

METAPHARMACEUTICAL

N DE LOTE:

0070122

12/04/2023

ASG Biochem Pvt. Ltd.

Ganganagar, 24 Parganas (N), West Bengal, PIN - 700132
T+ 91 033 2567 3236 / 3237, F +91 033 2567 4557
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 : 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 e) Unspecified impurities each: Not detected 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 _{TPD} & 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 h) Lithium (Li): NMT 55 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 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



An ISO 9001 &
ISO 14001 Certified Unit

Regd. Office: 607 Rohit House, 3 Tolstoy Marg, New Delhi 110 001. T + 91 11 4352 8248