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

# Analytical profile of Glycopyrronium Powder for Inhalation

**Analytical Profile No.:** Glycopy 079/080/AP 126

Glycopyrronium Powder for Inhalation contains not less than 85.0% and not more than 115.0% of the stated amount of Glycopyrronium.

**Usual Strength:** 50 mcg

**1. Identification:**

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

**2. Uniformity of Content**

Determine by liquid chromatography, as described in the Assay, using the following test solution.

**Test Solution:** Select not fewer than 30 capsules, take 10 capsules and open 1 capsule and transfer carefully the blend into 20 ml dry volumetric flask. Rinse the capsule shell with 5 to 10 ml diluent and transfer into above flask. Sonicate to dissolve the blend with intermittent shaking. Make up the volume with diluent and mix. Repeat the same operation on additional nine capsule.

**3. Assay:** *Determine by liquid chromatography*

**3.1 Diluent:** Mix Methanol and Water in the ration (40:60 v/v)

**3.2 Test solution:** Take 20 capsules, carefully empty the content and collect the powder blend. Weigh the blend equivalent to 1.25 mg of Glycopyrronium bromide into a 100 ml volumetric flask, add 70 ml of diluent and sonicate to dissolve with intermittent shaking. Cool to room temperature, make up the volume with diluent and mix. Dilute 5 ml of above solution to 20 ml with diluent.

**3.3 Reference solution:** Weigh accurately 15.6 mg of Glycopyrronium bromide W S in 100ml of volumetric flask, add 70 ml of diluent and sonicate to dissolve. Cool to room temperature, make up the volume with diluent and mix. Dilute 2 ml of above solution to 100 ml with diluent.

**3.4 Chromatographic system:**

**Column:** Kromasil C18 (4.6mmX 150-mm, 5µ)

**Flow rate:** 2.0 ml/min

**Wavelength:** 214 nm

**Injection volume:** 100µl

**Column Temperature:** 40ºC

**Mobile Phase:** A mixture of 60 volume of Buffer and 40 volume of Acetonitrile.

**Buffer:** Add 1.38 g of sodium dihydrogen phosphate monohydrate and 1.22 g of Decane -1 Sulphonic acid sodium salt in 1000 ml of water. Adjust pH 3.0 ± 0.05 with orthophosphoric acid.

**3.5 Procedure:** Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Glycopyrronium in Glycopyrronium Powder for Inhalation.

**4. Other tests:** As per pharmacopoeial requirements.