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Nalorphine Hydrochloride Injection

» Nalorphine Hydrochloride Injection is a suitably buffered, sterile solution of Nalorphine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of nalorphine hydrochloride ($C_{19}H_{21}NO_3 \cdot HCl$).

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

USP Reference standards ⟨11⟩—
USP Nalorphine Hydrochloride RS

Identification—Apply 15 µL of Injection and 15 µL of a Standard solution of USP Nalorphine Hydrochloride RS in methanol containing 5 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the applications to dry, and develop the chromatogram in an equilibrated chamber containing methanol until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Observe the plate under short- and long-wavelength UV light: the R_F value of the principal spot obtained from the Injection corresponds to that obtained from the Standard solution.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 11.6 USP Endotoxin Units per mg of nalorphine hydrochloride.

pH ⟨791⟩: between 6.0 and 7.5.

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

Assay—Transfer an accurately measured volume of Injection, equivalent to about 10 mg of nalorphine hydrochloride, to a 25-mL centrifuge separator, add 1 mL of 3 N hydrochloric acid, and dilute with water to about 10 mL. Extract with five 5-mL portions of chloroform, separating the layers by centrifugation before drawing off each chloroform extract, and discard the chloroform extracts. Transfer the aqueous layer to a 100-mL volumetric flask with the aid of water, dilute with water to volume, and mix. Proceed as directed in the *Assay* under *Nalorphine Hydrochloride*, beginning with "Concomitantly determine the absorbances." Calculate the quantity, in mg, of $C_{19}H_{21}NO_3 \cdot HCl$ in each mL of the Injection taken by the formula:

$$(0.1C/V)(A_U/A_S)$$

in which V is the volume, in mL, of Injection taken, and C, A_U, and A_S are as defined therein.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NALORPHINE 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

Most Recently Appeared In:
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