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

Analytical profile of Progesterone Sustained Release Tablets

Analytical Profile No.: Prog SR 076/077/AP 070

Progesterone Sustained Release Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Progesterone.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Progesterone.

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of 1.0 per cent sodium lauryl sulphate

Speed and time: 75 rpm and 2,8, 16 and 20 hours

Withdraw the suitable volume of the medium and filter. Replenish the volume after withdrawal or use the auto sampler program with medium replacement method.

Determine by Liquid Chromatography

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately about 22.2 mg Progesterone WS in 50 ml volumetric flask, add about 30 ml of mobile phase and dissolve with the aid of ultrasound and make up the volume to 50 ml with same solvent. Further dilute 5 ml of this solution to 10 ml with dissolution medium.

2.4 Chromatographic system:

- **Column:** C18, 25 cm x 4.6 mm, 5 µm
- **Flow rate:** 1.0 ml per minute
- **Wavelength:** 240 nm
- **Injection volume:** 20 µl

- **Detector:** UV
- **Mobile phase:** A mixture of 60 volumes of acetonitrile and 40 volumes of water.

2.4 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; the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak response.Calculate the percentage release of Progesterone.

2.5 Limit: 2nd hour: 10% - 30% of the stated amount

8th hour: 40% - 70% of the stated amount

16th hour: 65% - 95% of the stated amount

20th hour: NLT 85% of the stated amount

3. Assay: *Determine by Liquid Chromatography*

3.1 Test solution: Weigh individually 20 tablets and crush the tablet into fine powder. Weigh a quantity of powder equivalent to 50 mg of progesterone in 50 ml volumetric flask, add about 35ml of acetonitrile, sonicate to dissolve and make up the volume to 50 ml with same solvent.

3.2 Reference solution: Weigh accurately about 50 mg Progesterone WS in 50 ml volumetric flask, add 35 ml of acetonitrile, sonicate to dissolve and make volume to 50 ml with same solvent.

3.3 Chromatographic system:

- **Column:** C18, 25 cm x 4.6 mm, 5 µm
- **Flow rate:** 1.0 ml per minute
- **Wavelength:** 254 nm
- **Injection volume:** 10 µl
- **Detector:** UV
- **Mobile phase:** a mixture of 60 volumes of acetonitrile and 40 volumes of water.

3.4 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; the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent. Measure the peak response. Calculate the content of progesterone in the tablets.

4. Other tests: As per pharmacopoeial requirements.