DISINTEGRATION

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

For the purposes 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 disk, 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[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 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 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

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

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 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 Figure 1.

Disks. (The use of disks is permitted only where specified or allowed.) 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. 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 Figure 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 Figure 1[2].
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 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.

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

Apparatus for Disintegration Test A
(Figure 1)

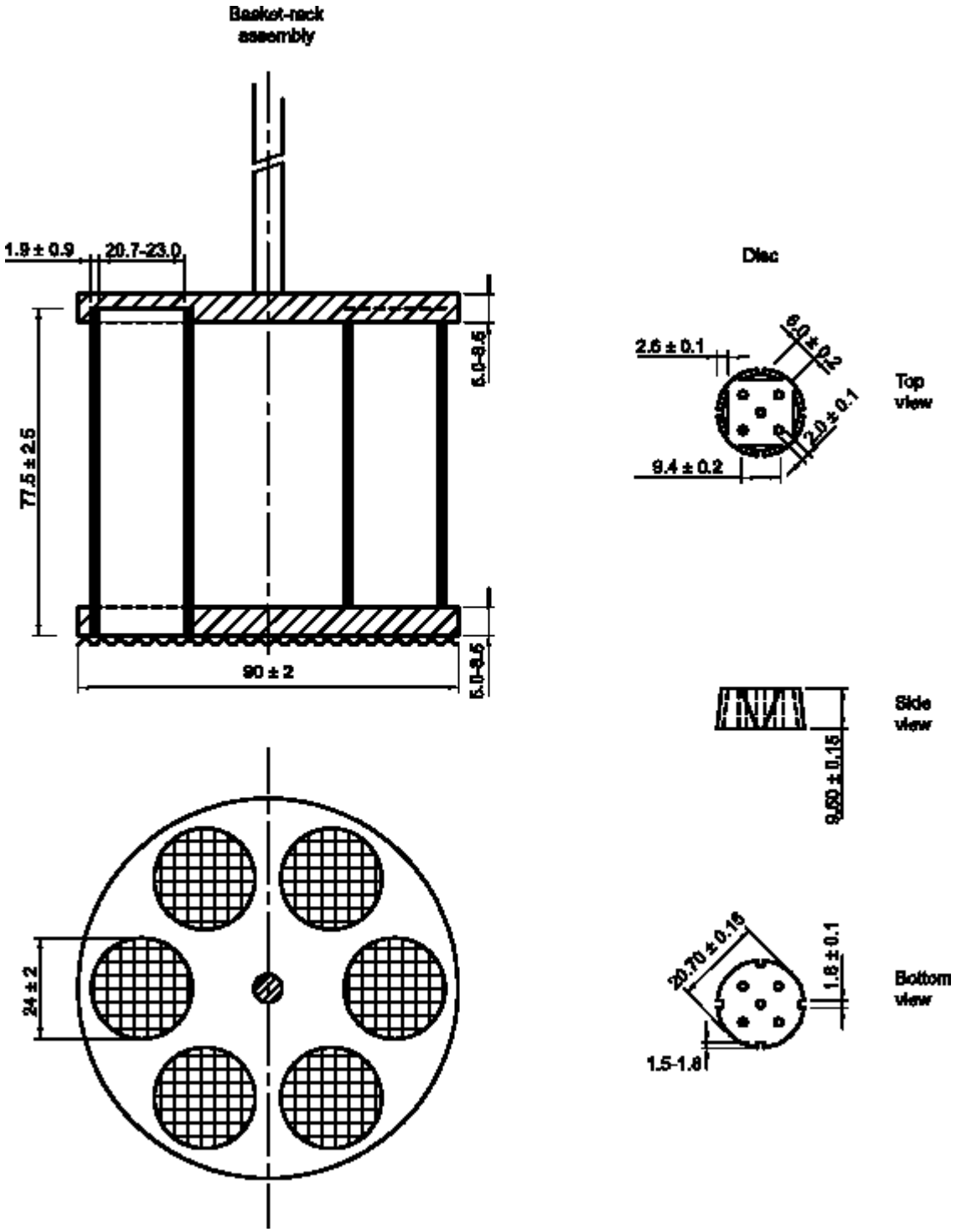

Figure 1. Apparatus for Disintegration Test A.
(All dimensions are expressed in mm.)

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 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 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 Figure 2.

