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# Progesterone Injection

» Progesterone Injection is a sterile solution of Progesterone in a suitable solvent. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{30}O_2$.

**Packaging and storage**—Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type III glass.

**USP Reference standards** ⟨11⟩—

USP Progesterone RS

**Identification**—Insert a pledget of fine glass wool into the base of a chromatographic tube of about 200 × 25 mm. Mix 8.0 mL of nitromethane with 7.0 g of purified siliceous earth in a 150-mL beaker until uniform, and transfer to the chromatographic tube, packing lightly with a suitable tamping rod. Pack a pledget of glass wool on the top of the column. Dilute 1 mL of the Injection with *n*-heptane to obtain a solution having a concentration of about 1 mg of progesterone per mL. Transfer 4.0 mL of this solution to the prepared column. Pass 300 mL of *n*-heptane through the column, discarding the first 120 mL of the eluate. Collect the subsequent eluate in a 250-mL beaker. Evaporate the solution under a stream of nitrogen on a steam bath to about 50 mL, transfer to a 100-mL beaker, and evaporate to dryness. Remove the last traces of *n*-heptane by adding 1 mL of methanol and again drying. Dry the specimen over silica gel for 4 hours: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Progesterone RS.

**Other requirements**—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

**Assay**—

*Mobile phase*—Prepare a degassed mixture of alcohol and water (11:9). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

*Standard preparation*—Dissolve an accurately weighed quantity of USP Progesterone RS in 20 mL of tetrahydrofuran, and dilute quantitatively, and stepwise if necessary, with alcohol to obtain a solution having a known concentration of about 0.08 mg per mL.

*Assay preparation*—Transfer an accurately measured volume of Injection, equivalent to about 100 mg of progesterone, to a 100-mL volumetric flask, add 20 mL of tetrahydrofuran to dissolve, and dilute with alcohol to volume. Transfer 8 mL of this solution to a 100-mL volumetric flask, dilute with alcohol to volume, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. The column temperature is maintained at about 40°. Chromatograph a sample of dimethyl sulfoxide, and identify the retention time, $t_\alpha$, of this nonretarded compound to calculate the capacity factor, $k'$. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the capacity factor, $k'$, for progesterone is not less than 2.0; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. [Note—The run time for the *Assay preparation* must be at least twice that of the *Standard preparation*.] Calculate the quantity, in mg, of progesterone ($C_{21}H_{30}O_2$) in each mL of Injection taken by the formula:

$$1250(C/V)(r_U/r_S)$$

in which $C$ is the concentration, in mg per mL, of USP Progesterone RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and $r_U$ and $r_S$ are the peak responses for progesterone obtained from the *Assay preparation* and the *Standard preparation*, respectively.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| PROGESTERONE INJECTION | Documentary Standards Support | SM52020 Small Molecules 5 |

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** Chromatographic Database

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