2.5.1 Disintegration Test

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. 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.

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2.5.1. Disintegration Test. Page 351

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 ~~dosage forms such as~~ tablets~~,~~ or capsules, ♦boluses, pessaries and suppositories♦ disintegrate within ~~a~~ the prescribed time when placed in a liquid medium ~~under the prescribed~~ at the experimental conditions presented below.

For the purpose of this test, disintegration does not imply complete ~~solution~~ dissolution of the ~~dosage~~ unit or even of its active constituent. Complete ~~Disintegration~~ disintegration is defined as that state in which ~~no~~ 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. ~~under test remains on the screen of the apparatus or, if a residue remains, it consists of fragments of disintegrated parts of tablets component parts such as insoluble coating of the tablets or of capsule shells, or of any melted fatty substance from the pessary or suppository or is a soft mass with no palpable core. If discs have been used with capsules, any residue remaining on the lower surfaces of the discs consists only of fragments of shells.~~

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.

~~*NOTE — Use apparatus A for tablets and capsules that are not more than 18 mm long. For larger tablets and capsules use apparatus B.*~~

~~**Apparatus A**~~

~~***For tablets, bolues and capsules of normal size***~~

Test A – Tablets and Capsules up to 18 mm

Apparatus

The apparatus consists of a basket-rack assembly, ~~a 1 litre beaker~~ a 1000-ml low-form beaker[1] 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 35° to 39°, and a ~~mechanical~~ device for raising and lowering the basket -rack assembly 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 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 is rigid and supports six cylindrical glass tubes, 77.5 ± 2.5 mm long, 21.5 mm in internal diameter and with a wall thickness of about 2 mm (Fig. 2.5.1 1). 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.~~ The basket-rack assembly consists of six open-ended transparent tubes, each 75.0 to 80.0 mm long with 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 ~~side~~ surface of the lower plate is a woven stainless steel wire cloth, which has a plain square weave with ~~2.0 ± 0.2~~ 1.8 to 2.2 mm ~~mesh~~ apertures and with a wire diameter of ~~0.615 ± 0.045 mm~~ 0.57 to 0.66 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. A suitable means is provided to suspend the basket rack assembly from the raising and lowering device using a point on its axis.~~ 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 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 the device for raising and lowering it smoothly at a constant frequency of between 29 and 32 cycles per minute through a distance of 55±2~~

[1] **1000-ml low-form beaker in line with the ISO 3819: 2015 or ASTM E 960 (2013) Type I or Type II.**

~~mm. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction should be smooth and not abrupt. There should be no appreciable horizontal motion or movement of the axis from the vertical.~~

The design of the basket-rack assembly may be varied somewhat, provided ~~with different~~ the specifications for the glass tubes and the screen mesh size are ~~unchanged.~~ 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 ~~A~~ cylindrical disc 9.35 to 9.65 ~~for each tube, each 20.7 ± 0.15~~ mm thick and 20.55 to 20.85 in diameter. ~~and 9.5 ± 0.15 mm thick,~~The disc is made of a suitable, transparent plastic material having a specific gravity ~~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 at 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.~~ 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. The disks conform to the dimensions shown in Fig. 2.5.1-1[2].

Operate the apparatus as directed under Procedure.

~~*Medium*. The assembly is suspended in the liquid medium in a suitable vessel, preferably a 1-litre beaker. The volume of liquid is such that the wire mesh at its highest point is at least 15 mm below the surface of the liquid, and at its lower point is at least 25 mm above the bottom of the beaker. At no time should the top of the basket-rack assembly become submerged. There is a thermostatic arrangement for heating the liquid and maintaining the temperature at 37° ± 2°.~~

~~**Method**. Unless otherwise stated in the individual monograph, introduce one tablet or capsule into each tube and, if directed in the appropriate general monograph, add a disc to each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time. Remove the assembly from the liquid. The tablets or capsules pass the test if all of them have disintegrated.~~

