



QUALITY CONTROL DEPARTMENT
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132
Drug License No. DL-802-MB

Ganganagar, 24 Parganas (N), West Bengal, PIN-700132
T + 91 033 2567 3236 / 3237
CIN: U24232DL2004PTC126594

CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Sl. No.	Test Parameters	Specification	Results
CHARACTERS			
01.	Appearance	White or almost white crystalline powder	White, crystalline powder.
02.	Solubility	Practically insoluble in water, sparingly soluble in ethanol (96%), Practically insoluble in dichloromethane.	Practically insoluble in water, sparingly soluble in ethanol (96%), Practically insoluble in dichloromethane.
IDENTIFICATION			
03.	A. Infrared absorption Spectrophotometry	Sample spectrum should be concordant with the spectrum of <i>Estriol CRS</i>	Sample spectrum concordant with the spectrum of reference standard (RS)
	B. Examine the chromatogram obtained in the Assay	The principal peak in the chromatogram obtained with test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
	C. Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet at 366 nm and size to the principle spot in the chromatogram obtained with the reference solution	The principal spot in the chromatogram obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet at 366 nm and size to the principle spot in the chromatogram obtained with the reference solution



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	TESTS		
04.	Specific Optical Rotation	+ 60° to + 65° (dried substance)	+ 62 °
05.	Loss on Drying	Maximum 0.5 per cent	0.12% (w/w)
06.	Assay (By Liquid Chromatography)	97.5 per cent to 102.0 per cent (dried substance)	99.5 % (w/w)
07.	Related Substance (By Liquid Chromatography)		
	Impurity F	Maximum 0.5 per cent	0.22% (a/a)
	Impurity E	Maximum 0.3 per cent	Not Detected
	Impurity A	Maximum 0.2 per cent	0.17% (a/a)
	Impurity D	Maximum 0.2 per cent	0.03% (a/a)
	Unspecified Impurities (for each impurity)	Maximum 0.10 per cent	0.06% at RRT 1.42
	Total	Maximum 1.0 per cent	0.48% (a/a)



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Additional Tests			
Sl. No.	Test Parameters	Specification	Results
01	Particle Size	Report Value	90% < 10µm

Remarks: In the opinion of the undersigned, the above mentioned product Meets/ ~~Does not Meet~~ the above test parameters as per specification.

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

Additional Information: Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR	K. B. Mishra	01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE	P. Basu	01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



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APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



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Sl. No.	Test Parameters	Specification	Results
01	Microbiological Tests	Total Aerobic Microbial Count: NMT 1000 cfu/gm	20 cfu/gm
		Total Yeast Mould Count: NMT 100 cfu/gm	NIL

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Sl. No.	Test Parameters	Specification	Results
01.	Residual Solvents: (By GC)		
	Dimethylformamide	NMT 880 ppm	Not Detected
	Methanol	NMT 3000 ppm	236 ppm
	1,2-Dichloroethane	NMT 5 ppm	Not Detected
	Ethyl Acetate	NMT 5000 ppm	Not Detected
	Ethanol	NMT 5000 ppm	59 ppm
	Acetone	NMT 5000 ppm	152 ppm

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Additional Tests

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01.	Elemental Analysis		
	Lead	NMT 0.5 µg/g	0.2 ppm
	Cadmium	NMT 0.5 µg/g	0.0 ppm
	Arsenic	NMT 1.5 µg/g	0.0 ppm
	Mercury	NMT 3 µg/g	0.0 ppm
	Cobalt	NMT 5 µg/g	0.0 ppm
	Vanadium	NMT 10 µg/g	0.0 ppm
	Nickel	NMT 20 µg/g	0.11 ppm
	Lithium	NMT 55 µg/g	0.0 ppm

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

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