AMRI®
Albany Molecular Research Inc.

AMRI India Private Limited
Factory / Office : Plot No. G-1/1, 1/2, Near MIDC Water Tank, MIDC Area, Waluj, Aurangabad, India -431 136
t : +91-240-2554006 / 2564456, www.amriglobal.com

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Type: Dispatch for Metapharmaceutical IND.S.L.	**Page:** 1 of 2
Product Name: FUROSEMIDE	**Batch Number:** AM20214088
Compendia: EP	**Quantity:** 475 Kg.
Mfg. Date: SEP-2014	**Retest Date:** AUG-2019
Date of Sampling: 30/09/2014	**Date of Analysis:** 30/09/2014
Date of Release: 09/10/2014	**A.R Number:** FPF/14/126

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 X-Ray Diffraction	Complies	XRD Diffractogram pattern of sample should be concordant with that of the standard pattern
4.	Identification		
	A) By UV	0.53	0.52 to 0.57
	B) By IR	Complies	Should be comparable with Furosemide working standard.
	C) By Color Test	Formation of red-violet color	Formation of a red to red-violet color.
5.	Related Substances		
	Impurity C	BDRL	NMT 0.2%
	Impurity D	BDRL	NMT 0.15%
	Unspecified Impurities	BDRL	NMT 0.10%
	Total Impurities	BDRL	NMT 0.5 %

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
11/10/2014	11/10/2014	11/10/14	11/10/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance

AMRI®
Albany Molecular Research Inc.

AMRI India Private Limited
Factory / Office : Plot No. G-1/1, 1/2, Near MIDC Water Tank, MIDC Area, Waluj, Aurangabad, India -431 136
t : +91-240-2554006 / 2564456, www.amriglobal.com

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Type: Dispatch for Metapharmaceutical IND.S.L.	**Page:** 2 of 2
Product Name: FUROSEMIDE	**Batch Number:** AM20214088
Compendia: EP	**Quantity:** 475 Kg.
Mfg. Date: SEP-2014	**Retest Date:** AUG-2019
Date of Sampling: 30/09/2014	**Date of Analysis:** 30/09/2014
Date of Release: 09/10/2014	**A.R Number:** FPF/14/126

Sr. No.	Test	Results	Specification
6.	Chlorides	Less than 200 ppm	NMT 200 ppm
7.	Sulphates	Less than 300 ppm	NMT 300 ppm
8.	Heavy Metals	Less than 20 ppm	NMT 20 ppm
9.	Loss on drying At 105 °C ± 2°C	0.25 % w/w	NMT 0.5 % w/w
10.	Sulphated Ash	0.04 % w/w	NMT 0.1 % w/w
11.	Assay by Potentiometry (ODB)	99.84 % w/w	98.5% to 101.0 % w/w
12.	*Additional Tests		
12.1	Foreign Particle	No black particles observed on filter paper	10gm sample dissolve in 100ml 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)	0.23 gm/mL 0.31 gm/mL	Informative
12.4	Particle size	100% sample passes through 40 mesh	100% passing through 40 mesh

*Additional tests determined as per in-house requirement.

- **BDRL** – Below Disregard Limit (Disregard Limit is 0.05% as per EP 8.0)
- **Remarks:-** The product Complies as per EP specification

We certify that the material manufactured in our factory, address - AMRI India Pvt. Ltd. G-1/1, MIDC, 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 05) of the monographs of the European Pharmacopoeia.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
11/10/2014	11/10/2014	11/10/14	11/10/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance