

Format No. QCD/021/F.01.02

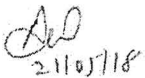
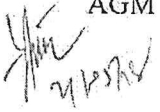
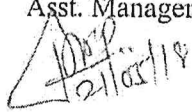
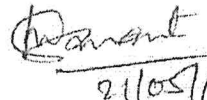
AMRI, India Pvt. Ltd. | G1/1, G1/2, MIDC area, Waluj, Aurangabad-431 135, India
T: +91-240-6658626 / 6658606 | www.amriolab.com

CERTIFICATE OF ANALYSIS

Product Name : FUROSEMIDE	Batch Number : I0032746
Compendia: EP	Batch Quantity: 510.350 kg
Mfg. Date : 09-MAY-2018	Retest Date : 08-MAY-2023
Date of Analysis : 11/05/2018	Date of Release : 18/05/2018
A.R Number : FP/18/0095	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 UV B) By IR	NA Complies	0.52 to 0.57 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	0.05%	NMT 0.15%
	Unspecified Impurities	BDL	NMT 0.10%
	Total Impurities	0.05 %	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	0.32 % 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)	99.4 % 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.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Arjun Gapat Asst. Manager  21/05/18	Rohidas Gilbile AGM  21/05/18	Prashant Joshi Asst. Manager  21/05/18	Hemant Udawant AGM  21/05/18
Quality Control	Quality Control	Quality Assurance	Quality Assurance



Complex Science. Expert Solutions.

Format No. QCD/021/F.01.02

AMRI, India Pvt. Ltd. | G1/1, G1/2, MIDC area, Waluj, Aurangabad-431 136, India
T: +91-240-6658626 / 6658606 | www.amriglobal.com

CERTIFICATE OF ANALYSIS

T: +91-240-6658626 / 6658606 | www.amriglobal.com

CERTIFICATE OF ANALYSIS			
Product Name : FUROSEMIDE		Batch Number : I0032746	
Compendia: EP		Batch Quantity: 510.350 kg	
Mfg. Date : 09-MAY-2018		Retest Date : 08-MAY-2023	
Date of Analysis : 11/05/2018		Date of Release : 18/05/2018	
A.R Number : FP/18/0095		Page 2 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

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)	0.25 gm/mL 0.35 gm/mL	Informative Informative
12.4	Particle size (By sieve method)	Complies	100% passing through 40 mesh

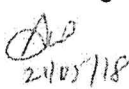
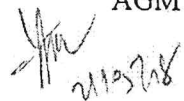
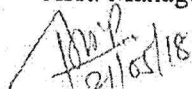
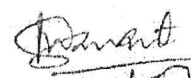
*Additional tests determined as per in-house requirement.

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

• BQL – Below Quantification Limit (Quantification Limit is 0.05%)

• BDL– Below Detection Limit (Detection Limit is 0.02%)

• Remarks: - The product Complies as per EP 9.0 Specification.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Arjun Gapat Asst. Manager  21/05/18	Rohidas Gilbile AGM  21/05/18	Prashant Joshi Asst. Manager  21/05/18	Hemant Udawant AGM  21/05/18
Quality Control	Quality Control	Quality Assurance	Quality Assurance