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Format No. QCD/021/F.01.02

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CERTIFICATE OF ANALYSIS

Product Name: FUROSEMIDE	**Batch Number:** I0028879
Compendia: EP	**Batch Quantity:** 511.560 kg
Mfg. Date: 06-MAR-2018	**Retest Date:** 05-MAR-2023
Date of Analysis: 07/03/2018	**Date of Release:** 17/03/2018
A. R Number: FP/18/0048	**Page 1 of 2**

Storage Condition: - Preserve in well-closed, light resistant container. Store at 25°C, excursions permitted between 15°C to 30°C

Sr.No.	Test	Results	Specification
1	Appearance	Almost white crystalline powder.	A white or almost white crystalline powder.
2	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 hydroxide.
3	Polymorphism test by DSC.	Complies	DSC pattern of sample should be concordant with that of the standard pattern
4	# Identification First Identification B Second Identification A,C		
	A) By UV	NA	0.52 to 0.57
	B) By IR	Complies	Should be comparable with Furosemide working standard.
	C) By Color Test	NA	Formation of a red to red-violet color.
5	Appearance of solution	Complies	The solution is clear and not more intensely colored than reference solution BY5.
6	Related Substances		
	Impurity C	BQL	NMT 0.2%
	Impurity D	BDL	NMT 0.15%
	Unspecified Impurities	BDL	NMT 0.10%
	Total Impurities	BQL	NMT 0.5 %
7	Chlorides	Less than 200 ppm	NMT 200 ppm
8	Sulphates	Less than 300 ppm	NMT 300 ppm
9	Loss on drying At 105 °C ± 2°C	0.30 % w/w	NMT 0.5% w/w
10	Sulphated Ash	0.07 % w/w	NMT 0.1% w/w

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Vaibhav Raskar officer 17/03/18	Arjun Gapat Asst. Manager 17/03/18	Sachin Jawale Executive 17/03/18	Sudhan Kuchekar Sr. Executive 17/03/18
Quality Control	Quality Control	Quality Assurance	Quality Assurance

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Sr.No.	Test	Results	Specification
11	Assay by Potentiometry (On Dried Basis)	100.0 % w/w	98.5% to 101.0% w/w
12	*Additional Tests		
12.1	Foreign Particle	Complies	10gm sample dissolve in 100mL to 120mL acetone and filtered through 0.45µ filter paper. NMT 5 black particles on filter paper.
12.2	Residual EDTA (In-house specification)	Less than 200 ppm	NMT 200 ppm
12.3	Bulk Density 1) Untapped 2) Tapped (By 50 strokes)	 0.26 gm/mL 0.37 gm/mL	 Informative Informative
12.4	Particle size (By sieve method)	Complies	100% passing through 40 mesh

*Additional tests determined as per in-house requirement.

If identification test by IR has been done then there is no need to perform by UV & Color test.

- **BQL** – Below Quantification Limit (Quantification Limit is 0.05%)
- **BDL**– Below Detection Limit (Detection Limit is 0.02%)
- **NA** – Not Applicable.
- **Remarks:** - The product Complies as per EP 9.2 Specification.

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