

Pentoxifylline Extended-Release Tablets

» Pentoxifylline Extended-Release Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of pentoxifylline ($C_{13}H_{18}N_4O_3$).

Packaging and storage—Preserve in well-closed containers. Protect from light, and store between 15° and 30°.

Labeling—The labeling indicates the *Dissolution Test* with which the product complies.

USP REFERENCE STANDARDS (11)—
[USP Pentoxifylline RS](#)

Identification—

Change to read:

A: [▲Spectroscopic Identification Tests \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-May-2020) —

Test specimen—Finely powder not fewer than 5 Tablets. (A coarse screen may be used to separate the powder from the tablet film-coating if necessary.) Transfer an accurately weighed portion of the powder, equivalent to about 200 mg of pentoxifylline, to a 15-mL centrifuge tube, add about 10 mL of methanol, cap the tube, and shake vigorously for about 5 minutes. Centrifuge for about 5 minutes to allow undissolved material to settle. Decant the supernatant into a suitable beaker, and evaporate the solution with the aid of a current of air to dryness at about 35°. Dissolve the residue in about 15 mL of methylene chloride, transfer to a separatory funnel, add about 10 mL of water, and shake. Allow the layers to separate, transfer the methylene chloride layer, and pass through a funnel partially filled with anhydrous sodium sulfate, collecting the filtrate in a small beaker. Evaporate the solution with the aid of a current of air to dryness at about 35°. Dissolve the residue so obtained in 8 to 10 mL of ether, and then chill in an ice bath, if necessary, to induce crystallization. Collect the crystals on filter paper, wash with about 2 mL of cold ether, and allow to air-dry. Prepare a mixture of about 1.5% (w/w) of the crystals in potassium bromide.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the Assay.

DISSOLUTION (711)—

TEST 1—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: water; 900 mL or 1000 mL.

Apparatus 2: 100 rpm.

Times: 1, 4, 8, and 12 hours.

Procedure—Determine the amount of $C_{13}H_{18}N_4O_3$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 274 nm on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of [USP Pentoxifylline RS](#) in the same *Medium*.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}N_4O_3$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	not more than 30%
4	between 30% and 55%
8	not less than 60%
12	not less than 80%

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: water; 900 mL.

Apparatus 2: 75 rpm.

Times: 1, 6, 10, and 20 hours.

Procedure—Proceed as directed for Test 1.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}N_4O_3$ dissolved at the times specified conform to the following table.

Time (hours)	Amount dissolved
1	between 8% and 30%
6	between 35% and 60%
10	between 53% and 78%
20	not less than 80%

TEST 3—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Times: 2, 8, 12, and 20 hours.

Procedure—Proceed as directed for Test 1.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}N_4O_3$ dissolved at the times specified conform to the following table.

Time (hours)	Amount dissolved
2	between 15% and 35%
8	between 55% and 75%
12	between 75% and 95%
20	not less than 85%

TEST 4—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Times: 1, 8, and 24 hours.

Procedure—Proceed as directed for Test 1.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}N_4O_3$ dissolved at the times specified conform to the following table.

Time (hours)	Amount dissolved
1	between 0% and 20%
8	between 35% and 60%
24	not less than 80%

TEST 5—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5*.

Medium: water; 900 mL.

Apparatus 2: 75 rpm.

Times: 1, 2, 4, 6, and 20 hours.

Procedure—Proceed as directed for Test 1, except to use the wavelength of maximum absorbance at about 264 nm instead of 274 nm.