Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical Profile of Salbutamol and Bromhexine HCl Syrup

Analytical Profile No.: Salb Brom 076/077/AP 064

Salbutamol and Bromhexine HCl Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Salbutamol and Bromhexine HCl.

1. Identification:

1.1 Salbutamol: To 5 ml of syrup add 50 ml of a 2 % w/v solution of borax, 1ml of a 3 % w/v solution of 4-aminophenazone, 10 ml of a 2 % w/v solution of potassium ferricyanide and 10 ml of chloroform. Shake and allow to separate; an orange-red color is produced in the chloroform layer.

1.2 Bromhexine Hydrochloride: Compare the spectra of both the color solution observed in assay, it shows maximum absorbance at about 525 nm.

2. pH: As per manufacturer's specification

3. wt/ml: As per manufacturer's specification

4. Assay:

4.1 Salbutamol

4.1.1 Test solution:

Weigh accurately sample equivalent to 4 mg of Salbutamol (10 ml of sample) in a 250 ml separating funnel, add 25 ml of 0.05 M sulphuric acid and extract with two quantities, each of 50 ml, of diethyl ether. Collect the aqueous layers into a 250 ml volumetric flask and combine the ether extracts. Wash the combined ether extracts with 50 ml of water and add the aqueous layer to the solution in 250 ml volumetric flask. Discard the ether extracts and dilute the aqueous solution with sufficient water to produce 250 ml.

4.1.2 Reference solution:

Weigh accurately about 48 mg of working standard of salbutamol sulphate in a 100 ml volumetric flask, add 25 ml of distilled water, shake to dissolve completely and make up the volume to mark

with water. Shake the flask for complete mixing of the solution and dilute 2 ml of the resulting solution to 50 ml with water.

4.1.3 Color development:

To 10.0 ml of standard and test solution add sufficient water to produce 80 ml and add 4 ml of a 5 per cent w/v solution of sodium bicarbonate, 4 ml N,N-dimethyl-4-phenylenediamine sulphate solution and 4 ml of freshly prepared 8 per cent w/v solution of potassium ferricyanide. Mix, allow to stand for 15 minutes, protected from light. Extract with two quantities, each of 10 ml of chloroform. Filter the extracts through a plug of cotton wool and dilute to 25.0 ml with chloroform. Measure the absorbance of the resulting solution at 602 nm. Calculate the content of salbutamol with reference to the absorbance obtained by the standard.

4.2 Bromhexine Hydrochloride

4.2.1 Test solution:

Weigh accurately sample equivalent 4 mg of Bromhexine hydrochloride (5 ml of the sample) add 25 ml propylene glycol and heat in water bath. Add 25 ml of dilute hydrochloric acid and make volume to 100 ml with water.

4.2.2 Reference solution:

Weigh accurately 40 mg of *Bromhexine hydrochloride WS*, add 15 ml of propylene glycol, heat in water bath with occasional shaking until the solution is clear. Dilute with water to 50 ml. To 5 ml of the resulting solution, add 25 ml of propylene glycol and 25 ml of dilute HCl and dilute to make volume to 100 ml with water.

4.2.3 Color development:

To 5.0 ml of standard and test solution add 1 ml of 5 M HCl and 1 ml of sodium nitrite, stand for 5 minutes. Then add 1 ml 5 % ammonium sulphamate wait for 3 minutes then add 1 ml of NED solution, wait for 10 minutes and adjust the volume to 25 ml with dilute HCl. Measure the absorbance of the resulting solution at 525 nm. Calculate the content of Bromhexine HCl in syrup.

5. Other tests: As per pharmacopoeial requirement.