DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Progesterone Sustained Release Tablets

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

Progesterone Sustained Release Tablets contains not less than 90 percent and not more than 110 percent of the stated amount of Progesterone.

1. Identification:

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

Tests:

2. Dissolution: *Determine by Liquid Chromatography*

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.

2.2 Test Solution: Filter the withdrawn solution through 0.2 µm membrane filter.

2.3 Reference Solution: Weigh accurately about 22.2 mg Progesterone RS in 50 ml volumetric flask, add about 30 ml 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. Filter the final solution through 0.2 µm membrane filter.

2.4 Chromatographic system:

Column:	a stainless steel column 25 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm)
Flow rate:	1.0 ml per minute,
Wavelength:	240 nm

Injection volume: 20 µl

Column temperature: ambient

Detector: UV

Mobile phase: a mixture of 60 volumes of acetonitrile and 40 volumes of water.

2.5 Procedure: Inject 20 µl of reference solution five/six times. 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%. After the completion of the system suitability test parameter, inject 20 µl of each of the sample solution separately. Calculate the percent release of Progesterone in each tablet at specified time.

2.6 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 35 ml of acetonitrile, sonicate to dissolve and make volume to 50 ml with same solvent. Filter the final solution through 0.2 µm membrane filter.

3.2 Reference solution: Weigh accurately about 50 mg Progesterone RS in 50 ml volumetric flask, add 35 ml of acetonitrile, sonicate to dissolve and make volume to 50 ml with same solvent. Filter the final solution through 0.2 µm membrane filter.

3.3 Chromatographic system:

Column:	a stainless steel column 25 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm)
Flow rate:	1.0 ml per minute
Wavelength:	254 nm
Injection volume:	10 µl
Column Temperature:	ambient
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 test solution. 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.

Calculate the content of progesterone in the tablets.

4. Other tests: As per pharmacopoeial requirements.