Disks. (The use of disks is permitted only where specified or allowed.) 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 suitable transparent plastic material having a specific gravity of 1.18 to 1.20. Each disk is pierced by seven parallel holes, each 3.05 to 3.25 mm in diameter. One of the holes is centred 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 centred from the axis. All surfaces of the disk are smooth. The disks conform to the

dimensions shown in Figure 2.

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 disk. The use of disks 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.

Apparatus for Disintegration Test B
(Figure 2)

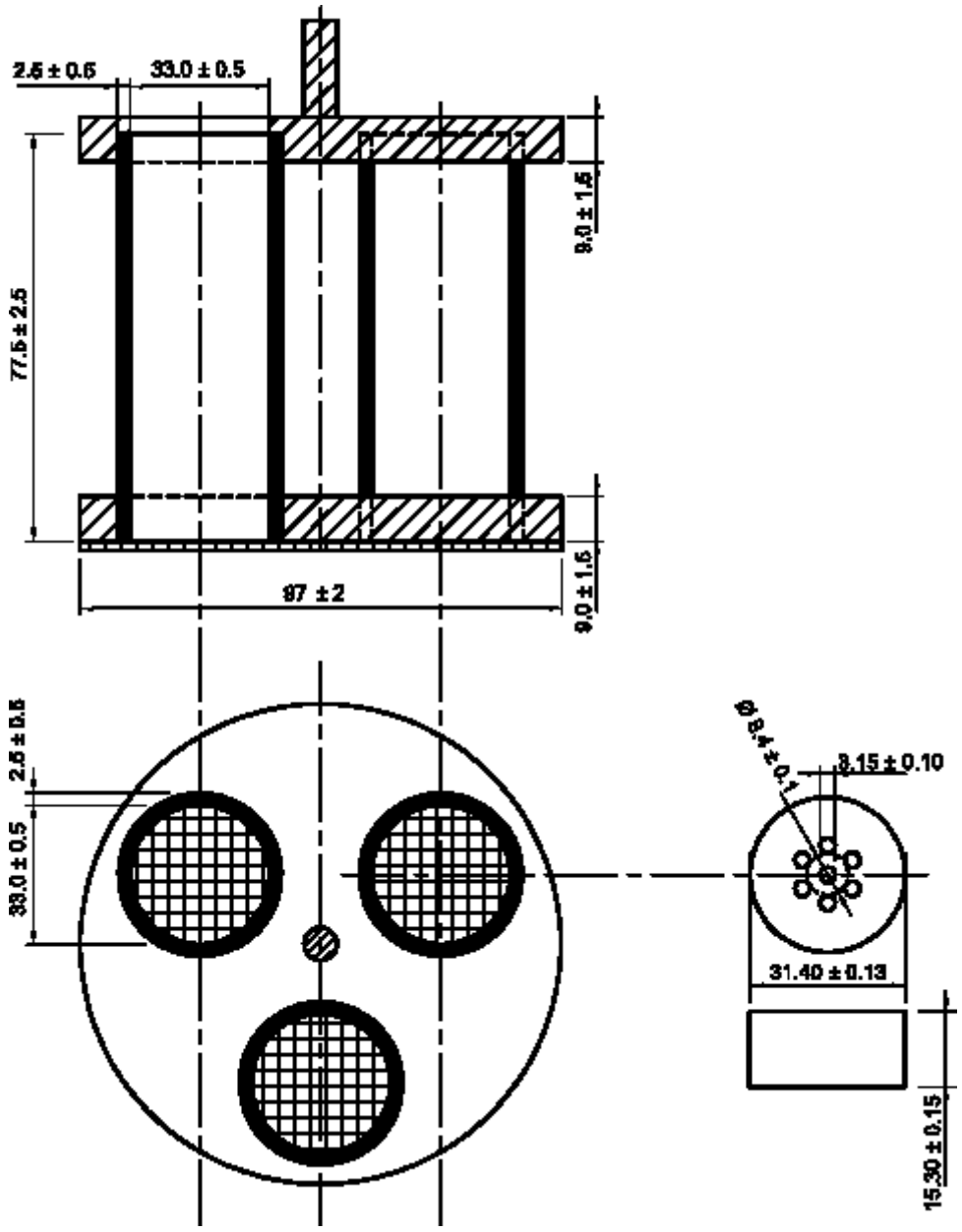

Figure 2. Apparatus for Disintegration Test B.
(All dimensions are expressed in mm)