Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-79166FEC-AA52-4822-8640-99DF17F46475_1_en-US
DOI: https://doi.org/10.31003/USPNF_M44625_01_01
DOI Ref: y1u25

Levamisole Hydrochloride Tablets

» Levamisole Hydrochloride Tablets contain an amount of Levamisole Hydrochloride equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of levamisole ($C_{11}H_{12}N_2S$).

Packaging and storage—Preserve in well-closed containers.

Labeling—Label it to state both the content of the active moiety and the content of the salt used in formulating the article.

USP Reference standards ⟨11⟩—
USP Levamisole Hydrochloride RS

Identification—

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

B: The R_F value of the principal spot obtained from *Test solution B* in the *Chromatographic purity* test corresponds to that from *Standard solution A*.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of levamisole ($C_{11}H_{12}N_2S$) dissolved by employing UV absorption at the wavelength of maximum absorbance at about 214 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Levamisole Hydrochloride RS in the same *Medium*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{11}H_{12}N_2S$ is dissolved in 45 minutes.

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

Chromatographic purity—

Test solution A—Transfer an amount of powdered Tablets, equivalent to 100 mg of levamisole, to a glass test tube. Add 5.0 mL of methanol, shake for 2 minutes, and filter.

Test solution B—Dilute 1.0 mL of *Test solution A* to 10 mL with methanol, and mix.

Standard solution A—Prepare a solution of USP Levamisole Hydrochloride RS in methanol having a concentration of 2.4 mg per mL (equivalent to 2.0 mg of levamisole per mL).

Standard solution B—Dilute 1.0 mL of *Standard solution A* to 20 mL with methanol, and mix.

Procedure—Apply separate 10-µL portions of *Test solutions A* and *B* and *Standard solutions A* and *B* to the starting line of 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 toluene, acetone, and ammonium hydroxide (60:40:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, and dry the plate at 105° for 15 minutes. Locate the spots on the plate by examination under short-wavelength UV light: any spot obtained from *Test solution A*, other than that of levamisole, does not exceed, in size or intensity, the principal spot obtained from *Standard solution B*, corresponding to not more than 0.5% of any individual impurity. Expose the plate to iodine vapor in a closed chamber for 15 minutes, and locate the spots on the plate: any spot obtained from *Test solution A*, other than that of levamisole, does not exceed, in size or intensity, the principal spot obtained from *Standard solution B*, corresponding to not more than 0.5% of any individual impurity.

Assay—

Solution A—Prepare a 0.75% solution of monobasic ammonium phosphate in water, and adjust with diisopropylamine to a pH of 7.

Solution B—Use acetonitrile.

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Transfer about 20 mg of USP Levamisole Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, add 10 mL of water, and swirl to dissolve. Dilute with methanol to volume, and mix to obtain a solution having a known concentration of about 0.2 mg

of USP Levamisole Hydrochloride RS per mL.

Resolution solution—Dissolve 20 mg of Levamisole Hydrochloride in 5 mL of 0.1 N sodium hydroxide, and heat at 100° in a closed vial for 5 hours. Allow to cool, and dilute 1 mL of the solution to 25 mL with methanol.

Assay preparation—Transfer an accurately counted number of Tablets, equivalent to about 150 mg of levamisole ($C_{11}H_{12}N_2S$), to a 100-mL volumetric flask. Add 25 mL of water, and shake by mechanical means for 30 minutes. Dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see Chromatography ⟨621⟩)—The liquid chromatograph is equipped with a 215-nm detector and a 4.6-mm × 10-cm column that contains 3-µm packing L1. The flow rate is about 2 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
0–5	80→20	20→80	linear gradient
5–7	20	80	isocratic
7–8	20→80	80→20	linear gradient
8–12	80	20	isocratic

Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are 1.0 for levamisole and about 1.3 for the major degradation product; and the resolution, *R,* between levamisole and the major degradation product is not less than 6.0. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the capacity factor, *k*', is not less than 3.0; the tailing factor is not more than 1.8; and the relative standard deviation for replicate injections 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 areas for the major peaks. Calculate the quantity, in mg, of levamisole ($C_{11}H_{12}N_2S$) in the Tablets taken by the formula:

$$(204.29/240.75)(1000C)(r_U/r_S)$$

in which 204.29 and 240.75 are the molecular weights of levamisole and levamisole hydrochloride, respectively; *C* is the concentration, in mg per mL, of USP Levamisole Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the levamisole 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
LEVAMISOLE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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

Current DocID: GUID-79166FEC-AA52-4822-8640-99DF17F46475_1_en-US
DOI: https://doi.org/10.31003/USPNF_M44625_01_01
DOI ref: y1u25