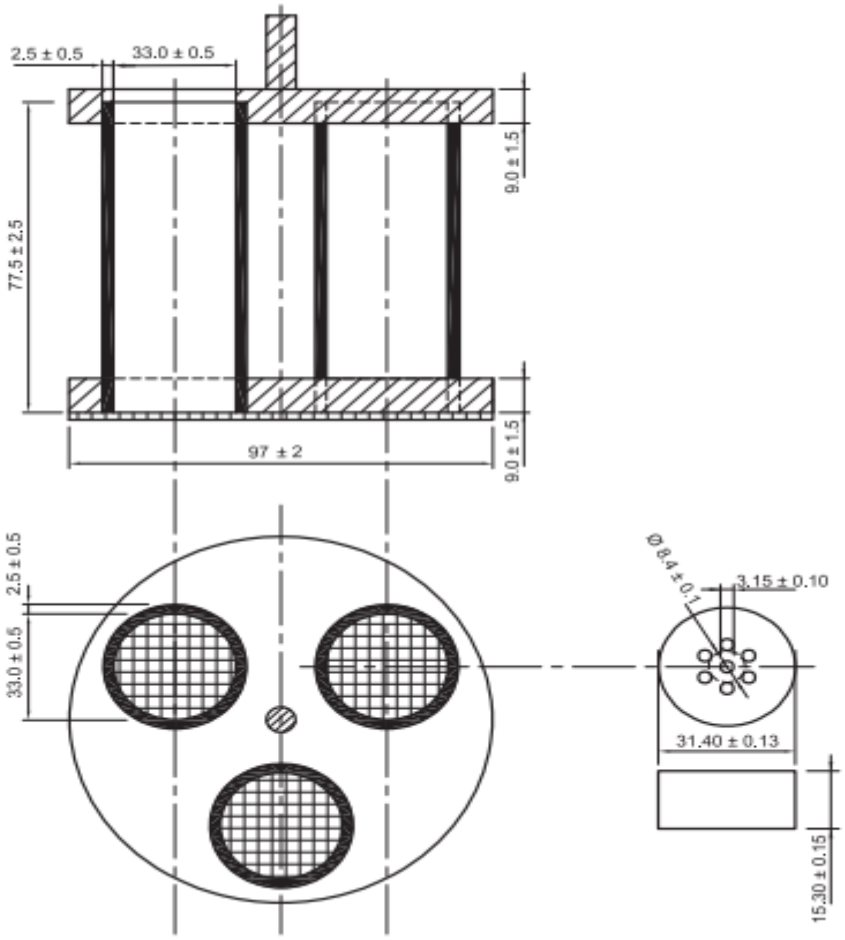
Basket-rack assembly. The Basket-rack assembly consists of 3 open-ended transparent tubes, each 75.0 to 80.0 mm long with an inside diameter of 32.5 to 33.5 mm, and a wall 2.0 to 3.0 mm thick. The tubes are held in a vertical position by 2 separate and superimposed rigid plastic plates, each 95 to 99 mm in diameter and 7.5 to 10.5 mm in thickness, with 3 holes, each 36.5 to 39.5 mm in diameter. The holes are equidistant from the centre of the plate and equally spaced from one another. Attached to the under surface of the lower plate is a woven stainless steel wire cloth, which has a plain square weave with mesh apertures of 1.8 to 2.2 mm and with a wire diameter of 0.60 to 0.66 mm. The plates are held firmly in position by vertical metal rods at the periphery. A metal rod is also fixed to the centre of the upper plate to enable the assembly to be attached to a mechanical device.

The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the screen mesh size are maintained. The basket-rack assembly conforms to the dimensions shown in fig. 2.5.1-2.

Disc. The use of disc is permitted only where specified or allowed. Each tube is provided with a cylindrical disc 15.15 to 15.45 mm thick and 31.27 to 31.53 mm in diameter and. The disc is made of suitable transparent plastic material having a specific gravity of 1.18 to 1.20. Each disc is pierced by 7 parallel holes, each 3.05 to 3.25 mm in diameter. One of the holes is centered on the cylindrical axis. The other holes are parallel to the cylindrical axis and spaced equally on a circle with a diameter of 8.3 to 8.5 mm centered from the axis. All surfaces of the disc are smooth.

