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Loperamide Hydrochloride Capsules

» Loperamide Hydrochloride Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of loperamide hydrochloride ($C_{29}H_{33}ClN_2O_2 \cdot HCl$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Loperamide Hydrochloride RS

Identification—

A: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Test solution—Transfer a quantity of the contents of the Capsules, equivalent to about 10 mg of loperamide hydrochloride, to a 37-mL stoppered vial, add 10 mL of methanol, shake for 5 minutes, and filter.

Standard solution: a solution of USP Loperamide Hydrochloride RS in methanol containing about 10 mg per mL.

Application volume: 10 µL of the *Test solution* and 1 µL of the *Standard solution*.

Developing solvent system: a mixture of chloroform, methanol, and formic acid (85:10:5).

Procedure—Proceed as directed in the chapter. Visualize the spots by exposing to iodine vapors.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Dissolution ⟨711⟩—

Medium: pH 4.7 acetate buffer, prepared by mixing 200 mL of 1 N acetic acid with 600 mL of water, adjusting with 1 N sodium hydroxide to a pH of 4.70 ± 0.05, diluting with water to 1000 mL, and mixing; 500 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Determine the amount of loperamide hydrochloride dissolved using the following method.

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay*.

Procedure—Inject a volume (about 50 µL) of a filtered portion of the solution under test into the chromatograph, record the chromatogram, and measure the response for the major peak. Calculate the quantity of $C_{29}H_{33}ClN_2O_2 \cdot HCl$ dissolved in comparison with a Standard solution having a known concentration of USP Loperamide Hydrochloride RS in the same medium and similarly chromatographed.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{29}H_{33}ClN_2O_2 \cdot HCl$ is dissolved in 30 minutes.

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

Assay—

Mobile phase—Transfer 500 mL of acetonitrile to a 1000-mL volumetric flask. Dilute with water to volume, add 20 drops of phosphoric acid, mix, and filter. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Loperamide Hydrochloride RS in a mixture of acetonitrile and 0.5 N hydrochloric acid (1:1) to obtain a solution having a known concentration of about 0.2 mg per mL. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with a mixture of acetonitrile and water (1:1) to volume, and mix to obtain a solution having a known concentration of about 10 µg per mL.

Assay preparation—Transfer, as completely as possible, the contents of not less than 20 Capsules to a suitable tared container, and determine the average weight per capsule. Mix the combined contents, and transfer an accurately weighed portion of the powder, equivalent to about 20 mg of loperamide hydrochloride, to a 100-mL volumetric flask. Add about 35 mL of 0.5 N hydrochloric acid and sonicate for 15 minutes. Add 35 mL of acetonitrile and sonicate for an additional 15 minutes. Dilute with a mixture of acetonitrile and 0.5 N hydrochloric acid (1:1) to volume, mix, and filter. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with a mixture of acetonitrile and water (1:1) to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm × 25-cm column that contains 10-µm packing L10. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the

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peak responses as directed under *Procedure:* the column efficiency, N, determined from the analyte peak is not less than 1900 theoretical plates, the capacity factor, *K′*, is not less than 3.5, and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 50 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 $C_{29}H_{33}ClN_2O_2 \cdot HCl$ in the portion of Capsules taken by the formula:

$$2000C(r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Loperamide 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
LOPERAMIDE HYDROCHLORIDE CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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