



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,

Aurangabad-431154, Maharashtra, India.

Tel: +91 8767062101 Email: enquiry@sdp.org.in

Website: www.sdp.org.in

CERTIFICATE OF ANALYSIS

Product Name	ETHINYLESTRADIOL BP	CAS No:	57-63-6
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 slightly yellowish white, crystalline powder.	Slightly yellowish, crystalline powder
2	Solubility	Practically insoluble in water, freely soluble in ethanol (96 per cent). It dissolves in dilute alkaline solutions.	Complies
3	Identification (IR)	Compare the sample spectrum with that obtained with Ethinylestradiol RS or with the reference spectrum of Ethinylestradiol.	Complies
4	Identification by - TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, color, fluorescence and size to the principal spot in the chromatogram obtained with the reference solution.	Complies
5	Related Substance (By HPLC) Impurity B	NMT 0.5% w/w	0.15%
6	Related Substance (By HPLC) Impurity C	NMT 0.15% w/w	0.05%
7	Related Substance (By HPLC) Impurity F	NMT 0.15% w/w	ND
8	Related Substance (By HPLC) Impurity H	NMT 0.2% w/w	0.09%
9	Related Substance (By HPLC) Impurity I	NMT 0.2% w/w	ND
10	Related Substance (By HPLC) Impurity K	NMT 0.2% w/w	ND
11	Related Substance (By HPLC) Unspecified Impurity	NMT 0.1% W/W	ND
12	Related Substance (By HPLC) Total Impurities	NMT 0.8% w/w	0.29%
13	Loss on drying	NMT 1.0% w/w	0.81% w/w
14	Assay (By HPLC)	NLT 97.5% w/w and NMT 102.0 % w/w of C20H24O2 calculated on dried basis.	98.2% w/w

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
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Sonali Nirmal
Date: 23/05/2026



Dadarao Kakde
Date: 23/05/2026



Nayna Nehete
Date: 23/05/2026

