PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT

CODE: Q-02
NAME: Disintegration

REVISION 2

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia's reference materials and general chapters.

Harmonised provisions:

Provision	EP	IP	JP	USP
Introduction	+	+	+	+
Test A – tablets and capsules up to 18 mm	+	+	+	+
Test B – tablets and capsules larger than 18 mm	+	+	+	+

Legend
+ will adopt and implement; — will not stipulate

Non-harmonised provisions:
None.

Local requirements

EP	None
IP	• Application of the disintegration text extended to boluses, pessaries and suppositories • Provision for omitting the disc given • Procedure and Criteria for: o For pessaries and suppositories

JP	• Procedure and criteria for enteric-coated preparations; • Application of the disintegration test extended to granules, preparations for dry syrups and pills, and procedure and criteria for those preparations; • Supplementary explanation of accessories permitted for the apparatus; • Water shall be used as the immersion fluid, unless otherwise specified; • Test time for each preparation, unless otherwise specified; • Supplementary explanation regarding definition of disintegration.
USP	• Added as national text in Disintegration <701>: • Application of the disintegration test extended to granules. • Procedure and Criteria for: o Delayed-release tablets and capsules; o Buccal tablets, sublingual tablets, tablets for oral suspension, tablets for oral solution, tablets for topical solution, orally disintegrating tablets, and chewable tablets; o Effervescent tablets for oral solution; o Effervescent granules.

European Pharmacopoeia

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Indian Pharmacopoeia Commission

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United States Pharmacopeia

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DISINTEGRATION

This test is used to determine whether tablets or capsules disintegrate within the prescribed time when placed in a liquid medium under the experimental conditions presented below.

For the purposes of this test, disintegration does not imply complete dissolution of the dosage unit or even of its active substance. Complete disintegration is defined as that state in which any residue of the dosage unit, except fragments of insoluble coating or capsule shell, remaining on the woven stainless steel wire cloth of the basket-rack assembly or adhering to the lower surface of the disk, if used, is a soft mass having no palpably firm core.
Test A is intended for tablets or capsules measuring not more than 18 mm on their longest axis. 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 (see Figure 1) consists of the following:

- a 1000-mL low-form beaker
- a basket-rack assembly,
- disks, if applicable,
- a thermostatic device for heating the immersion fluid at 37 ± 2°,
- a device for raising and lowering the basket-rack assembly in the immersion fluid at a constant rate of 29 to 32 cycles per minute through a distance of 53 mm to 57 mm, and
- an automatic-detection system, if applicable.

The volume of the immersion fluid in the beaker is usually 700 mL but must be adjusted such that at the highest point of the upward stroke the woven stainless steel wire cloth remains at least 15 mm below the surface of the immersion fluid. The basket-rack assembly 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.

Beaker. A 1000 mL low-form beaker, 138 to 160 mm in height with an inside diameter of 97 to 115 mm.

Basket-rack assembly. 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 separated and superimposed rigid plastic 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. The holes are 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 mesh apertures of 1.8 to 2.2 mm and a wire diameter of 0.57 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 center of the upper plate to enable the basket-rack assembly to be attached to the raising and lowering device.

The design of the basket-rack assembly may be varied somewhat, provided the specifications for the glass tubes and the aperture pf the woven stainless steel wire cloth are maintained. The basket-rack assembly complies with the dimensions shown in Figure 1.

Disks[1)]. Each tube is provided with a cylindrical disk 9.35 to 9.65 mm thick and 20.55 to 20.85 mm in diameter. The disk is made of a suitable transparent plastic material having a specific gravity of 1.18 to 1.20 and is pierced by five parallel holes each 1.9 to 2.1 mm in diameter. One of the holes is centered on the vertical axis of the disk. The other holes are parallel to the axis and spaced equally on a circle, centered on the axis with a diameter of 5.8 to 6.2 mm. Four identical trapezoidal-shaped planes are cut into the wall of the disk, nearly perpendicular to its ends. The trapezoidal shape is symmetrical; its parallel sides coincide with the ends of the disk and are parallel to an imaginary line connecting the centers of two adjacent holes 6 mm from the axis. The small lower side of the trapezoid on the bottom of the disk 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 circumference of the disk. The large upper side of the trapezoid on the top of the disk 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 circumference of the disk. All surfaces of the disk are smooth. Each disk complies with the dimensions shown in Figure 1.Where modified disks are required to achieve automatic detection of the disintegration time, they

[1] *The use of disks is permitted only where specified.*

must comply with the requirements for specific gravity and dimensions given in this general chapter.

Operate the apparatus as directed under *Procedure.*

PROCEDURE

Place 1 dosage unit in each of the six tubes of the basket-rack assembly and, if prescribed, add a disk. The use of disks is permitted only where specified. 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 dosage units must 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.