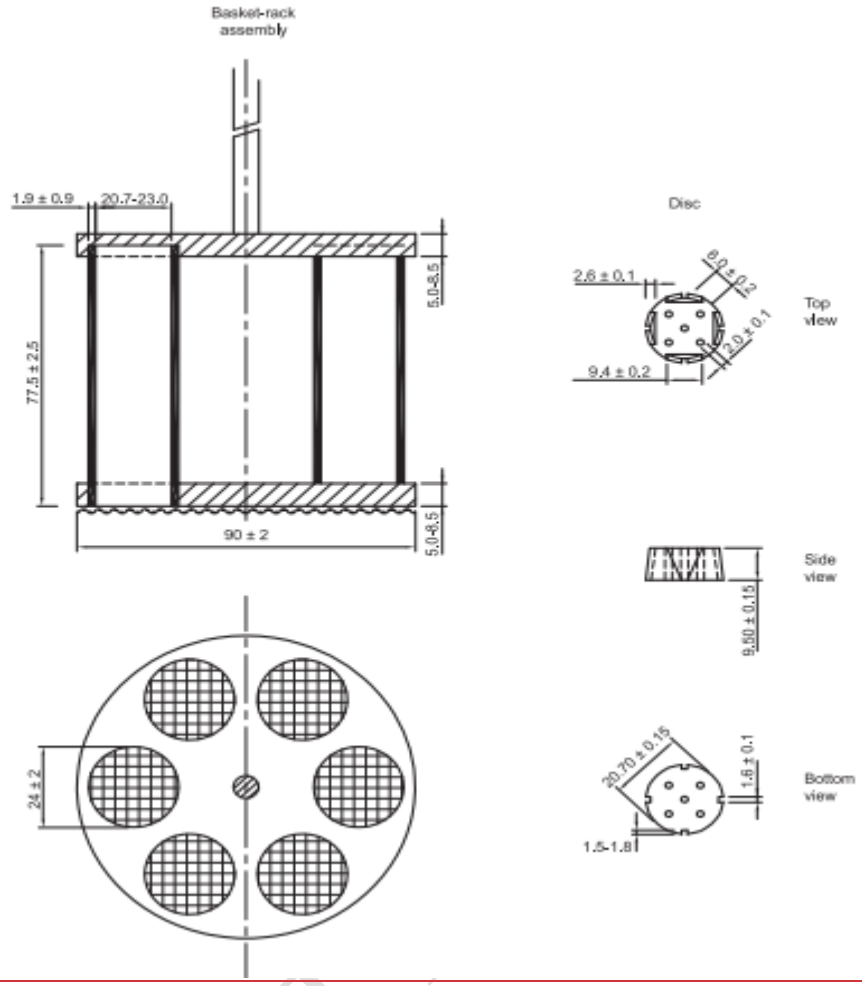
Procedure. Place 1 dosage unit in each of the six tubes of the basket-rack assembly and, if prescribed, add a disc. The use of discs is permitted only where specified or allowed. Operate the apparatus, using the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of the specified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

In case when the apparatus is equipped with an automatic detection of the disintegration, record the time when all dosage units have disintegrated. All dosage units have to disintegrate within the specified time.

If 1 or 2 ~~tablets or capsules~~ dosage units fail to disintegrate, repeat the test on 12 additional ~~tablets or capsules;~~ dosage units. ~~not less~~ The requirements of the test are met if not fewer than 16 of the total of 18 ~~tablets or capsules~~ 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.~~

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



(Dimensions in mm)

Fig. 2.5.1-1: Apparatus for Disintegration ~~of Tablets and Capsules~~ Test A

~~**Apparatus B**~~

~~***For tablets, boluses and capsules of large size***~~

Test B. Tablets and Capsules larger than 18 mm

Apparatus

The apparatus consists of a 1000 ml low form beaker[1], a basket-rack assembly, a thermostatic arrangement and a device for raising and lowering the basket-rack assembly in the immersion fluid. The apparatus operates similarly to the one described for tablets and capsules up to 18 mm.

Beaker. A 1000 ml low-form beaker[1], 138 to 160 mm in height with an inside diameter of 97 to 115 mm for which the difference between the beaker's inside diameter and the diameter of the plastic plates of the basket-rack assembly is not more than 6 mm.

Basket-rack assembly. The Basket-rack assembly ~~(Fig. 2.5.1.-2.)~~ consists of three open-ended ~~is a rigid basket-rack assembly supporting 3 cylindrical~~ transparent tubes, each 75.0 to 80.0 ~~77.5 ± 2.5~~ mm long, ~~-~~ with an inside diameter of 32.5 to 33.5 ~~33.0 ± 0.5~~ mm ~~in internal diameter~~, and ~~with~~ a wall ~~thickness of~~ ~~2.5 ± 0.5~~ 2.0 to 3.0 mm thick. The tubes are held in a vertical ~~vertically by~~ position by 2 separate and superimposed rigid plastic plates, each 95 to 99

mm 97 mm in diameter and 9 mm thick 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 side surface of the lower plate is a piece of woven gauze made from 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. 0.63 ± 0.03 mm in diameter and having mesh apertures of 2.0 ± 0.2 mm. The plates are held rigidly firmly in position and 77.5 mm apart 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. capable of raising and lowering it smoothly at a constant frequency of between 29 and 32 cycles per minute, through a distance of 55 ± 2 mm.

