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

# Analytical Profile of Natural Micronized Progesterone Gel

**Analytical Profile No.:** Proges G 082/083 AP 177

Progesterone Gel contains not less than 90.0% and not more than 110.0% of the stated amount of Progesterone.

Usual Strength: 8.0% w/w

**1. Identification:**

In the Assay, the retention time of the principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution.

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

**2.1 Test solution:** Weigh the test sample of gel equivalent to 40 mg of Progesterone (i.e., 0.5 g) in a 100 ml dry volumetric flask, add 50 ml of Acetonitrile, and heat on a heating plate at 80°C until complete dispersion. Cool to room temperature using ice water and make up the volume with same solvent up to the mark. Mix well and filter the solution through a 0.2 µm membrane filter paper.

**2.2 Reference solution:** Weigh accurately about 20 mg of Progesterone RS and transfer to a 50 ml completely dried volumetric flask. Dissolve in 25 ml of Acetonitrile with the aid of ultrasound for 5 minutes, cool to room temperature, and make up the volume with same solvent. Filter through a 0.2 µm membrane filter.

**2.3 Chromatographic system:**

**Column:** C 18 (4.6mmX 150-mm, 5µm)

**Flow rate:** 1.0 ml/min

**Wavelength:** 254 nm

**Injection volume:** 10 µl

**Column Temperature:** 40ºC

**Mobile Phase:** Water: Acetonitrile: 40:60 (V/V)

**2.4 Procedure:** Inject the reference solution five times and the sample solutions. The test is valid if the column efficiency is not less than 2000 theoretical plates, the 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 Progesterone.

**3. Other tests:** As per Pharmacopoeial requirements.