Apparatus for Disintegration Test A
(Figure 1)

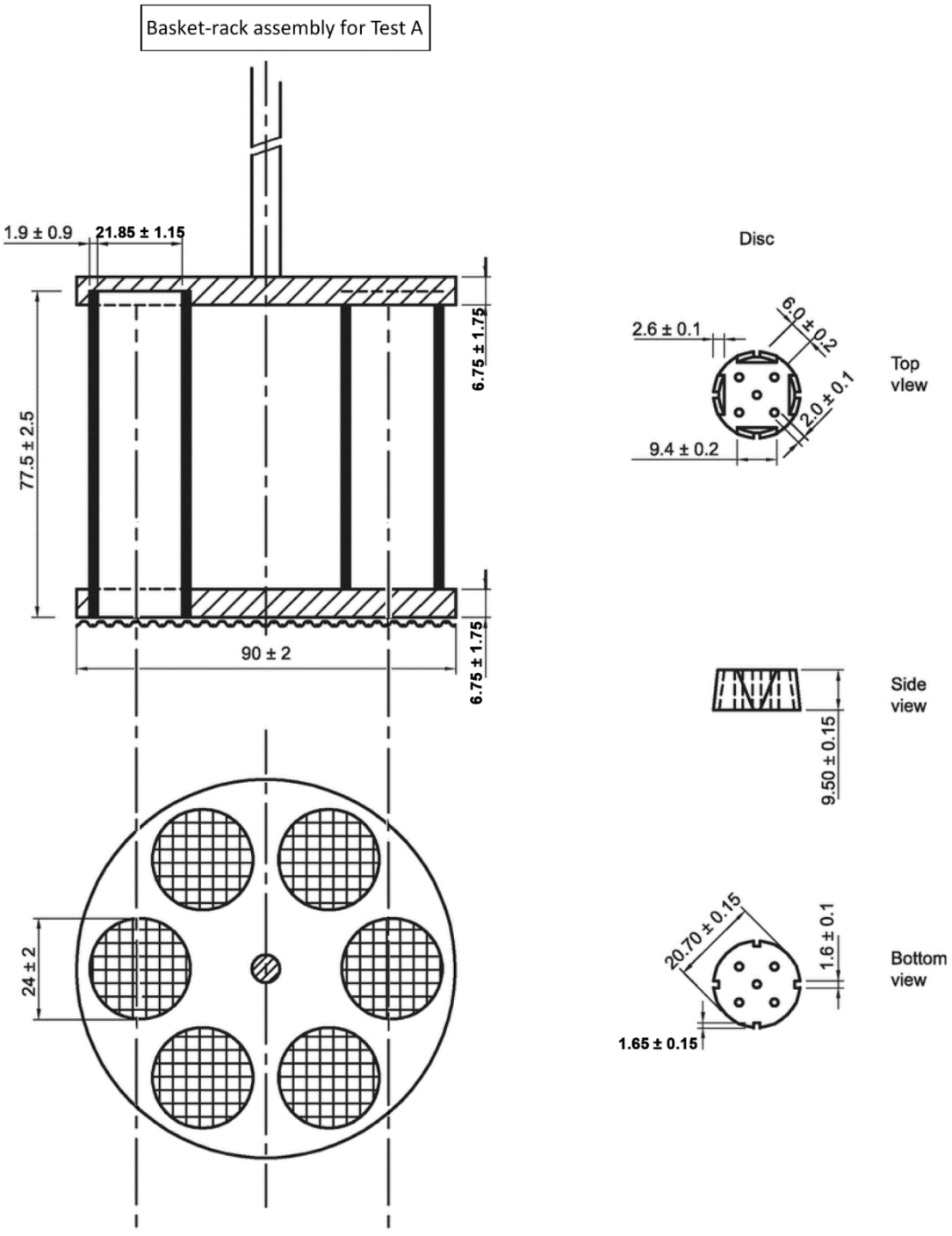

Figure 1. Apparatus for Disintegration Test A.
Dimensions in mm.

TEST B –TABLETS AND CAPSULES LARGER THAN 18 MM

APPARATUS

The apparatus (see Figure 2) consists of the following:

- a 1000 mL low form beaker,
- a basket-rack assembly,
- disks, if applicable,
- a thermostatic device to heat the immersion fluid at 37 ± 2°,
- a device for raising and lowering the basket-rack assembly in the immersion fluid, and
- an automatic-detection system, if applicable.

The apparatus is prepared and operated as described under Test A (tablets and capsules up to 18 mm).

Beaker. A 1000 mL low-form beaker, 138 to 160 mm in height with an inside diameter of 97 to 115 mm; the difference between the inside diameter of the beaker 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 consists of three 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 two separate and superimposed rigid plastic plates, each 95 to 99 mm in diameter and 7.5 to 10.5 mm in thickness, with three 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 a wire diameter of 0.57 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 the raising and lowering device.

The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the aperture of the woven stainless steel wire cloth are maintained. The basket-rack assembly complies with the dimensions shown in Figure 2.

