(1)-Ephedrine Hydrochloride USP

Molecular Formula: \( \text{C}_{10}\text{H}_{15}\text{NO} \cdot \text{HCl} \)

Molecular weight: 201.69

CAS No.: [50-98-6]

Chemical Name:
1. Benzenemethanol, \( \alpha \)-[1-(methylamino)ethyl]-, hydrochloride [R-(R*,S*)], salt
2. (1R,2S)-2-Methylamino-1-phenyl propan-1-ol Hydrochloride

Specifications:
1. Description: Colourless crystals or white crystalline powder
2. Identification: a) Infrared spectrum of sample is concordant with the reference spectrum.
   b) A solution of sample respond to the test for chloride
3. Solubility: Freely soluble in water and soluble in alcohol
4. Melting range: Between 217° and 220°C; the range between beginning and end of melting does not exceed 2°C
5. Specific rotation: Between -33.0° and -35.5° (5% solution in water)
6. Acidity & alkalinity: NMT 0.10 ml of 0.02 N \( \text{H}_2\text{SO}_4 \) or NMT 0.20 ml of 0.02 N \( \text{NaOH} \) solution
7. Sulfate: Must pass the test. No turbidity develops within 10 min.
8. Ordinary impurities: NMT 2.0 %
9. Residue on ignition: NMT 0.1 %
10. Loss on drying: NMT 0.5 %
11. Organic volatile impurities: Must pass the test
12. Assay: Between 98.0 % and 100.5 % (dried basis)

Therapeutic indications: Bronchodilator

Packing: Packed in double lined polyethylene bags in 25 kg fiber drums.

Storage: Store below 35°C.