METAPHARMACEUTICAL

N DE LOTE: 0090122

13/01/2022.

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 2023**
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 :** A) Spectroscopic Identification test (by IR): Sample spectrum should be concordant with standard spectrum. 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 B) Conforms requirement
04.	**Specific optical rotation :** +60° to +65° (0.8% w/v solution in anhydrous ethanol, on dry basis)	+62.1°
05.	**Related Substances** : By HPLC a) Impurity F: ≤ 0.5% (a/a) b) Impurity E: ≤ 0.3% (a/a) c) Impurity A,D: ≤ 0.2% (a/a) d) Unspecified impurities each : ≤ 0.10% (a/a) e) Total impurity : ≤ 1.0% (a/a)	a) Impurity F : 0.24% (a/a) b) Impurity E: Not detected c) Impurity A: 0.09% (a/a) d) Impurity D: Not detected d) Unspecified impurities each: Not detected 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) **a. Total Aerobic Microbial Count:** (<1000 CFU/gm) **b. Total Yeast Mould Count:** (<100 CFU/gm)	a. 60 CFU/gm b. 30 CFU/gm
10.	**Residual Solvents** (As per ICH Q3C) **a. Dimethyl Formamide:** (≤ 880 ppm) **b. Methanol:** (≤ 3000 ppm) **c. 1,2-Dichloroethane :** (≤ 5 ppm)	a. Not detected b. 196 ppm c. Not detected
11.	**Elemental Impurities** (As per ICH Q3D, based on Max_{TDD} & PDE limit) **a) Cadmium (Cd):** NMT 0.5 ppm **b) Lead (Pb):** NMT 0.5 ppm **c) Arsenic (As):** NMT 1.5 ppm **d) Mercury (Hg):** NMT 3 ppm **e) Nickel (Ni):** NMT 20 ppm **f) Cobalt (Co):** NMT 5 ppm **g) Vanadium (V):** NMT 10 ppm	a) Cadmium (Cd): Not detected b) Lead (Pb): Not detected c) Arsenic (As): Not detected d) Mercury (Hg): Not detected e) Nickel (Ni): 1.3 ppm f) Cobalt (Co): 0.0 ppm g) Vanadium (V): 0.4 ppm

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

Remarks: In the opinion of the undersigned, product referred above is of Standard Quality as per specification / ~~is not of Standard Quality for reasons given below:~~

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.

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

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY	A. P. MAJUMDER	Analyst - Quality Control	A.Paul	16/11/2021
CHECKED BY	K. B. MISHRA	Supervisor - Quality Control	K.B. Mishra	16/11/2021
APPROVED BY	I. BHATTACHARYYA	Manager - Quality Control		16/11/2021
APPROVED BY	D. BANERJEE	Manager - Quality Assurance		16/11/2021

*COA Reissued

GCA-07741

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