

Smilax Laboratories Limited

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 Jeedimetla Village, Outhbullapur Mandal, Medchal - Malkajgiri Dist, Telangana State.
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 E-mail: info@smilaxlabs.com, www.smilaxlabs.com
 CIN : U24230AP2004PLC44461



CERTIFICATE OF ANALYSIS

Product	OMEPRAZOLE USP		
Batch Number	OPV2410022	Page Number	Page 1 of 2
Manufacturing Date	September 2024	A.R. Number	FP/24100010
Batch Quantity	352.10 Kg	Expiry Date	August 2027

TEST	SPECIFICATION	OBSERVATION
Description	White to off-white / almost white powder	White powder.
Solubility	Very slightly soluble in water	Very slightly soluble in water
	Soluble in Methylene dichloride	Soluble in Methylene dichloride
	Sparingly soluble in Ethanol (96%)	Sparingly soluble in Ethanol (96%)
	Sparingly soluble in Methanol	Sparingly soluble in Methanol
Identification	A) By IR The IR absorption spectrum of test sample should be concordant with that of Omeprazole reference spectrum	The IR absorption spectrum of test sample is concordant with that of Omeprazole reference spectrum.
	B) By HPLC The retention time of the major peak of the sample solution must correspond to that of the Standard solution, as obtained in the Assay.	The retention time of the major peak of the sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Residue on ignition (% w/w)	Not more than 0.1	0.04
Completeness of solution (20mg/ml solution in Methylene dichloride)	Should meet the requirement	Complies
Limit of Omeprazole Related compounds F and G	The absorbance should be Not more than 0.10	0.02
Organic impurities (by HPLC, % w/w)		
5-Methoxy-1H-benzimidazol-2-thiol	Not more than 0.15	Not detected
Omeprazole N-oxide (RC-E)	Not more than 0.15	Not detected
Omeprazole Sulfone N-oxide (RC-I)	Not more than 0.15	0.01
Desmethoxy Omeprazole	Not more than 0.15	0.004
Omeprazole sulfone (RC-A)	Not more than 0.15	0.03

Prepared By	Checked By	Approved By
<i>PVK</i> 07/10/2024	<i>Creedy</i> 07/10/2024	<i>D.K.</i> 07.10.2024
P.Vishnu Kumar Asst.Manager-QCD	M.T.R.Chowdary AGM-QCD	Dinesh Kumar DGM-QAD

Form No: FM12/QAD025/02

Works : Smilax Laboratories Limited, Unit - IV, Plot No: 70, J.N. Pharma City, E. Bonangi (V), Parawada (M), Anakapalli (D)-531 019, Visakhapatnam, Andhra Pradesh, India. **Fax :** +91 8924 236123, **Tel :** +91 9177417770.

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CREATING VALUE IN YOUR VALUE CHAIN

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TEST	SPECIFICATION	OBSERVATION
Omeprazole 4-chloro analog	Not more than 0.15	0.01
Ufiprazole	Not more than 0.15	0.03
Omeprazole thioxo-pyrido analogs	For information	Not detected
Any other individual impurity	Not more than 0.10	0.02
Total impurities	Not more than 1.0	0.1
Loss on drying (% w/w, Dried at 60°C for 4 hours under vacuum)	Not more than 0.5	0.1
Assay by HPLC (% w/w determined on dried basis)	Not less than 98.0 and Not more than 102.0	99.5
Additional Tests:		
Acetic acid content By HPLC (ppm)	Not more than 5000	Not detected
Residual solvents by HSGC(ppm)		
Toluene	Not more than 890	26
Methanol	Not more than 3000	87
Acetone	Not more than 5000	592
Isopropyl alcohol	Not more than 5000	Not detected
Triethylamine content	Not more than 320	22

Report: The above material CONFORMS with the requirements of USP monograph

Storage Condition: Store in air tight containers at 2 °C and 8°C. Protect from light and moisture.

Prepared By	Checked By	Approved By
<i>P.Vishnu Kumar</i> 07/10/2024	<i>M.T.R. Chowdary</i> 07/10/2024	<i>Dinesh Kumar</i> 07/10/2024
P.Vishnu Kumar Asst.Manager-QCD	M.T.R.Chowdary AGM-QCD	Dinesh Kumar DGM-QAD

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