



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	Eltrombopag Olamine	CAS No:	496775-62-3
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	Red to brown color powder.	Brown color powder
2	Solubility	Soluble in Dimethyl sulfoxide, slightly soluble in methanol, very slightly soluble in anhydrous ethanol, practically insoluble in water.	Complies
3	Identification – By IR	The IR absorption spectrum of the sample should be concordant with that of Eltrombopag olamine standard spectrum.	Complies
4	Identification – HPLC	The retention time of major peak in the test solution chromatogram should match with that of principal peak obtained from standard solution in assay by HPLC.	Complies
5	Moisture content by KF (% w/w)	Not more than 0.50	0.18
6	Residue on ignition (% W/W)	Not more than 0.10	0.06
7	Related substances by HPLC (% W/W) KSM-1 (M-297)	Not more than 0.15	Not Detected
8	Related substances by HPLC (% W/W) Methyl ester impurity	Not more than 0.15	Not Detected
9	Related substances by HPLC (% W/W) Ethyl ester impurity	Not more than 0.15	Not Detected
10	Related substances by HPLC (% W/W) Olamine ester impurity	Not more than 0.15	0.04
11	Related substances by HPLC (% W/W) Methoxy impurity	Not more than 0.15	Not Detected
12	Related substances by HPLC (% W/W) Maximum single unknown impurity	Not more than 0.10	0.05
13	Related substances by HPLC (% W/W) Total impurities	Not more than 1.0	0.26

Sr No	Test	Acceptance Criteria	Results
14	KSM-2 (M-298) content by HPLC (% w/w)	Not more than 0.15	Not Detected
15	Assay by HPLC on anhydrous basis (% w/w)	Not less than 98.0 and not more than 102.0	100.8
16	Olamine content by Potentiometry (% W/W)	Between 20.0 - 24.0	21.0
17	Residual solvents by GC-HS (ppm) Methanol	Not more than 3000	11
18	Residual solvents by GC-HS (ppm) Ethanol	Not more than 5000	920
19	Residual solvents by GC-HS (ppm) Dichloromethane	Not more than 600	Not Detected
20	Residual solvents by GC-HS (ppm) Methyl tertiary butyl ether	Not more than 5000	Not Detected
21	Residual solvents by GC-HS (ppm) Ethyl acetate	Not more than 5000	Not Detected
22	Residual solvents by GC-HS (ppm) n-Heptane	Not more than 5000	Not Detected
23	Residual solvents by GC-HS (ppm) N, N-Dimethyl formamide	Not more than 880	Not Detected
24	Residual solvents by GC-HS (ppm) Dimethyl sulfoxide	Not more than 5000	Not Detected

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 
--	---	--

SWAPNROOP DRUGS & PHARMACEUTICALS