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Phentolamine Mesylate for Injection

» Phentolamine Mesylate for Injection is sterile Phentolamine Mesylate or a sterile mixture of Phentolamine Mesylate with a suitable buffer or suitable diluents. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{17}H_{19}N_3O \cdot CH_4O_3S$.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Phentolamine Mesylate RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Identification—Mix a portion of it, equivalent to about 40 mg of phentolamine mesylate, with about 15 mL of chloroform. Filter into a beaker, and evaporate to dryness, taking precautions against introducing moisture: the residue so obtained responds to *Identification* test *A* under *Phentolamine Mesylate.*

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 5.8 USP Endotoxin Units per mg of phentolamine mesylate.

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

Procedure for content uniformity—Dissolve the contents of 1 container in water to provide a solution containing about 20 µg of phentolamine mesylate per mL. Concomitantly determine the absorbances of this solution and of a solution of USP Phentolamine Mesylate RS, in the same medium, at a concentration of about 20 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 278 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of $C_{17}H_{19}N_3O \cdot CH_4O_3S$ in the Phentolamine Mesylate for Injection taken by the formula:

$$(T/D)C(A_U/A_S)$$

in which T is the labeled quantity, in mg, of phentolamine mesylate in the Phentolamine Mesylate for Injection, D is the concentration, in µg per mL, of phentolamine mesylate in the solution from the Phentolamine Mesylate for Injection, based on the labeled quantity per container and the extent of dilution, C is the concentration, in µg per mL, of USP Phentolamine Mesylate RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Phentolamine Mesylate for Injection and the Standard solution, respectively.

pH ⟨791⟩: between 4.5 and 6.5, in a freshly prepared solution having a concentration of about 1 in 100.

Other requirements—It meets the requirements for *Sterility Tests ⟨71⟩* and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

Standard preparation—Transfer about 25 mg of USP Phentolamine Mesylate RS, accurately weighed, to a 50-mL volumetric flask, add water to volume, and mix.

Assay preparation—Dissolve the contents of 10 containers of Phentolamine Mesylate for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Transfer an aliquot, equivalent to about 25 mg of phentolamine mesylate, to a 50-mL volumetric flask, add water to volume, and mix.

Procedure—Pipet 5-mL portions, respectively, of the *Standard preparation*, *Assay preparation*, and water to provide a blank, into separate 125-mL separators. Into each separator pipet 5-mL portions of 0.1 N hydrochloric acid and saturated picric acid solution. Extract with three 25-mL portions of chloroform, filtering each portion through chloroform-washed cotton into a 100-mL volumetric flask. Dilute with chloroform to volume, and mix. Concomitantly determine the absorbances of the solutions from the *Assay preparation* and the *Standard preparation* in 1-cm cells at the wavelength of maximum absorbance at about 410 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{17}H_{19}N_3O \cdot CH_4O_3S$ in the aliquot of Phentolamine Mesylate for Injection taken by the formula:

$$50C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of USP Phentolamine Mesylate RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions 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
PHENTOLAMINE MESYLATE FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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