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Flurazepam Hydrochloride Capsules

» Flurazepam Hydrochloride Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of flurazepam hydrochloride ($C_{21}H_{23}ClFN_3O \cdot 2HCl$).

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

USP Reference standards ⟨11⟩—
USP Flurazepam Hydrochloride RS

Identification—

A: Dissolve a portion of Capsules, equivalent to about 30 mg of flurazepam hydrochloride, in 10 mL of methanol, filter, and proceed as directed for *Identification* test *C* under *Flurazepam Hydrochloride*.

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

C: Capsules meet the requirements under *Identification—Organic Nitrogenous Bases* ⟨181⟩.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 20 minutes.

Standard solution—Prepare a solution of USP Flurazepam Hydrochloride RS having an accurately known concentration similar to the concentration of the solution under test. Pipet 5 mL of this solution to a 10-mL volumetric flask, and dilute with 1% ammonium acetate to volume.

Test solution—Pipet 5 mL of a filtered portion of the solution under test into a 10-mL volumetric flask, and dilute with 1% ammonium acetate to volume.

Procedure—Determine the amount of $C_{21}H_{23}ClFN_3O \cdot 2HCl$ dissolved, using the *Chromatographic system* as set forth in the *Related compounds* test under *Flurazepam Hydrochloride*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{21}H_{23}ClFN_3O \cdot 2HCl$ is dissolved in 20 minutes.

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

Assay—

Mobile phase, System suitability solution, and Chromatographic system—Prepare as directed for *Related compounds* under *Flurazepam Hydrochloride*.

Standard preparation—Dissolve an accurately weighed quantity of USP Flurazepam Hydrochloride RS in methanol, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.15 mg per mL. Prepare fresh daily.

Assay preparation—[Note—Prepare fresh daily.] Weigh and mix the contents of not fewer than 20 Capsules. Transfer an accurately weighed portion of the Capsule contents, equivalent to about 30 mg of flurazepam hydrochloride, to a 200-mL volumetric flask. Add 40 mL of methanol, and shake by mechanical means for 10 minutes. Add 10 mL of 1% ammonium acetate, and shake by mechanical means for 5 minutes. Dilute with *Mobile phase* to volume, mix and sonicate for 2 minutes, and filter.

Procedure—Separately inject equal volumes (about 20 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 flurazepam hydrochloride ($C_{21}H_{23}ClFN_3O \cdot 2HCl$) in the portion of Capsules taken by the formula:

$$200C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Flurazepam 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
FLURAZEPAM HYDROCHLORIDE CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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