Test solution—Transfer about 38 mg of Betahistine Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Procedure—Inject about 10 µL of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the per centage of each impurity in the portion of Betahistine Hydrochloride taken by the formula:

$$100F(r_i / r_s)$$

in which F is the response factor of the respective impurity (see *Table 1*) and 1.0 for all other peaks; r_i is the peak response for each impurity; and r_s is the sum of the responses of all of the peaks, adjusted for the relative response factor.

Table 1

Impurity Name	Relative Retention Time	Response Factor (F)	Limit (%)
2-(2-Hydroxy-ethyl)pyridine	0.3	0.5	0.2
2-Vinylpyridine	0.4	0.4	0.2
N-Methyl-*N*,*N*-bis(2-pyridin-2-yl-ethyl)-amine	2.4	1.4	0.2

In addition to not exceeding the limits for impurities in *Table 1,* not more than 0.1% of any other individual impurity is found; and not more than 0.5 % of total impurities is found.

Assay—

Ammonium acetate buffer—Dissolve about 0.69 g of ammonium acetate in 1000 mL of water. Adjust with glacial acetic acid to a pH of 4.7.

Mobile phase—Prepare a filtered and degassed mixture of 350 mL of acetonitrile and 650 mL of *Ammonium acetate buffer,* containing 2.88 g of sodium laur yl sulfate. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Betahistine Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 0.38 mg per mL.

Assay preparation—Transfer about 38 mg of Betahistine Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

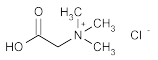
Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and 3.0-mm × 15-cm column that contains packing L1. The column temperature is maintained at 40 °. The flow rate is about 0.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 5000 theoretical plates; the tailing factor for the betahistine peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 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 $C_8H_{12}N_2 \cdot 2HCl$ in the portion of Betahistine Hydrochloride taken by the formula:

$$100C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Betahistine 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.

Betaine Hydrochloride



$C_5H_{11}NO_2 \cdot HCl$ 153.61
Methanaminium, 1-carboxy-*N*, *N*, *N*-trimethyl-, chloride.
Betaine hydrochloride.
(Carboxymethyl)trimethylammonium chloride [590-46-5].

» Betaine Hydrochloride contains not less than 98.0 percent and not more than 100.5 per cent of $C_5H_{11}NO_2 \cdot HCl$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Betaine Hydrochloride RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: A solution (1 in 20) responds to the tests for *Chloride* ⟨191⟩.

pH ⟨791⟩: between 0.8 and 1.2, in a solution (1 in 4).

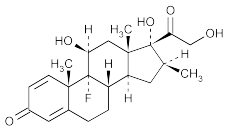
Water, *Method I* ⟨921⟩: not more than 0.5%.

Residue on ignition ⟨281⟩: not more than 0.1%.

Heavy metals ⟨231⟩: 0.001%.

Assay— Transfer about 400 mg of Betaine Hydrochloride, accurately weighed, to a conical flask, add 50 mL of glacial acetic acid, and heat gently with swirling until solution is complete. Add 25 mL of mer curic acetate TS, cool, add 2 drops of cr ystal violet TS, and titrate with 0.1 N per chloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N per chloric acid is equivalent to 15.36 mg of $C_5H_{11}NO_2 \cdot HCl$.

Betamethasone



$C_{22}H_{29}FO_5$ 392.46
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16β)-.
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione [378-44-9].

» Betamethasone contains not less than 97.0 percent and not more than 103.0 per cent of $C_{22}H_{29}FO_5$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers. Store between 2° and 30°.

USP Reference standards ⟨11⟩**—**
USP Betamethasone RS

Identification—

A: *Infrared Absorption* ⟨197M⟩.

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

Test solution—Prepare a solution of Betamethasone in dehydrated alcohol containing 0.5 mg per mL.

Developing solvent system: a mixture of chloroform and diethylamine (2:1).