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 31.27 to 31.53 31.4 ± 0.13 mm in diameter and 15.15 to 15.45 15.3 ± 0.15 mm thick, . The disc is made of suitable transparent plastic material having with a relative density a specific gravity of 1.18-1.20. Each disc is pierced by 7 parallel holes, each 3.05 to 3.25 3.15 ± 0.1 mm in diameter, . One of the holes is in the centred on the cylindrical axis. The other holes are parallel to the cylindrical axis and the other 6 spaced equally on a circle of radius 4.2 mm from the centre of the disc. with a diameter of 8.3 to 8.5 mm centred from the axis. All surfaces of the disc are smooth. The discs conform to the dimensions shown in fig. 2.5.1-2.

Medium. The assembly is suspended in the specified liquid medium in a suitable vessel, preferably a 1 liter beaker. The volume of the liquid is such that when the assembly is in the highest position the wire mesh is at least 15 mm below the surface of the liquid, and when the assembly is in the lowest position the wire mesh is at least 25 mm above the bottom of the beaker and the upper open ends of the tubes remain above the surface of the liquid. A suitable device maintains the temperature of the liquid at 35–39°.

The design of the basket rack assembly may be varied provided the specifications for the tubes and wire mesh are maintained.

Method. Unless otherwise stated in the individual monograph, introduce one tablet or capsule into each of the three tubes and, if directed in the appropriate general monograph, add a disc to each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time, Remove the assembly from the liquid. The tablets or capsules pass the test if all six have disintegrated

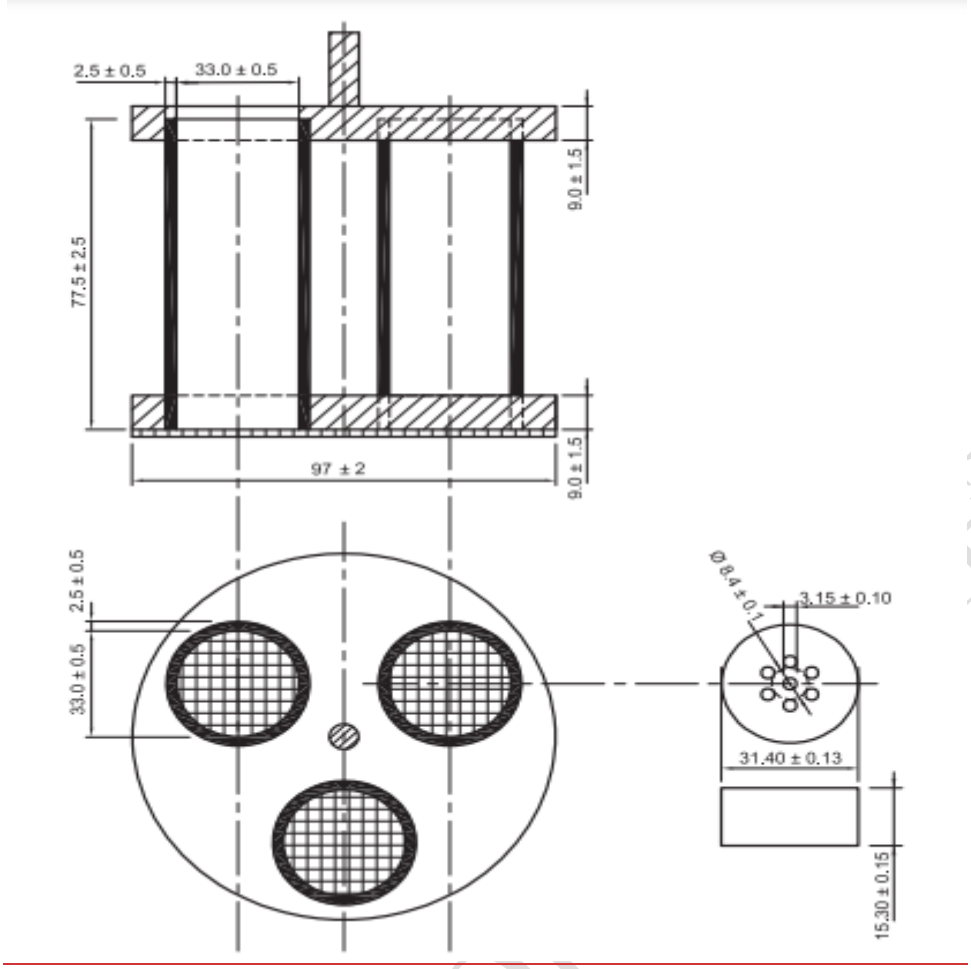
Operate the apparatus as directed under Procedure.

