Table 3 *(Continued)*

Compound	Relative Retention Time	Acceptance Criteria, NMT (%)
Any other individual unspecified impurity	—	0.2
Total impurities	—	1.5[b]

[a] 2,2′-Oxybis(methylene)bis{4-[2-(*tert*-butylamino)-1-hydroxyethyl]phenol}.
[b] From the sum of the impurities in *Procedure 1* and *Procedure 2*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Albuterol Sulfate RS
  USP Albuterol Related Compound B RS
  2-(*tert*-Butylamino)-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanone.
  $C_{13}H_{19}NO_3$ 237.29
  USP Albuterol Related Compound E RS
  2,2′-Oxybis(methylene)bis{4-[2-(*tert*-butylamino)-1-hydroxyethyl]phenol}.
  $C_{26}H_{40}N_2O_5$ 460.61
  USP Levalbuterol Related Compound C RS
  α-[{(1,1-Dimethylethyl)amino}methyl]-4-hydroxy-3-(methoxymethyl)-benzenemethanol.
  $C_{14}H_{23}NO_3$ 253.34
  USP Levalbuterol Related Compound D RS
  5-[2-{(1,1-Dimethylethyl)amino}-1-hydroxyethyl]-2-hydroxy-benzaldehyde sulfate salt.
  $(C_{13}H_{19}NO_3)_2 \cdot H_2SO_4$ 572.67

USP Monographs

Albuterol Sulfate

$(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$ 576.70
1,3-Benzenedimethanol, α¹-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-, sulfate (2:1) (salt).
α¹-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α′-diol sulfate (2:1) (salt) [51022-70-9].

» Albuterol Sulfate contains not less than 98.5 percent and not more than 101.0 percent of $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$, calculated on the anhydrous basis.

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

USP Reference standards ⟨11⟩—
USP Albuterol Related Compound A RS
4-[2-[(1,1-Dimethylethyl)amino]-1-hydroxyethyl]-2-methylphenol sulfate.
USP Albuterol Sulfate RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 80 µg per mL.

Medium: 0.1 N hydrochloric acid.

C: Shake a quantity of it, equivalent to 4 mg of albuterol, with 10 mL of water, and filter: the filtrate so obtained meets the requirements of the tests for *Sulfate* ⟨191⟩.

D: 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.*

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

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

Chromatographic purity—It meets the requirements of the test for *Organic Impurities* under *Albuterol,* except to read Albuterol Sulfate in place of Albuterol and to use water instead of methanol as the solvent to prepare the *Standard solution* and the *Sample solution.*

Assay—

0.05 ± 0.01 M Ammonium acetate solution—Dissolve 3.85 g of ammonium acetate in 1000 mL of water, and mix.

Mobile phase—Prepare a degassed mixture of water, *0.05 ± 0.01 M Ammonium acetate solution,* and isopropanol [65:30:(5 ± 1)], and adjust dropwise with acetic acid to a pH of 4.5 ± 0.3.

Resolution solution—Dissolve accurately weighed quantities of USP Albuterol Sulfate RS and USP Albuterol Related Compound A RS in water, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.140 mg per mL and 0.030 mg per mL, respectively.

Standard preparation—Dissolve an accurately weighed quantity of USP Albuterol Sulfate RS in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 0.6 mg per mL.

Assay preparation—Transfer about 60 mg of Albuterol Sulfate, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

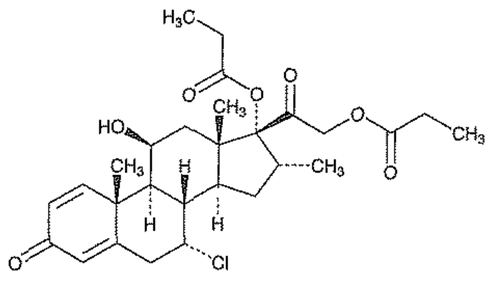
Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 276-nm detector and a 4.6-mm × 20-cm column that contains packing L10. The flow rate is about 2.0 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between albuterol and albuterol related compound A is not less than 1.5; and the relative standard deviation for replicate injections is not more than 1.5%.

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 $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$ in the portion of Albuterol Sulfate taken by the formula:

$$100C(r_U / r_S)$$

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

Alclometasone Dipropionate



$C_{28}H_{37}ClO_7$ 521.04
Pregna-1,4-diene-3,20-dione, 7-chloro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-, (7α,11β,16α)-;
7α-Chloro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate [66734-13-2].

DEFINITION

Alclometasone Dipropionate contains NLT 97.0% and NMT 102.0% of $C_{28}H_{37}ClO_7$, calculated on the dried basis.