The apparatus consists of a basket-rack assembly, a 1000-mL low-form beaker 138–160 mm in height and having an inside diameter of 97–115 mm for the immersion fluid, a thermostatic arrangement for heating the fluid 35°–39°, and a device for raising and lowering the basket in the immersion fluid at a constant frequency 29–32 cycles/min through a distance of NLT 53 mm and NMT 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 NLT 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 basket-rack assembly consists of 6 open-ended transparent tubes, each having an inside diameter of 20.7–23 mm and a wall 1.0–2.8 mm thick; the tubes are held in a vertical position by two plates, each 88–92 mm in diameter and 5–8.5 mm in thickness, with 6 holes, each 22–26 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 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 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 wire cloth, which have a plain square weave with 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 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 use of disks is permitted only where specified or allowed in the monograph. If specified in the individual monograph, each tube is provided with a cylindrical disk having a specific gravity of 1.18–1.20. Five parallel 1.9–2.1 mm-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 5.8–6.2 mm from the axis on imaginary lines perpendicular to the axis and 1.9–2.1 mm-mm thick and 20.55–20.85 mm-mm diameter. The disk is made of a suitable transparent plastic material having a specific gravity of 1.8–2.2 mm in diameter and 5–8.5 mm in thickness, with 6 holes, each 22–26 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 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 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 wire cloth, which have a plain square weave with 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 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 use of disks is permitted only where specified or allowed in the monograph. If specified in the individual monograph, each tube is provided with a cylindrical disk having a specific gravity of 1.18–1.20. Five parallel 1.9–2.1 mm-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 5.8–6.2 mm from the axis on imaginary lines perpendicular to the axis and 1.9–2.1 mm-mm thick and 20.55–20.85 mm-mm diameter. The disk is made of a suitable transparent plastic material having a specific gravity of 1.8–2.2 mm in diameter and 5–8.5 mm in thickness, with 6 holes, each 22–26 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 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 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 wire cloth, which have a plain square weave with 1.8–2.2-mm apertures and with a wire diameter of 0.57–0.66 mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis.
Figure 1. Disintegration apparatus. (All dimensions are expressed in mm.)
Change to read:

**PROCEDURE AND CRITERIA**

Procedure and Criteria for Uncoated or Plain-Coated Tablets USP 1-Aug-2019

Place 1 dosage unit in each of the 6 tubes of the basket and, if prescribed, add a disk. Operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of the time limit specified in the monograph, lift the basket from the fluid, and observe the tablets. All of the tablets should have disintegrated completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets.

**CRITERIA FOR UNCOATED OR PLAIN-COATED TABLETS**

1. If 6 tablets are tested, all 6 of the tablets are disintegrated.
2. If 18 tablets are tested, the requirement is met if not fewer than 16 of the total of 18 tablets are disintegrated.

Procedure and Criteria for Delayed-Release Tablets and Capsules (tablets or capsules that are formulated with acid-resistant or enteric coatings)

**PROCEDURE FOR DELAYED-RELEASE TABLETS AND CAPSULES**

Place 1 dosage unit in each of the 6 tubes of the basket. If the dosage units are not sugar-coated, proceed to the Acid stage. If testing tablets that have a soluble external sugar coating, immerse the basket in water at room temperature for 5 min and then immediately proceed to the Acid stage. If specified in the monograph, add 1 disk to each tube.

**Acid stage**
- Immersion fluid: 0.1 M hydrochloric acid, or simulated gastric fluid TS, or as specified in the monograph
- Temperature: 37 ± 2°
- Time: 1 h

If after 1 h no dosage unit shows evidence of disintegration, cracking, or softening, proceed with the Buffer stage.

**Buffer stage**
- Immersion fluid: pH 6.8 phosphate buffer, or simulated intestinal fluid TS, or as specified in the monograph
- Temperature: 37 ± 2°
- Time: As specified in the individual monograph

**CRITERIA FOR DELAYED-RELEASE TABLETS AND CAPSULES**

Acid stage: No dosage unit shows evidence of disintegration, cracking, or softening.
Buffer stage: Apply the Criteria for Uncoated or Plain-Coated Tablets.

Procedure and Criteria for Buccal Tablets, Sublingual Tablets, Capsules, Tablets for Oral Suspension, Tablets for Oral Solution, Tablets for Topical Solution, Orally Disintegrating Tablets, and Chewable Tablets

Apply the Procedure and Criteria for Uncoated or Plain-Coated Tablets.

Procedure and Criteria for Effervescent Tablets for Oral Solution

**PROCEDURE FOR EFFERVESCENT TABLETS FOR ORAL SOLUTION**

Place 1 tablet in each of 6 beakers containing 200 mL of water. A suitable beaker will have a nominal volume of 250–400 mL.
- Time: 5 min or as specified in the individual monograph

**CRITERIA FOR EFFERVESCENT TABLES FOR ORAL SOLUTION**

Numerous bubbles of gas are evolved. After 5 min or as specified in the individual monograph, the evolution of gas around each tablet or its fragments has ceased. Each tablet has dissolved or disintegrated and has been dispersed in the water so that no appreciable agglomerates remain.
**Procedure and Criteria for Effervescent Granules**

**PROCEDURE FOR EFFERVESCENT GRANULES**

In each of 6 beakers containing 200 mL of water place 1 dose of the effervescent granules. A suitable beaker will have a nominal volume of 250–400 mL.

**Time:** 5 min or as specified in the individual monograph

**CRITERIA FOR EFFERVESCENT GRANULES**

Numerous bubbles of gas are evolved. After 5 min or as specified in the individual monograph, the evolution of gas around the granules in each beaker has ceased. The granules have dissolved or disintegrated and have been dispersed in the water. ▲ USP 1-Aug-2019 ▼