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. The use of discs is permitted only where specified or allowed. 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.

In case when the apparatus is equipped with an automatic detection of the disintegration, record the time when all dosage units have disintegrated. All dosage units have to disintegrate within the specified time.

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 total of 18 dosage units tested have disintegrated.

NOTE — Test six tablets or capsules either by using 2 basket rack assemblies in parallel or by repeating the procedure.



(Dimensions in mm)

Fig. 2.5.1-2: Apparatus for Disintegration of ~~Tablets and capsules of large size~~ Test B

~~**Apparatus**~~

♦ ***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 ruptures, releasing the contents;

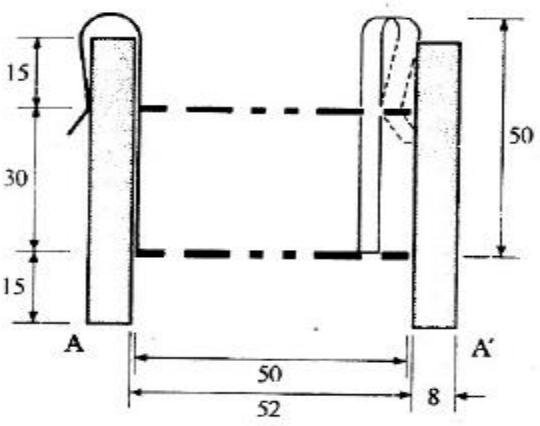
e) No residue remains on the perforated disc or, if a residue remains, it consists only of a soft and/or frothy mass with no solid core offering resistance to the pressure of a glass rod (vaginal tablets).

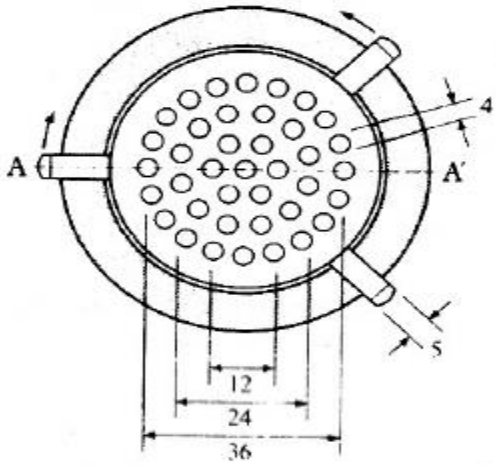
a) ~~A transparent sleeve of glass or plastic, 60 mm high with an internal diameter of 52 mm and an appropriate wall thickness (Fig. 2.5.1-3a).~~

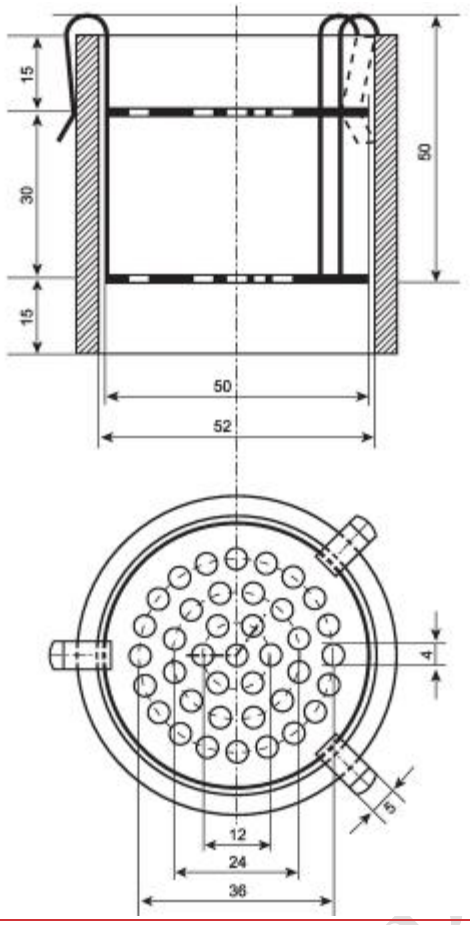
b) ~~A metal device consisting of two stainless steel discs each of which contains 39 holes, each 4 mm in diameter, being distributed as indicated in Fig. 2.5.1-3a. The diameter of the disc is closely similar to the internal diameter of the sleeve. The discs are separated by a distance of about 30 mm. The metal device is attached to the outer sleeve by means of three equally spaced hooks.~~

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

~~For Compressed Pessaries use with the hook-end downwards as in Fig. 2.5.1-3b.~~

Procedure for Suppository and Vaginal Dosage Forms other than Compressed Pessaries

~~For Moulded Pessaries, Moulded Suppositories, Shell Pessaries and Shell Suppositories~~

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.

