

Status: Currently Official on 15-Feb-2025  
Official Date: Official as of 01-May-2018  
Document Type: USP Monographs  
DocId: GUID-2012FA7F-31AE-49B2-8B22-682034B539E7\_3\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M40060\\_03\\_01](https://doi.org/10.31003/USPNF_M40060_03_01)  
DOI Ref: g09ss

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# Imipramine Hydrochloride Injection

» Imipramine Hydrochloride Injection is a sterile solution of Imipramine Hydrochloride in Water for Injection. It contains, in each mL, not less than 11.5 mg and not more than 13.5 mg of  $C_{19}H_{24}N_2 \cdot HCl$ .

**Packaging and storage**—Preserve in single-dose containers, preferably of Type I glass.

**USP REFERENCE STANDARDS (11)**—

[USP Imipramine Hydrochloride RS](#)

**Identification**—Transfer 10 mL of Injection to a separator, add 2 mL of 2 N hydrochloric acid, extract with 10 mL of chloroform, filter, and evaporate the chloroform solution to about 2 mL. Carefully add ether until the liquid becomes turbid, heat on a steam bath to produce a clear solution, then cool, and allow to stand. Filter the crystalline precipitate, wash with ether, and dry in vacuum at 105° for 30 minutes: the precipitate so obtained responds to [Identification](#) test [A](#) under [Imipramine Hydrochloride](#).

**BACTERIAL ENDOTOXINS TEST (85)**—It contains not more than 5.0 USP Endotoxin Units per mg of imipramine hydrochloride.

**pH (791)**: between 4.0 and 5.0.

**Other requirements**—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

**Assay**—Transfer an accurately measured volume of Injection, equivalent to about 25 mg of imipramine hydrochloride, to a 100-mL volumetric flask, add 0.5 N hydrochloric acid to volume, and mix. Pipet 10 mL of this solution into a separator, add 10 mL of 1 N sodium hydroxide, and extract with four 20-mL portions of ether, shaking each portion for 2 minutes and collecting the extracts in a second separator. Extract the combined ether extracts with four 20-mL portions of 0.5 N hydrochloric acid, and combine the extracts in a 250-mL beaker. Aerate this solution with nitrogen to remove residual ether, then transfer to a 100-mL volumetric flask, and rinse the beaker with 0.5 N hydrochloric acid, collecting the rinsings in the flask. Add the 0.5 N acid to volume, and mix. Dissolve an accurately weighed quantity of [USP Imipramine Hydrochloride RS](#) in 0.5 N hydrochloric acid, and dilute quantitatively and stepwise with the same solvent to obtain a Standard solution having a known concentration of about 25 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 250 nm, with a suitable spectrophotometer, using 0.5 N hydrochloric acid as the blank. Calculate the quantity, in mg, of  $C_{19}H_{24}N_2 \cdot HCl$  in each mL of the Injection taken by the formula:

$$(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of [USP Imipramine Hydrochloride RS](#) in the Standard solution; V is the volume, in mL, of Injection taken; and  $A_U$  and  $A_S$  are the absorbances of the solution from the Injection and the Standard solution, respectively.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
IMIPRAMINE HYDROCHLORIDE INJECTION	<a href="#">Documentary Standards Support</a>	SM42020 Small Molecules 4

**Chromatographic Database Information:** [Chromatographic Database](#)

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

**Current DocID:** [GUID-2012FA7F-31AE-49B2-8B22-682034B539E7\\_3\\_en-US](#)  
**Previous DocID:** [GUID-2012FA7F-31AE-49B2-8B22-682034B539E7\\_1\\_en-US](#)  
**DOI:** [https://doi.org/10.31003/USPNF\\_M40060\\_03\\_01](https://doi.org/10.31003/USPNF_M40060_03_01)  
**DOI ref:** [g09ss](#)