

Mangalam Drugs and Organics Limited

Unit II: Plot No. 1203, 3rd Phase, G. I. D. C., VAPI, Dist. Valsad - 396195 (Gujarat) ☎ 91 - 0260 - 2432669 / 07490052669
 ☎ 91 - 0260 2432669 / 2424970 ☎ mdol2@mangalamdrugs.com • CIN : L24230MH1972PLC116413



CERTIFICATE OF ANALYSIS

Page No. 1 of 2

Page No. 1 of 1

Name of the Material: Furosemide Ph. Eur. 10			
Mfg. License No.	G/1315	CAS No.	54-31-9
Batch No.	FRD-2B-222023	Batch Size	375.00 Kg
Mfg. Date	April-2022	Expiry Date	March-2027
Received Date	02/05/2022	Release Date	17/05/2022
A. R. No.	FRD-22/24		
Storage Conditions	Store in well closed containers, protected from light.		

RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
01	Description	White crystalline powder	White or almost white, crystalline powder.
02	Solubility	Complies	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96%), Practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.
03	Identification:		
	Test B: (By Infrared Absorption Spectrophotometry)	Complies	The infra-red absorption spectrum of the test sample is concordant with the spectrum obtained from Furosemide RS/WS.
04	Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution BY ₃
05	Related Substance (By HPLC):		
	Impurity A	0.03% w/w	Not more than 0.10% w/w
	Impurity B	0.01% w/w	Not more than 0.10% w/w
	Impurity C	0.08% w/w	Not more than 0.20% w/w
	Impurity D	BQL	Not more than 0.15% w/w
	Impurity E	BDL	Not more than 0.10% w/w
	Impurity F	0.01% w/w	Not more than 0.10% w/w
	Unspecified impurities	Below Disregard Limit	Not more than 0.10% w/w
	Total impurities	0.13% w/w	Not more than 0.5% w/w

Prepared by (Jr. Executive - Q.C.) Ms. Krishna Patel	Checked by (Sr. Manager - Q.C.) Mr. Machindra Mungase	Approved by (Sr. Manager - Q.A.) Mr. Chetan Sarda
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Regd. Office : Rupam Building, 3rd Floor, 239 P. D'Mello Road, Near G. P. O. Mumbai - 400 001. ☎ 91-22-22616200 / 6300 / 8787
 ☎ 91-22-22619090 ☎ contactus@mangalamdrugs.com ☎ http://www.mangalamdrugs.com

METAPHARMACEUTICAL

N. DE LOTE:

0250623

27 JUN. 2023

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Page No. 2 of 2

Page No. 2 of 3

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RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
06	Chlorides	Less than 200 ppm	Not more than 200 ppm
07	Sulfates	Less than 300 ppm	Not more than 300 ppm
08	Loss on drying	0.23% w/w	Not more than 0.5% w/w
09	Sulfated Ash	0.03% w/w	Not more than 0.1% w/w
10	Assay (By Potentiometrically)	99.8% w/w	Not less than 98.5% w/w and Not more than 101.0% w/w (Calculated on dried basis)

Additional In house tests:

11	Residual Solvents (By GC-MS):		
	Methanol	183 ppm	Not more than 3000 ppm
	Ethanol	Not detected	Not more than 5000 ppm
	Isopropyl alcohol	Not detected	Not more than 5000 ppm
	Ethyl Acetate	Not detected	Not more than 5000 ppm
	Methyl Acetate	Not detected	Not more than 5000 ppm
12	Bulk Density:		
	Untapped density	0.36 g/ml	For Record
	Tapped density	0.63 g/ml	For Record
13	Particle size	100% passing through 40 mesh	For Record

Remark: The material Complies as per Ph. Eur. 10 and In-House specification.

Note: BQL: Below Quantification Limit, BDL: Below Detection Limit.

This COA is generated for Gemini Export.

Prepared by <i>(Signature)</i> (Jr. Executive - Q.C.) Ms. Krishna Patel	Checked by <i>(Signature)</i> (Sr. Manager - Q.C.) Mr. Machindra Mungase	Approved by <i>(Signature)</i> (Sr. Manager - Q.A.) Mr. Chetan Sarda
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