~~Place a pessary or suppository on the lower perforated disc of the metal device and then insert the device into the cylinder and attach this to the sleeves. Repeat the operation with a further two pessaries or suppositories and metal devices and sleeves. Unless otherwise specified, place each piece of apparatus in a vessel containing at least 4 litres of water at 36º to 37º and fitted with a slow stirrer and a means of holding the top of the apparatus 90 mm below the surface of the water. A suitable thermostatic arrangement may be provided for maintaining the temperature of the bath. Alternatively, all three pieces of apparatus may be placed together in a vessel containing at least 12 litres of water. After each 10 minutes invert each apparatus without removing it from the liquid.~~

~~Disintegration is considered to be complete when the moulded pessary or suppository~~

~~a) is completely dissolved or~~

~~b) has dispersed into its component parts, which may remain on the surface (in the case of melted fatty substances), sink to the bottom (in case of insoluble powders) or dissolve (in case of soluble components) or may be distributed in one or more of these ways or~~

~~c) has become soft with appreciable change in shape, without necessarily separating into its components, and the mass has no solid core which cannot be pressed with a glass rod.~~

~~**Apparatus**~~

~~***For Compressed Pessaries***~~

~~Place the apparatus in a vessel of suitable diameter containing water at 36º to 37º. Adjust the level of the liquid by the gradual addition of water at 36º to 37º until the perforations in the metal disc are just covered by a uniform layer of water. Place one compressed pessary on the upper perforated disc and cover the apparatus with a glass plate to ensure a humid atmosphere. Repeat the operation with a further two compressed pessaries.~~

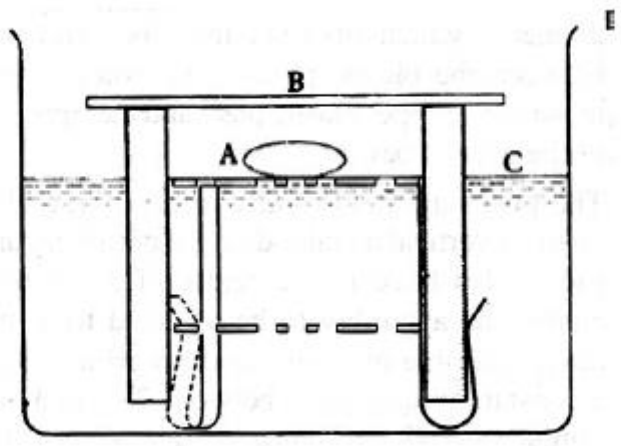
~~Disintegration is considered to be complete when~~

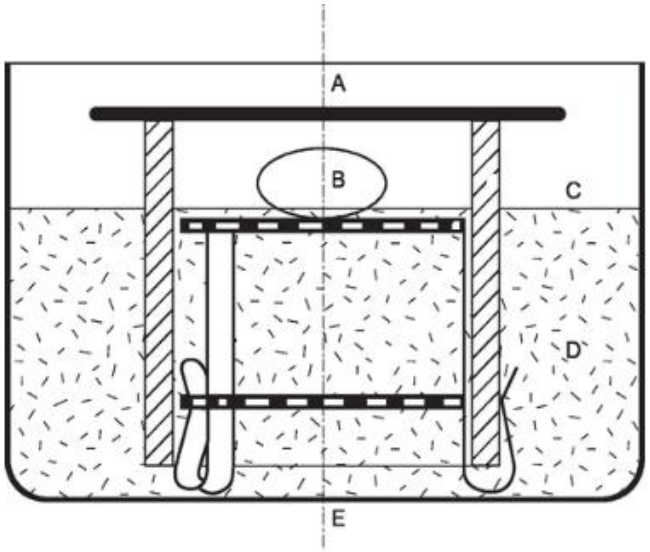
~~a) There is no residue on the perforated plate or~~

~~b) If a residue remains, it consists only of a soft mass having no solid core which cannot be pressed with a glass rod.~~

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- Compressed pessary; B- Glass Plate; C- Water surfre~~

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

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