ASG Biochem Pvt. Ltd.
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CIN: U24232DL2004PTC126594

# QUALITY CONTROL DEPARTMENT

**P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132**

**Drug License No. DL-802-MB**

## CERTIFICATE OF ANALYSIS

***Product Name: ESTRIOL Ph. Eur***

| | | | |
|---|---|---|---|
| **Batch No.:** | **ESTZ01A007** | **Quantity:** | **23010.00 Gm.** |
| **Manufacturer:** | **ASG Biochem Pvt. Ltd.** | **Supplier:** | **ASG Biochem Pvt. Ltd.** |
| **Mfg. Date:** | **JUNE 2020** | **Retest Date:** | **MAY 2024** |
| **STP No.:** | **MOA-ESTZ(EP)-02** | **Control No.:** | **AA-2334** |
| **Specification No.:** | **FPS-74662114.02-EP** | **Pharmacopoeial Reference:** | **EP** |

| Sl. No. | Specification with release limit | Results |
|---|---|---|
| 01. | **Appearance :** White or almost white, crystalline powder | White crystalline powder |
| 02. | **Solubility:** Practically insoluble in water, sparingly soluble in ethanol (96%) | Conforms requirement |
| 03. | **Identification :**<br>A) Spectroscopic Identification test (by IR): Sample spectrum should be concordant with standard spectrum.<br>B) Retention Time (by HPLC): The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution. | A) Sample spectrum was concordant with the standard spectrum<br>B) Conforms requirement |
| 04. | **Specific optical rotation :** +60° to +65°<br>(0.8% w/v solution in anhydrous ethanol, on dry basis) | +62.1° |
| 05. | **Related Substances** : By HPLC<br>a) Impurity F: ≤ 0.5% (a/a)<br>b) Impurity E: ≤ 0.3% (a/a)<br>c) Impurity A,D: ≤ 0.2% (a/a)<br>d) Unspecified impurities each : ≤ 0.10% (a/a)<br>e) Total impurity : ≤ 1.0% (a/a) | a) Impurity F : 0.24% (a/a)<br>b) Impurity E: Not detected<br>c) Impurity A: 0.09% (a/a)<br>d) Impurity D: Not detected<br>d) Unspecified impurities each: Not detected<br>e) Total impurity: 0.33% (a/a) |
| 06. | **Loss on drying :** Maximum 0.5% (w/w) | 0.03% (w/w) |
| 07. | **Assay (By Chromatography) :** 97.5% - 102.0% ( w/w, on dry basis) | 99.42% (w/w) |
| 08. | **Particle Size** ( At least 90% less than 10 micron) | 90% < 10 micron |
| 09. | **Microbiological Test** (As per BP)<br>**a. Total Aerobic Microbial Count:** (<1000 CFU/gm)<br>**b. Total Yeast Mould Count:** (<100 CFU/gm) | a. 60 CFU/gm<br>b. 30 CFU/gm |
| 10. | **Residual Solvents** ( As per ICH Q3C)<br>**a. Dimethyl Formamide:** (≤ 880 ppm)<br>**b. Methanol:** (≤ 3000 ppm)<br>**c. 1,2-Dichloroethane :** (≤ 5 ppm) | a. Not detected<br>b. 196 ppm<br>c. Not detected |
| 11. | **Elemental Impurities** (As per ICH Q3D, based on $Max_{TDD}$ & PDE limit)<br>**a) Cadmium (Cd):** NMT 0.5 ppm<br>**b) Lead (Pb):** NMT 0.5 ppm<br>**c) Arsenic (As):** NMT 1.5 ppm<br>**d) Mercury (Hg):** NMT 3 ppm<br>**e) Nickel (Ni):** NMT 20 ppm<br>**f) Cobalt (Co):** NMT 5 ppm<br>**g) Vanadium (V):** NMT 10 ppm<br>**h) Lithium (Li):** NMT 55 ppm | a) Cadmium (Cd): Not detected<br>b) Lead (Pb): Not detected<br>c) Arsenic (As): Not detected<br>d) Mercury (Hg): Not detected<br>e) Nickel (Ni): 1.3 ppm<br>f) Cobalt (Co): 0.0 ppm<br>g) Vanadium (V): 0.4 ppm<br>h) Lithium (Li): < LOD (LOD: 2.93 ppm) |

**Tested according to: [MOA-ESTZ(EP)-02]**

**Remarks: In the opinion of the undersigned, product referred above complies/ ~~does not comply~~ with above limits of quality attributes.**

**N.B-1: Particle Size Distribution done by Cubic Analytical Solution.**

**N.B-2: Elemental analysis: Class I: Done by EFRAC Limited.**
**Class II A: Done by ALS Testing Service Pvt. Ltd.**
**Lithium (Li): Done by Shiva Analyticals**

**Storage:** To be kept in well closed containers and stored at a temperature not exceeding 25°C.

| | NAME | DESIGNATION | SIGNATURE | DATE |
|---|---|---|---|---|
| **PREPARED BY** | S. SAMANTA | Analyst - Quality Control | | 02/09/2022 |
| **CHECKED BY** | P. BASU | Executive- Quality Control | | 02/09/2022 |
| **APPROVED BY** | I. BHATTACHARYYA | Manager - Quality Control | | 02/09/2022 |
| **APPROVED BY** | D. BANERJEE | Manager - Quality Assurance | | 02/09/2022 |

***COA Reissued after introducing Lithium report**
**** COA Reissued**

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**An ISO 9001 & ISO 14001 Certified Unit**