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Tamoxifen Citrate Tablets

» Tamoxifen Citrate Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of tamoxifen ($C_{26}H_{29}NO$).

Packaging and storage—Preserve in well-closed, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Tamoxifen Citrate RS

Identification—

A: The UV absorption spectrum of the *Test preparation*, obtained as directed in the test for *Content uniformity*, exhibits maxima and minima at the same wavelengths as that of the *Standard preparation,* concomitantly measured.

B: To 1 Tablet contained in a 15-mL tube add 4 mL of pyridine and 2 mL of acetic anhydride: an immediate yellow color is produced on shaking. Then heat gently on a steam bath: a rose-pink to a deep red color develops, indicating the presence of citrate ion.

Dissolution ⟨711⟩—

Medium: 0.02 N hydrochloric acid; 1000 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of tamoxifen ($C_{26}H_{29}NO$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 275 nm of 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 Tamoxifen Citrate RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{26}H_{29}NO$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

PROCEDURE FOR CONTENT UNIFORMITY—

Standard solution—Dissolve an accurately weighed quantity of USP Tamoxifen Citrate RS in methanol to obtain a solution having a known concentration of about 15 µg per mL.

Test solution—Place 1 Tablet in a 100-mL volumetric flask, and crush with a stirring rod. Add about 75 mL of methanol, and shake for about 5 minutes. Dilute with methanol to volume, mix, and filter the solution through paper. Pipet 10 mL of the filtrate into a 100-mL volumetric flask, dilute with methanol to volume, and mix.

Procedure—Determine the absorbances of the *Test solution* and the *Standard solution* in 1-cm cells at the wavelength of maximum absorbance at about 275 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of tamoxifen ($C_{26}H_{29}NO$) in the Tablets taken by the formula:

$$(371.51/563.64)(TC/D)(A_U/A_S)$$

in which 371.51 and 563.64 are the molecular weights of tamoxifen and tamoxifen citrate, respectively; T is the labeled quantity, in mg, of tamoxifen in the Tablet; C is the concentration, in µg per mL, of USP Tamoxifen Citrate RS in the *Standard solution; D* is the concentration, in µg per mL, of tamoxifen in the solution from the Tablet, based upon the labeled quantity per Tablet and the extent of dilution; and A_U and A_S are the absorbances of the *Test solution* and the *Standard solution*, respectively.

Assay—

Mobile phase—Prepare a methanol solution containing, in each liter, 320 mL of water, 2 mL of glacial acetic acid, and 1.08 g of sodium 1-octanesulfonate.

Standard preparation—Dissolve a suitable quantity, accurately weighed, of USP Tamoxifen Citrate RS in *Mobile phase* to obtain a solution having a known concentration of about 200 µg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of tamoxifen, to a stoppered, 50-mL centrifuge tube. Pipet 30 mL of *Mobile phase* into the tube, and shake by mechanical means

for not less than 15 minutes. Centrifuge at about 1000 rpm, pipet 5 mL of the clear supernatant into a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L11. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak areas as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph by means of a suitable sampling valve, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of tamoxifen ($C_{26}H_{29}NO$) in the portion of Tablets taken by the formula:

$$0.15C(371.51/563.64)(r_U/r_S)$$

in which 371.51 and 563.64 are the molecular weights of tamoxifen and tamoxifen citrate, respectively; C is the concentration, in µg per mL, of USP Tamoxifen Citrate RS in the *Standard preparation;* and r_U and r_S are the peak areas obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TAMOXIFEN CITRATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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