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Flavoxate Hydrochloride Tablets

» Flavoxate Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of $C_{24}H_{25}NO_4 \cdot HCl$, based on the label claim.

Packaging and storage—Preserve in well-closed containers, protected from light.

USP REFERENCE STANDARDS (11)—

[USP Flavoxate Hydrochloride RS](#)

[USP Flavoxate Related Compound A RS](#)

3-Methylflavone-8-carboxylic acid.



Identification—

A: [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#)—

Test specimen—Grind at least 4 Tablets into a fine powder. Use an amount of powder equivalent to about 100 mg of flavoxate hydrochloride. Add 30 mL of methanol, and stir for about 10 minutes. Pass through a Whatman #1 filter paper, and collect the filtrate. Evaporate the methanol to dryness on a steam bath with the help of nitrogen gas. Dry the residue in vacuum at 60° for about 30 minutes. Mix 1 to 2 mg of dried residue with 200 mg of potassium bromide, and grind thoroughly for 10 to 15 minutes.

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

DISSOLUTION (711)—

Medium: 0.1 N hydrochloric acid; 900 mL, deaerated.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Standard solution—Transfer an accurately weighed quantity of [USP Flavoxate Hydrochloride RS](#) to a suitable volumetric flask, dissolve in a small amount of methanol (not more than 2% of the final volume), and dilute with *Medium* to volume to obtain a solution having a known concentration of about 0.11 mg per mL.

Test solution—Pass a portion of the solution under test through a suitable filter having a porosity of 45 µm.

Procedure—Determine the amount of $C_{24}H_{25}NO_4 \cdot HCl$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 294 nm, in portions of the *Test solution* in comparison with the *Standard solution*, using a cell with a path length of 0.2 cm and using *Medium* as the blank. Calculate the percentage of $C_{24}H_{25}NO_4 \cdot HCl$ dissolved by the formula:

$$\frac{A_U \times C_S \times 900 \times 100}{A_S \times L}$$

in which A_U and A_S are the absorbances obtained from the *Test solution* and the *Standard solution*, respectively; C_S is the concentration, in mg per mL, of the *Standard solution*; 900 is the volume, in mL, of *Medium*; 100 is the conversion factor to percentage; and L is the Tablet label claim, in mg.

Tolerances—Not less than 70% (Q) of the labeled amount of $C_{24}H_{25}NO_4 \cdot HCl$ is dissolved in 30 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Related compounds—

Mobile phase—Prepare as directed in the Assay.

Standard stock solution—Dissolve an accurately weighed quantity of [USP Flavoxate Hydrochloride RS](#) in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL.

[USP FLAVOXATE RELATED COMPOUND A RS](#) *stock solution*—Dissolve an accurately weighed quantity of [USP Flavoxate Related Compound A RS](#) in acetonitrile to obtain a solution having a known concentration of about 0.3 mg per mL.

Standard solution—Quantitatively dilute suitable volumes of *Standard stock solution* and [USP Flavoxate Related Compound A RS](#) *stock solution* with *Mobile phase* to obtain a solution having a final known concentration of about 0.001 mg per mL of flavoxate hydrochloride and about 0.003 mg per mL of flavoxate related compound A.

Test solution—Filter the *Assay stock preparation*, prepared as directed in the Assay, through a 0.45-µm filter (polyvinylidene fluoride [PVDF] or equivalent). Use the filtrate.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—Prepare as directed in the Assay. Chromatograph the *Standard solution*, and record the peak areas as directed for *Procedure*: the resolution, R , between flavoxate hydrochloride and flavoxate hydrochloride related compound A is

not less than 10.0; the column efficiency is not less than 3000 plate counts; the tailing factor is not more than 2.0 for flavoxate hydrochloride; and the relative standard deviation for five replicate injections is not more than 2.0% for both peaks.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, and record the chromatograms. Measure the peak areas of all the peaks in the *Test solution*. Identify the peaks using the relative retention times as given in [Table 1](#).

Table 1

Component Name	Relative Retention Time	Relative Response Factor	Limit (%)
Flavoxate hydrochloride	1.0	—	—
Flavoxate related compound A [*]	2.5	1.5	0.3
Any individual unspecified degradation product	—	1.0	0.1
Total impurities	—	—	1.0

^{*} 3-Methylflavone-8-carboxylic acid.

Calculate the percentage of each impurity relative to flavoxate hydrochloride in the portion of Tablets taken by the formula:

$$100(C_s/C_u)(r_i/r_s)(1/F)$$

in which C_s is the concentration, in mg per mL, of flavoxate hydrochloride in the *Standard solution*; C_u is the nominal concentration, in mg per mL, of flavoxate hydrochloride, based on label claim, in the *Test solution*; r_i is the peak response of each individual impurity; r_s is the response of the flavoxate hydrochloride peak obtained from the *Standard solution*; and F is the relative response factor for each of the impurities relative to flavoxate hydrochloride, as shown in [Table 1](#).

Assay—

Mobile phase—Dissolve 1.0 g of sodium hexanesulfonate, 1.0 mL of triethylamine, and 1.0 mL of phosphoric acid in 650 mL of water. Filter and degas. To the filtrate, add 350 mL of acetonitrile. Mix well. Make adjustments if necessary (see *System Suitability* under [Chromatography \(621\)](#)).

Standard preparation—Dissolve an accurately weighed quantity of [USP Flavoxate Hydrochloride RS](#), and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.05 mg per mL.

Assay stock preparation—Weigh and finely powder not fewer than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 100 mg of flavoxate hydrochloride based on label claim, and transfer to a 100-mL volumetric flask. Add about 80% volume of *Mobile phase*. Sonicate for 10 minutes, and stir for 15 minutes. Dilute with *Mobile phase* to volume.

Assay preparation—Dilute the *Assay stock preparation* quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution with a nominal concentration of about 0.05 mg per mL of flavoxate hydrochloride, based on label claim. Filter the solution through a 0.45-µm filter (polyvinylidene fluoride [PVDF] or equivalent). Use the filtrate.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—The liquid chromatograph is equipped with a 293-nm detector and a 4.6-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the column efficiency is not less than 3000; the tailing factor is not more than 2.0; and the relative standard deviation for five replicate injections is not more than 2.0%.

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 flavoxate hydrochloride peak whose retention time is about 4.0 minutes. Calculate the percentage of the label claim of flavoxate hydrochloride ($C_{24}H_{25}NO_4 \cdot HCl$) in the portion of the Tablets taken by the formula:

$$100(C_s/C_u)(r_u/r_s)$$

in which C_s is the concentration, in mg per mL, of flavoxate hydrochloride in the *Standard preparation*; C_u is the nominal concentration of flavoxate hydrochloride in the *Assay preparation*, based on the label claim; 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
FLAVOXATE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM42.20 Small Molecules 4