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Papaverine Hydrochloride Injection

» Papaverine Hydrochloride Injection is a sterile solution of Papaverine Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{20}H_{21}NO_4 \cdot HCl$.

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

USP Reference standards ⟨11⟩—
USP Papaverine Hydrochloride RS

Identification—

A: Add 2 mL of alcohol to 1 mL of Injection, and evaporate on a steam bath, with the aid of a stream of nitrogen, to dryness. Dry the residue at 105° for 2 hours: it responds to *Identification* test *A* under *Papaverine Hydrochloride*.

B: It responds to *Identification* test *C* under *Papaverine Hydrochloride*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 2.9 USP Endotoxin Units per mg of papaverine hydrochloride.

pH ⟨791⟩: not less than 3.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—Transfer 1.0 mL of Injection to a 200-mL volumetric flask, and dilute with water to volume. Pipet 3 mL of this solution into a separator, add 10 mL of water, and render alkaline with 6 N ammonium hydroxide. Extract the alkaloid with successive 5-mL portions of chloroform, and evaporate the extracts to dryness. Dissolve the residue in 0.1 N hydrochloric acid, and dilute with the same medium to 100.0 mL. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Papaverine Hydrochloride RS in 0.1 N hydrochloric acid having a known concentration of about 4.5 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 251 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_{20}H_{21}NO_4 \cdot HCl$ in the portion of Injection taken by the formula:

$$6.67C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Papaverine Hydrochloride RS in the Standard solution, 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
PAPAVERINE HYDROCHLORIDE 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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