Disks[2)]. Each tube is provided with a cylindrical disk 15.15 to 15.45 mm thick and 31.27 to 31.53 mm in diameter. The disk is made of a suitable transparent plastic material having a specific gravity of 1.18 to 1.20 and is pierced by seven parallel holes, each 3.05 to 3.25 mm in diameter. One of the holes is centred on the vertical axis of the disk. The other holes are parallel to the axis and spaced equally on a circle, centred on the axis, with a diameter of 8.3 to 8.5 mm. All surfaces of the disk are smooth. Each disk complies with the dimensions shown in Figure 2. Where modified disks are required to achieve automatic detection of the disintegration time, they must comply with the requirements for specific gravity and dimensions given in this general chapter.

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 of the basket-rack assembly and, if prescribed, add a disk. The use of disks is permitted only where specified. 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 dosage units must 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.

Apparatus for Disintegration Test B
(Figure 2)

[2] *The use of disks is permitted only where specified.*

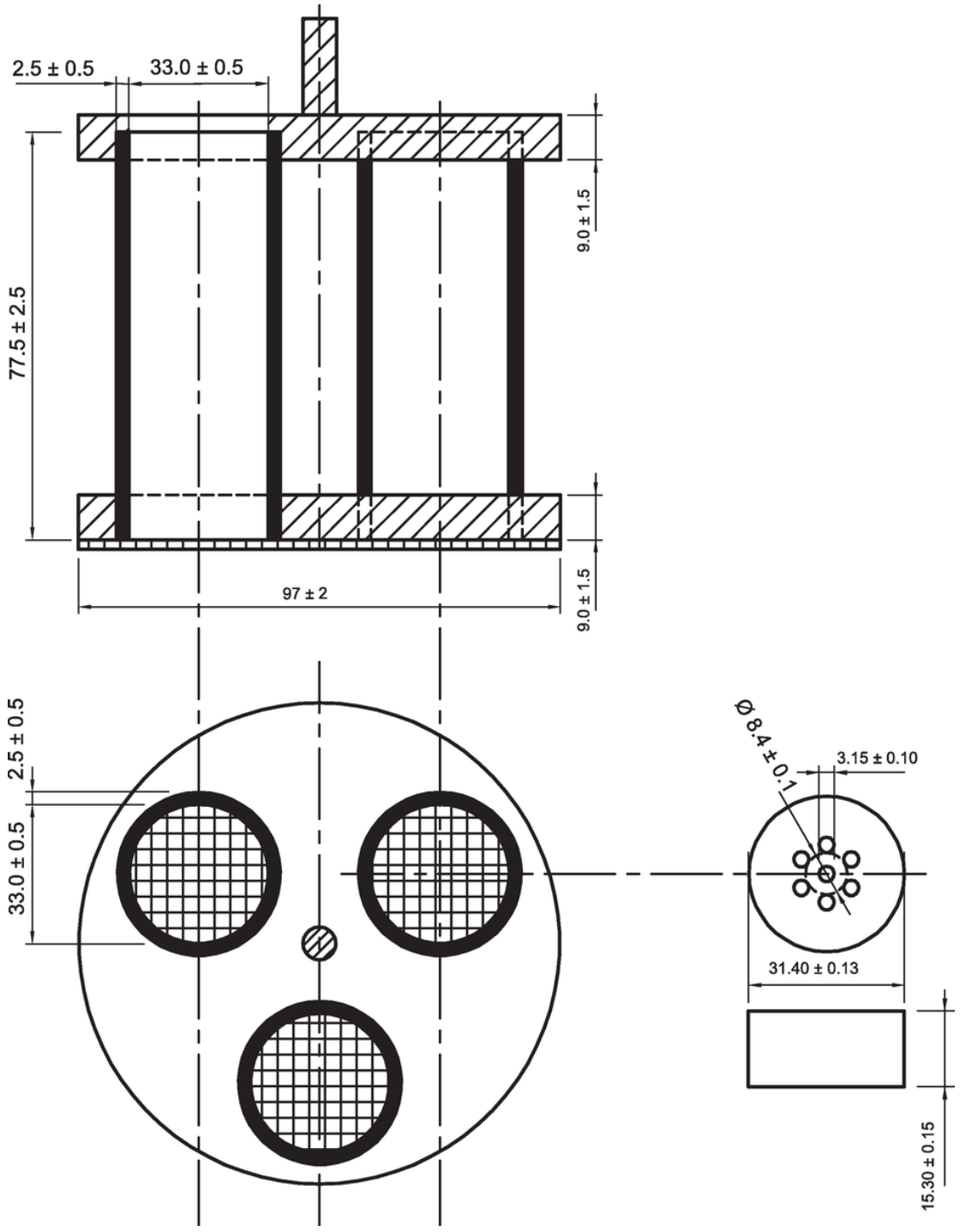

Figure 2. Apparatus for Disintegration Test B.
Dimensions in mm