Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-CBA499C2-F79C-498A-9881-DA330D088459_1_en-US
DOI: https://doi.org/10.31003/USPNF_M83110_01_01
DOI Ref: 1ud99

Thiothixene Capsules

» Thiothixene Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{23}H_{29}N_3O_2S_2$.

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

USP Reference standards ⟨11⟩—

USP Thiothixene RS

Identification—Dissolve a portion of the contents of Capsules in a solvent consisting of equal volumes of chloroform and methanol to obtain a solution containing 1 mg of thiothixene per mL. Shake by mechanical means for 10 minutes, clarify a portion of the mixture by centrifugation, filter, if necessary, and use the clear supernatant or filtrate for the test. Apply 10 µL of this test solution, 10 µL of a Standard solution containing 1 mg of USP Thiothixene RS per mL in the same medium, and 10 µL of a mixture of equal volumes of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of ethyl acetate, methanol, and diethylamine (65:35:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and locate the spots on the plate by viewing under short- and long-wavelength UV light. Spray the plate lightly with acidified iodoplatinate spray reagent (prepared by mixing 1 volume of hydrochloric acid with 50 volumes of potassium iodoplatinate TS): the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution and the mixed test-Standard solution.

Dissolution ⟨711⟩—

Medium—Dissolve 2.0 g of sodium chloride and 7 mL of hydrochloric acid in water to make 1000 mL, and mix; 900 mL.

Apparatus 1: 100 rpm.

Time: 20 minutes.

Buffer solution—On the day of use, prepare a mixture of 55 volumes of dibasic potassium phosphate solution (87 in 1000), 20 volumes of citric acid monohydrate solution (21 in 200), and 40 volumes of sodium hydroxide solution (1 in 25).

Methyl orange solution—Transfer 15.5 g of boric acid and 2.0 g of methyl orange to a glass-stoppered, 1000-mL flask. Add 500 mL of water, insert the stopper, and shake by mechanical means for not less than 3 hours. Filter through retentive filter paper, and wash the filtrate with two 100-mL portions of chloroform, discarding the chloroform washings. Store the *Methyl orange solution* over 50 mL of chloroform in a glass-stoppered bottle.

Procedure—Prepare a *Test preparation* by passing a 60-mL portion of the dissolution solution through a suitable filter, discarding the first 5 mL of the filtrate, and diluting the subsequent filtrate quantitatively, if necessary, to obtain a concentration of about 1 µg of thiothixene per mL. Prepare a *Standard preparation* of USP Thiothixene RS in *Dissolution Medium* having a known concentration of about 1 µg per mL. Transfer 40.0 mL each of the *Test preparation*, the *Standard preparation,* and *Dissolution Medium* to provide the blank, to individual separators, each containing 8.0 mL of *Buffer solution*, 10.0 mL of *Methyl orange solution*, and 50.0 mL of chloroform. Shake for 3 minutes, allow the layers to separate, transfer 40.0 mL of the chloroform layer, clarified by centrifugation, to a 60-mL separator containing 8.0 mL of dilute hydrochloric acid (1 in 120), shake for 1 minute, and allow the layers to separate. Concomitantly determine the absorbances of the aqueous layers in 1-cm cells, at the wavelength of maximum absorbance at about 508 nm, with a suitable spectrophotometer, using the blank to set the instrument. Calculate the quantity, in µg per mL, of $C_{23}H_{29}N_3O_2S_2$ in the *Test preparation* taken by the formula:

$$C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Thiothixene RS in the *Standard preparation,* and A_U and A_S are the absorbances of the solutions from the *Test preparation* and the *Standard preparation,* respectively, and, from the known extent of dilution, determine the amount of it in the dissolution solution.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{23}H_{29}N_3O_2S_2$ is dissolved in 20 minutes.

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

Assay—[Note—Perform the dilution operations in low-actinic glassware.]

Mobile phase, *Standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay* under *Thiothixene.*

Assay preparation—Transfer, as completely as possible, the contents of not less than 20 Capsules to a tared beaker, and weigh. Mix, and transfer an accurately weighed portion of the powder, equivalent to about 10 mg of thiothixene, to a 500-mL volumetric flask. Add about 400 mL of methanol, shake by mechanical means for 10 minutes, place in an ultrasonic bath for 5 minutes, dilute with methanol to volume, and filter the suspension through a 5-µm polytef membrane filter.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Thiothixene.* Calculate the quantity, in mg, of $C_{23}H_{29}N_3O_2S_2$ in the portion of Capsules taken by the formula:

$$500C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Thiothixene RS in the *Standard preparation,* and r_U and r_S are the peak responses 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
THIOTHIXENE CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-CBA499C2-F79C-498A-9881-DA330D088459_1_en-US
DOI: https://doi.org/10.31003/USPNF_M83110_01_01
DOI ref: 1ud99