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 USP

Batch No.:	**ESTZ01A006**	**Quantity:**	**24100.00 gm.**
Manufacturer:	**ASG Biochem Pvt. Ltd.**	**Supplier:**	**ASG Biochem Pvt. Ltd.**
Mfg. Date:	**JUNE 2020**	**Retest Date:**	**MAY 2025**
Specification No.:	**FPS-74662114.03-USP**	**Control No.:**	**AA-2333**
Pharmacopoeial reference:		**USP**	

Sl. No.	Specification with release limit	Results
01.	**Identification:** a) Spectroscopic Identification test (by IR) : Sample spectrum should be concordant with standard spectrum. b) By Retention time (by HPLC): The retention time of the major peak of the sample solutions corresponds to that of the standard solution as obtained in the assay.	a) Sample spectrum was concordant with the standard spectrum b) Conforms requirement
02.	**Assay:** 97.0% - 102.0% (w/w, on dried basis)	99.81%((w/w)
03.	**Residue on Ignition:** NMT 0.1% (w/w)	0.04% (w/w)
04.	**Organic Impurities** a) 16ß,17α- Estriol: NMT 0.5% (a/a) b) Estriol related comp A: NMT 0.5% (a/a) c) 16ß Estriol: NMT 0.5% (a/a) d) 17α Estriol: NMT 0.5% (a/a) e) Estrone: NMT 0.5% (a/a) f) Estradiol: NMT 0.5% (a/a) g) 3-O-Methyl Estriol: NMT 0.5% (a/a) h) Any Individual Unspecified Impurity: NMT 0.10% (a/a) i) Total Impurities (excluding Estriol Related compound A): NMT 1% (a/a)	a) 16ß,17α- Estriol: Not detected b) Estriol related comp A: 0.06% (a/a) c) 16ß Estriol: 0.20% (a/a) d) 17α Estriol: Not detected e) Estrone: Not detected f) Estradiol: Not detected g) 3-O-Methyl Estriol: Not detected h) Any Individual Unspecified Impurity: Not detected i) Total Impurities: 0.20% (a/a)
05.	**Specific Optical Rotation:** +54° to +62° (4 mg per ml in dioxane)	+58.0°
06.	**Loss on Drying:** NMT 0.5% (w/w, at 105°C for 3 hours)	0.17 % (w/w)
07.	**Particle Size** (At least 90% less than 10 micron)	90% < 10 micron
08.	**Microbiological Test** (As per USP) **a) Total Aerobic Microbial Count:** (<1000 CFU/gm) **b) Total Yeast Mould Count:** (<100 CFU/gm)	a) 30 CFU/gm b) Nil CFU/gm
09.	**Residual Solvents** (As per ICH Q3C) **a) Dimethyl Formamide:** (≤ 880 ppm) **b) Methanol:** (≤ 3000 ppm) **c) 1,2-Dichloroethane:** (≤ 5 ppm)	a) Dimethyl Formamide: Not detected b) Methanol: 58 ppm c) 1,2-Dichloroethane: Not detected
10.	**Elemental Impurities** (As per ICH Q3D, based on Max_{TDD} & PDE limit) **a) Cadmium (Cd):** ≤ 625 ppm **b) Lead (Pb):** ≤625 ppm **c) Arsenic (As):** ≤1875 ppm **d) Mercury (Hg):** ≤3750 ppm	a) Cadmium (Cd): Not detected b) Lead (Pb): Not detected c) Arsenic (As): Not detected d) Mercury (Hg): 0.149 ppm

Tested according to: [MOA-ESTZ (USP)-03]

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.B1: Testing of Assay, Organic Impurity Elemental Impurity and Particle Size Distribution has been outsourced from EFRAC Limited, address: Subhas Nagar, PO: Nilgunj Bazar, Barasat, Kolkata700121, INDIA

Storage: Preserve in tight containers protected from light and store at a temperature not exceeding 25°C.

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY	A. PAUL MAJUMDER	Analyst – Quality Control	A.Paul	27/06/2020
CHECKED BY	B. PAL	Executive – Quality Assurance	Baphaditya Pal	27/06/2020
APPROVED BY	M. CHAKRABORTY	Executive – Quality Assurance	Monodip Chakraborty	27/06/2020

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