

QUALITY CONTROL DEPARTMENT

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

Drug License No. DL-802-MB

CERTIFICATE OF ANALYSIS
Product Name: ESTRIOLE EP

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	Specification No. :	FPS-74662114.02-EP
Control No. :	AA-2334	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 f) 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 EP) 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 MaxTDD & PDE limit) a) Cadmium (Cd): ≤ 0.5 ppm b) Lead (Pb): ≤ 0.5 ppm c) Arsenic (As): ≤ 1.5 ppm d) Mercury (Hg): ≤ 3 ppm	a) Cadmium (Cd): Not detected b) Lead (Pb): Not detected c) Arsenic (As): Not detected d) Mercury (Hg): Not detected

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 & Elemental Impurity has been outsourced from EFRAC Limited, address: Subhas Nagar, PO: Nilgunj Bazar, Barasat, Kolkata-700121, INDIA

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

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY	ARGHA SEN	Analyst -Quality Control	A. Sen	23/06/2021
CHECKED BY	A. PAUL MAJUMDER	Analyst -Quality Control	A. Paul	23/06/2021
APPROVED BY	I BHATTACHARYYA	Manager -Quality Control	I. Bhattacharyya	23/06/2021
APPROVED BY	P MAITY	Executive- Quality Assurance	P. Maity	23/06/2021

*COA Reissued


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ISO 14001 Certified Unit