



SWAPNROOP DRUGS & PHARMACEUTICALS

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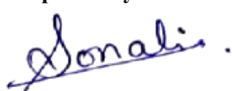
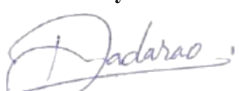
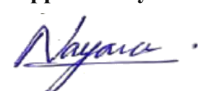
CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL	CAS No:	50-27-1
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White or almost white, crystalline powder	White crystalline powder
2	Solubility	Practically insoluble in water, sparingly soluble in ethanol (96%)	Complies
3	Identification (IR)	Sample spectrum should be concordant with standard spectrum	Complies
4	Identification by - TLC	The principal spot in the chromatogram obtained with test solution is similar in position, color and size to the principal spot in the chromatogram obtained with reference solution (a)	Complies
5	Melting Point	282°C	280°C to 283°C
6	Specific optical rotation	+60° to +65° (0.8% w/v solution in anhydrous ethanol, on dry basis)	+63.6°
7	Related substances: By HPLC a) Impurity A	≤ 0.5% (a/a)	≤ 0.3% (a/a)
8	Related substances: By HPLC b) Impurities B, C, D, E, F, G each	≤ 0.5% (a/a)	0.1% (a/a)
9	Related substances: By HPLC c) Unspecified impurities each	≤ 0.10% (a/a)	Not detected
10	Related substances: By HPLC d) Sum of impurities other than A	≤ 1% (a/a)	0.1% (a/a)
11	Loss on drying	Maximum 0.5% (w/w, at 105°C for 3 hrs.)	0.10% (w/w)
12	Assay (By UV)	97.0%-103.0% (w/w, on dry basis)	100.21% (w/w)

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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