






## CERTIFICATE OF ANALYSIS

Page No. 1 of 3

<b>Name of the Material:</b> FUROSEMIDE Ph. Eur.			
<b>Mfg. License No.</b>	G/1315	<b>CAS No.</b>	54-31-9
<b>Batch No.</b>	FRD-2B-202010	<b>Batch Size</b>	366.00 Kg
<b>Mfg. Date</b>	June-2020	<b>Expiry Date</b>	May-2025
<b>Received Date</b>	24/06/2020	<b>Release Date</b>	01/07/2020
<b>A. R. No.</b>	FRD-20/10		
<b>Storage Conditions</b>	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 A: (By Infrared Absorption Spectrophotometry)	Complies	The infra-red absorption spectrum of the test sample is concordant with the spectrum obtained from Furosemide RS/WS.
	Test B: By TLC	Complies	Result A: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.
		Complies	Result B: The Principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference
04	Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution BY <sub>5</sub>

<b>Prepared by</b>  (Jr.Executive - Q.C.) Ms.Krishna Patel	<b>Checked by</b>  (Sr.Manager- Q.C.) Mr.Machindra Mungase	<b>Approved by</b>  (Sr.Manager - Q.A.) Mr.Hemant Patel
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Page No. 2 of 3

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Sr. No.	Test	Observation	Specification
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	0.03% w/w	Not more than 0.20% w/w
	Impurity D	Below Quantification Limit	Not more than 0.15% w/w
	Impurity E	Below Detection Limit	Not more than 0.10% w/w
	Impurity F	Below Quantification Limit	Not more than 0.10% w/w
	Unspecified impurities	Below Disregard Limit	Not more than 0.10% w/w
	Total impurities	0.07% w/w	Not more than 0.5% w/w
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	0.04% w/w	Not more than 0.1% w/w
10	Assay (By Potentiometrically)	99.3% w/w	Not less than 98.5% w/w and Not more than 101.0% w/w (Calculated on dried basis)

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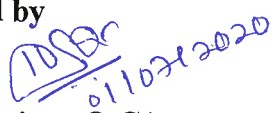


Page No. 3 of 3

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Sr. No.	Test	Observation	Specification
<b>Additional In house tests:</b>			
11	Residual Solvents (By GC-HS):		
	Methanol	188 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	Below Quantification Limit	Not more than 5000 ppm
	Methyl Acetate	Below Detection Limit	Not more than 5000 ppm
12	Furfurylamine Content (By GC)	Not detected	Not more than 1000 ppm
13	Furfuraldehyde Content (By GC)	Not detected	Not more than 1500 ppm
14	Bulk Density:		
	Untapped density	0.35 gm/ml	For Record
	Tapped density	0.56 gm/ml	For Record
15	Particle size	100.0% passing through 40 mesh	For Record

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

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