Procedure. Test 6 dosage units either by using 2 basket-rack assemblies in parallel or by repeating the procedure. Place 1 dosage unit in each of the 3 tubes and, if prescribed, add a disc. Operate the apparatus using the specified medium as the immersion fluid, maintained at 37° ± 2°. At the end of the specified time, lift the basket-rack assembly from the immersion fluid and observe the dosage units: all of the dosage units have disintegrated completely.

If 1 or 2 dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of the test are met if not fewer than 16 of the totals of 18 dosage units tested have disintegrated. ♦



(Dimensions in mm)

Fig. 2.5.1-2: Apparatus for Disintegration of Test B

♦ ***For pessaries and suppositories***

This test is performed to determine whether solid rectal or vaginal dosage forms soften or disintegrate within the prescribed time when placed in a liquid medium under the experimental conditions described below.

Disintegration is considered to be achieved when, depending on the dosage form, one or more of the following are observed:

a) The dosage unit has completely dissolved;

b) The components of the dosage unit have separated: melted fatty substances collect on the surface of the liquid, insoluble powders fall to the bottom and soluble components dissolve; depending on the type of preparation, the components may be distributed in one or more of these ways;

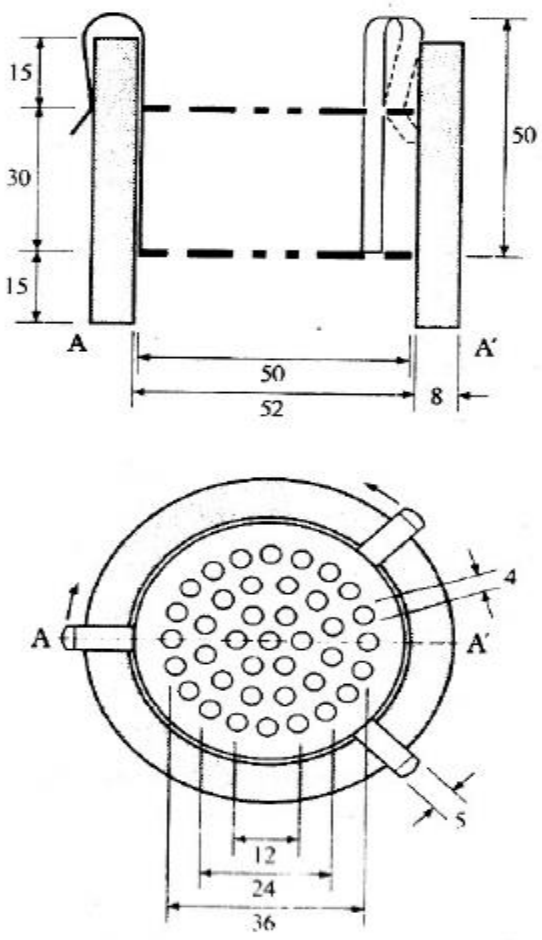
c) Softening of the dosage unit occurs, possibly accompanied by an appreciable change in shape but without complete separation of the components; the softening is such that the dosage unit no longer has a solid core offering resistance to the pressure of a glass rod;

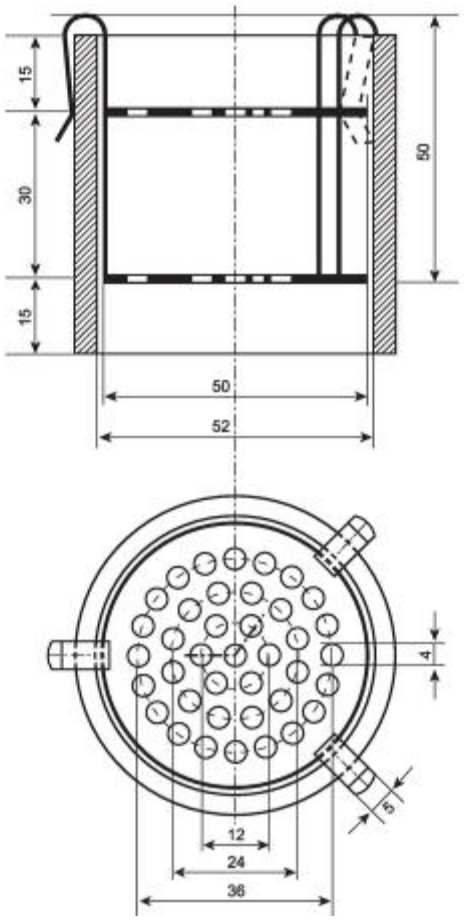
d) The shell of a rectal or vaginal capsule rupture, releasing the contents;

