

# **CERTIFICATE of ANALYSIS**

## **11- $\alpha$ -HYDROXIPROGESTERONE**

**BATCH No.:** U0373/0 10040

**MAN DATE:** Feb/11

**RE-TEST DATE:** Feb/16

| TEST                           | SPECIFICATIONS                                                                                                                                                                       | RESULTS                                                                                     |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| 1. Description                 | White to almost white crystalline powder                                                                                                                                             | Complies                                                                                    |
| 2. Identification              |                                                                                                                                                                                      |                                                                                             |
| 2.1. IR                        | According to reference standard                                                                                                                                                      | Complies                                                                                    |
| 2.2. HPLC                      | According to reference standard                                                                                                                                                      | Complies                                                                                    |
| 3. Loss on drying              | $\leq 1.0 \%$                                                                                                                                                                        | 0.1 %                                                                                       |
| 4. Specific optical rotation   | $+175.0^{\circ}$ to $+182.0^{\circ}$                                                                                                                                                 | $+179.7^{\circ}$                                                                            |
| 5. Residue on ignition         | $\leq 0.10\%$                                                                                                                                                                        | $< 0.10 \%$                                                                                 |
| 6. Heavy Metals                | $\leq 10$ ppm                                                                                                                                                                        | $< 10$ ppm                                                                                  |
| 7. Molybdenum                  | $\leq 25$ ppm                                                                                                                                                                        | $< 25$ ppm                                                                                  |
| 8. HPLC chromatographic purity | I0373-01 $\leq 0.15 \%$<br>I0373-02 $\leq 0.15 \%$<br>I0373-03 $\leq 0.15 \%$<br>I0373-04 $\leq 0.15 \%$<br>I0373-05 $\leq 0.15 \%$<br>Unknown $\leq 0.10 \%$<br>Total $\leq 1.0 \%$ | $< 0.05 \%$<br>$< 0.05 \%$<br>$< 0.05 \%$<br>$< 0.05 \%$<br>$< 0.05 \%$<br>0.06 %<br>0.06 % |
| 9. HPLC Assay (dried basis)    | 98.0 – 102.0 %                                                                                                                                                                       | 99.3%                                                                                       |
| 10. Residual solvents          | Ethyl Acetate $< 5000$ ppm<br>Methanol $< 3000$ ppm<br>THF $< 720$ ppm<br>Methyl-THF $< 5000$ ppm                                                                                    | 4936 ppm<br>102 ppm<br>$< \text{LOD}^*$<br>$< \text{LOD}^*$                                 |

\*LOD: limit of detection

  
 14/07/15  
 Quality Assurance Department