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Hydromorphone Hydrochloride Tablets

» Hydromorphone Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydromorphone hydrochloride ($C_{17}H_{19}NO_3 \cdot HCl$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Hydromorphone Hydrochloride RS
USP Morphine Sulfate RS

Identification—Place a quantity of finely powdered Tablets, equivalent to about 10 mg of hydromorphone hydrochloride, in a separator, and proceed as directed in the *Identification* test under *Hydromorphone Hydrochloride Injection*, beginning with "Extract with four 10-mL portions of chloroform".

Dissolution ⟨711⟩—
Medium: water; 500 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.
Determine the amount of $C_{17}H_{19}NO_3 \cdot HCl$ dissolved by employing the following method.

Buffer solution, *Mobile phase*, and *System suitability solution*—Proceed as directed in the *Assay*.

Test solution—Withdraw a 15-mL portion of the solution under test, filter, and discard the first few mL of the filtrate.

Standard solution—Dissolve an accurately weighed quantity of USP Hydromorphone Hydrochloride RS in water at a concentration similar to that of the *Test solution*.

Chromatographic system—Proceed as directed in the *Assay*, except to inject the *Standard solution* instead of the *Standard preparation* to obtain the relative standard deviation for replicate injections of not more than 5.0%.

Procedure—Proceed as directed in the *Assay*, except to use an injection volume of about 200 µL.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{17}H_{19}NO_3 \cdot HCl$ is dissolved in 45 minutes.

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

Assay—
Buffer solution—Dissolve 10 g of sodium dodecyl sulfate and 20 mL of glacial acetic acid in 1.2 liters of water, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Buffer solution* and acetonitrile (33:17). Make adjustments if necessary.

System suitability solution—Dissolve suitable quantities of USP Morphine Sulfate RS and USP Hydromorphone Hydrochloride RS in water to obtain a solution containing about 30 and 40 µg of each per mL, respectively.

Standard preparation—Dissolve an accurately weighed quantity of USP Hydromorphone Hydrochloride RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 40 µg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer a portion of the powder, equivalent to about 4 mg of hydromorphone hydrochloride, to a 100-mL volumetric flask, dissolve in and dilute with water to volume, sonicate if necessary, and mix. Filter a portion of the solution using a glass fiber filter, and discard the first 5 mL.

Chromatographic system (see Chromatography ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 15-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between morphine and hydromorphone is not less than 2.0. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor for the hydromorphone hydrochloride peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 100 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of hydromorphone hydrochloride

($C_{17}H_{19}NO_3 \cdot HCl$) in the portion of Tablets taken by the formula:

$$0.1C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Hydromorphone Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained 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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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