e) No residue remains on the perforated disc or, if a residue remains, it consists only of a soft and/or frothy mass with no solid core offering resistance to the pressure of a glass rod (vaginal tablets).

Apparatus.

The apparatus (Fig 2.5.1-3a) consists of a 60 mm long cylinder of glass or transparent plastic and a metal device consisting of 2 perforated stainless-steel discs, held about 30 mm apart. These discs each have 39 holes, 4 mm in diameter, which are evenly spaced in a concentric pattern. The diameter of the discs is marginally less than that of the interior of the cylinder. Once inserted into the cylinder, the metal device is attached to the rim of the cylinder by means of 3 spring clips. The test is carried out using 3 such apparatuses each containing a single sample. Each apparatus is placed in a beaker with a capacity of at least 4 litre filled with water maintained at 36 -37°, unless otherwise prescribed. The apparatuses may also be placed together in a vessel with a capacity of at least 12 litre. The beaker is fitted with a slow stirrer and a device that will hold the cylinders vertically not less than 90 mm below the surface of the water and allow them to be inverted without emerging from the water.





(Dimensions in mm)

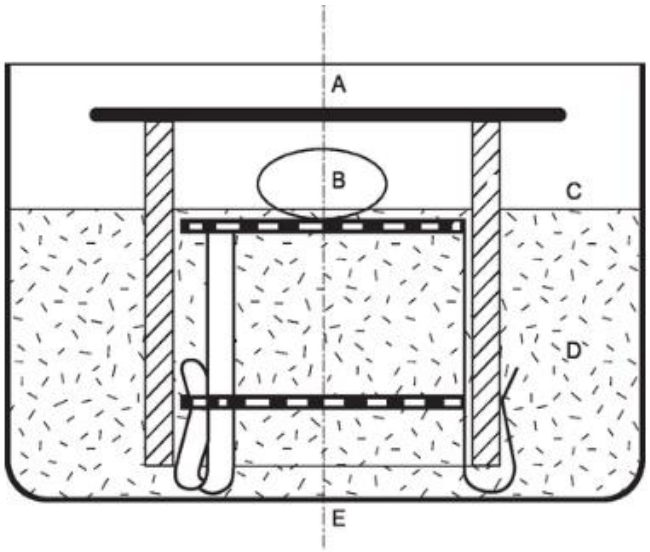
Fig. 2.5.1-3a: Apparatus for Disintegration of Pessaries and Suppositories

Procedure for Suppository and Vaginal Dosage Forms other than Compressed Pessaries

Test 3 dosage units. Place each one on the lower disc of a metal device, place the latter in the cylindrical sleeve and secure. Invert the apparatuses every 10 minutes. At the end of the specified time, examine the samples. The requirements of the test are met if all the samples have disintegrated.

Procedure for Compressed Pessaries

Use the apparatus described above, turning it upside down so it rests on the spring clips (see Fig. 2.5.1-3b). Place it in a beaker of suitable diameter containing water maintained at 36 -37° with the level just below the upper perforated disc. Using a pipette, adjust the level with water until a uniform film covers the holes in the disc. Test 3 compressed pessaries. Place each one on the upper disc of an apparatus and cover the latter with a glass plate to maintain appropriate humidity. At the end of the specified time, examine the samples. The requirements of the test are met if all the samples have disintegrated.



A. glass plate
B. compressed pessary
C. water surface
D. water
E. beaker

Fig. 2.5.1-3b: Apparatus for Disintegration of compressed pessaries

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