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Hydromorphone Hydrochloride Injection

» Hydromorphone Hydrochloride Injection is a sterile solution of Hydromorphone 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 hydromorphone hydrochloride ($C_{17}H_{19}NO_3 \cdot HCl$).

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

USP Reference standards ⟨11⟩—
USP Hydromorphone Hydrochloride RS

Identification—Place a volume of Injection, equivalent to about 10 mg of hydromorphone hydrochloride, in a separator. Extract with four 10-mL portions of chloroform, and discard the extracts. Add 1 mL of sodium carbonate TS, and extract with three 10-mL portions of chloroform. Filter the chloroform extracts into a glass-stoppered, 50-mL flask, and evaporate on a steam bath with the aid of a current of air to dryness. Dissolve the residue in 1 mL of chloroform: the IR absorption spectrum of the solution so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Hydromorphone Hydrochloride RS.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 88.0 USP Endotoxin Units per mg of hydromorphone hydrochloride.

pH ⟨791⟩: between 3.5 and 5.5.

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

Assay—

Standard preparation—Using an accurately weighed quantity of USP Hydromorphone Hydrochloride RS, prepare a solution in water having a known concentration of about 0.2 mg per mL.

Assay preparation—Quantitatively dilute an accurately measured volume of Injection, if necessary, with water to obtain a solution containing about 0.2 mg per mL.

Procedure—Transfer 20.0 mL each of the *Standard preparation* and the *Assay preparation* to separate 50-mL volumetric flasks. To each flask add, with mixing, 1.0 mL of hydrochloric acid and 1.0 mL of sodium nitrite solution (1 in 20). Insert the stoppers, allow to stand for 40 to 45 minutes, with occasional swirling, then add 2 mL of ammonium hydroxide, and mix. Allow to stand for 2 minutes, then dilute with water to volume, and mix. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 440 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of hydromorphone hydrochloride ($C_{17}H_{19}NO_3 \cdot HCl$) in each mL of the Injection taken by the formula:

$$(V_A/V_I)(C)(A_U/A_S)$$

in which V_A is the volume, in mL, of the *Assay preparation*; V_I is the volume, in mL, of Injection taken to prepare the *Assay preparation*; C is the concentration, in mg per mL, of USP Hydromorphone Hydrochloride 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
HYDROMORPHONE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

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