System suitability preparation—Dissolve 100 mg of mesoridazine besylate in 100 mL of methanol. Mix 1.0 mL of this solution with 9.0 mL of the *Standard preparation*.

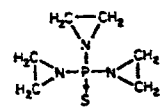
Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 265-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 2.5 mL per minute. Chromatograph the *Standard preparation* and the *System suitability preparation*, and record the peak responses as directed under *Procedure:* the resolution, R, between the mesoridazine and thioridazine peaks is not less than 1.0, and the relative standard deviation for replicate injections of the *Standard preparation* is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{26}N_2S_2$.HCl in the portion of Tablets taken by the formula:

$$0.8C(r_U/r_S),$$

in which C is the concentration, in µg per mL, of USP Thioridazine Hydrochloride 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.

Thiotepa



$C_6H_{12}N_3PS$ 189.21
Aziridine, 1,1′,1″-phosphinothioylidynetris-.
Tris(1-aziridinyl)phosphine sulfide [*52-24-4*].

» Thiotepa contains not less than 97.0 percent and not more than 102.0 percent of $C_6H_{12}N_3PS$, calculated on the anhydrous basis.

Caution—Great care should be taken to prevent inhaling particles of Thiotepa or exposing the skin to it.

Packaging and storage—Preserve in tight, light-resistant containers, and store in a refrigerator.

Reference standard—*USP Thiotepa Reference Standard*—Dry over silica gel for 24 hours before using.

Identification—The infrared absorption spectrum, determined in a 0.1-mm cell, of a 3 in 400 solution in carbon disulfide of Thiotepa, previously dried over silica gel for 24 hours, exhibits maxima only at the same wavelengths as that of a similar solution of USP Thiotepa RS.

Melting range ⟨741⟩: between 52° and 57°.

Water, *Method I* ⟨921⟩: not more than 2.0%.

Assay—Transfer about 200 mg of Thiotepa, accurately weighed, to a 250-mL iodine flask with the aid of 50 mL of sodium thiosulfate solution (1 in 5), and add 1 drop of methyl orange TS. Titrate the solution immediately with 0.1 *N* hydrochloric acid VS until a faint red color appears and the end-point persists for not less than 10 seconds. Insert the stopper in the flask, and allow to stand for 30 minutes. Add 4 drops of phenolphthalein TS, and titrate with 0.1 *N* sodium hydroxide VS. Repeat the titration (blank determination) on 50 mL of sodium thiosulfate solution (1 in 5). Determine the number of mL of 0.1 *N* hydrochloric acid consumed by the assay specimen by subtracting the number of mL of 0.1 *N* sodium hydroxide used from the number of mL of 0.1 *N* hydrochloric acid used, and correct it by subtracting the corresponding difference in consumption of 0.1 *N* hydrochloric acid and 0.1 *N* sodium hydroxide for the blank. Each mL of 0.1 *N* hydrochloric acid is equivalent to 6.307 mg of $C_6H_{12}N_3PS$.

Thiotepa for Injection

» Thiotepa for Injection is a sterile mixture of 1 part of Thiotepa, 5.33 parts of Sodium Chloride, and 3.33 parts of Sodium Bicarbonate. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_{12}N_3PS$.

Packaging and storage—Preserve in *Containers for Sterile Solids* as described under *Injections* ⟨1⟩, and store in a refrigerator, protected from light.

Reference standard—*USP Thiotepa Reference Standard*—Dry over silica gel for 24 hours before using.

Completeness of solution ⟨641⟩—The contents of 1 container dissolve in 4 mL of water to yield a clear solution.

Identification—The infrared absorption spectrum of the solution employed for measurements of absorbance in the *Assay* exhibits maxima only at the same wavelengths as that of the Standard solution, prepared as directed in the *Assay*.

pH ⟨791⟩: between 7.0 and 8.2, in a solution, reconstituted in Sterile Water for Injection, containing 10 mg of thiotepa per mL.

Loss on drying ⟨731⟩—Dry the contents of 1 container, accurately weighed, over silica gel for 24 hours: it loses not more than 0.5% of its weight.

Bacterial endotoxins—When tested as directed under *Bacterial Endotoxins Test* ⟨85⟩, the USP Endotoxin RS being used, it contains not more than 6.25 USP Endotoxin Units for each mg of Thiotepa.

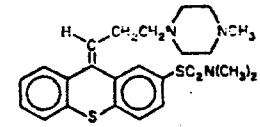
Other requirements—It meets the requirements for *Sterility Tests* ⟨71⟩, *Uniformity of Dosage Units* ⟨905⟩, and *Labeling* under *Injections* ⟨1⟩.

Assay—Remove, as completely as possible, the contents of not less than 20 containers of Thiotepa for Injection, weigh, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 75 mg of thiotepa, to a suitable container, extract with three 5-mL portions of carbon disulfide, and filter the carbon disulfide extract with the aid of vacuum. Concentrate the combined filtrates under vacuum to approximately 5 mL. Transfer the carbon disulfide solution to a 10-mL volumetric flask with the aid of a few mL of carbon disulfide, and dilute with carbon disulfide to volume. Concomitantly determine the absorbances of this solution and a Standard solution of USP Thiotepa RS in the same medium having a known concentration of about 7.5 mg per mL, in 0.1-mm cells, at the wavelength of maximum absorbance at about 10.75 µm, with a suitable infrared spectrophotometer, using carbon disulfide as the blank. Calculate the quantity, in mg, of $C_6H_{12}N_3PS$ in the portion of Thiotepa for Injection taken by the formula:

$$10C(A_U/A_S),$$

in which C is the concentration, in mg per mL, of USP Thiotepa RS in the Standard solution, and A_U and A_S are the absorbances of the Assay solution and the Standard solution, respectively.

Thiothixene



$C_{23}H_{29}N_3O_2S_2$ 443.62
9*H*-Thioxanthene-2-sulfonamide, *N*,*N*-dimethyl-9-[3-(4-methyl-1-piperazinyl)propylidene]-, (*Z*)-.
N,*N*-Dimethyl-9-[3-(4-methyl-1-piperazinyl)propylidene]thioxanthene-2-sulfonamide [*5591-45-7; 3313-26-6*].