



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	Fesoterodine fumarate	CAS No:	286930-03-8
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 to off-white powder	white powder
2	Solubility	Easily soluble in water, methanol, ethanol	Complies
3	Identification – By HPLC	Conform with reference standard	Complies
4	Melting point	72 ~ 78°C	73.5°C
5	Identification RT (BY HPLC)	should be Complies	Complies
6	P-XRD	Conform with reference standard	Complies
7	Loss on drying	≤ 0.5%	Complies
8	Heavy metal	≤ 20ppm	Complies
9	Maximum single impurity	≤ 0.15%	0.07%
10	Total impurity	≤ 1.0%	0.26%
11	Purity	≥ 99.0%	99.74%
12	Residual solvents Methanol	≤ 3000ppm	50ppm
13	Residual solvents Ethyl Acetate	≤ 5000ppm	N.D
14	Residual solvents Acetonitrile	≤ 410ppm	N.D
15	Assay (by hplc)	99.0% - 101.0%	100.1%

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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