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Albany Molecular Research Hyderabad Research Centre Private Limited Unit-2,
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CERTIFICATE OF ANALYSIS

Product Name : FUROSEMIDE	**Batch Number :** I0049829
Compendia: EP	**Batch Quantity:** 512.750 Kg
Mfg. Date : 21-AUG-2019	**Retest Date :** 20-AUG-2024
Date of Analysis : 31/08/2019	**Date of Release :** 05/09/2019
A.R Number : FP/19/0202	**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 A) By TLC	NA	Result A: The principle 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 Result B: The principle 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 solution.
	B) By IR	Complies	Should be comparable with furosemide working standard.
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	BQL	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

Prepared By /Date	Approved By / Date
Arjun Gapat Asst. Manager 27/11/19	Dr. Rohidas Gilbile AGM 27/11/19
Quality Control	**Quality Assurance**

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Sr.No.	Test	Results	Specification
9.	Loss on drying At 105 °C ± 2°C	0.35 % w/w	NMT 0.5% w/w
10.	Sulphated Ash	0.06 % w/w	NMT 0.1% w/w
11.	Assay by Potentiometry (On Dried Basis)	99.8 % 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 g/mL 0.37 g/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 no need to perform by TLC 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 Specification.
  We certify that the material manufactured in our factory, address - Albany Molecular Research Hyderabad Research Centre Private Limited Unit-2, G-1/1, 1/2, MIDC, Waluj, Aurangabad is as per process described in the certificate of suitability. We also certify that the quality of the material complies according to the certificate of suitability (COS No.: R1-CEP 1999-069-REV 08) of the monographs of the European Pharmacopoeia.

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Arjun Gapat Asst. Manager 27/11/19	Dr. Rohidas Gilbile AGM 27/11/19
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