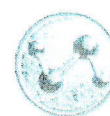




AMRI[®]
Albany Molecular Research Inc.

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 3														
Product Name: FUROSEMIDE	Batch Number: AM20213004A														
Compendia: EP	Quantity: 50 KG														
Mfg. Date: JAN -2013	Retest Date: DEC-2017														
Date of Sampling: 29/01/2013	Date of Analysis: 29/01/2013														
Date of Release: 09/02/2013	A.R Number: FPF/13/039														
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 solution 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	0.56	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 red to red-violet color.												
5.	Related Substances by HPLC														
	Impurity C	BDRL	NMT 0.2%												
	Impurity D	BDRL	NMT 0.15%												
	Unspecified Impurity	BDRL	NMT 0.10%												
	Total Impurities	BDRL	NMT 0.5 %												
<table border="1"> <thead> <tr> <th>Prepared By /Date</th> <th>Checked By / Date</th> <th>Reviewed By / Date</th> <th>Approved By / Date</th> </tr> </thead> <tbody> <tr> <td> 09/10/2014</td> <td> 09/10/2014</td> <td> 09/10/2014</td> <td> 09/10/2014</td> </tr> <tr> <td>Quality Control</td> <td>Quality Control</td> <td>Quality Assurance</td> <td>Quality Assurance</td> </tr> </tbody> </table>				Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date	 09/10/2014	 09/10/2014	 09/10/2014	 09/10/2014	Quality Control	Quality Control	Quality Assurance	Quality Assurance
Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date												
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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Type: Dispatch for Metapharmaceutical IND.S.L.	Page: 2 of 3		
Product Name: FUROSEMIDE	Batch Number: AM20213004A		
Compendia: EP	Quantity: 50 KG		
Mfg. Date: JAN -2013	Re-test Date: DEC-2017		
Date of Sampling: 29/01/2013	Date of Analysis: 29/01/2013		
Date of Release: 09/02/2013	A.R Number: FPF/13/039		
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	0.32 % w/w	NMT 0.5% w/w
10.	Sulphated Ash	0.06 % w/w	NMT 0.1% w/w
11.	Assay by Potentiometry (ODB)	99.52 % 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 observed 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 0.36 gm/mL	Informative
12.4	Particle size (By sieve method)	100% sample pass through 40 mesh	100% passing through 40 mesh
Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
<i>Juno</i> 09/10/2014	<i>Devi</i> 09/10/2014	<i>Gf</i> 09/10/2014	<i>Sh</i> 09/10/14
Quality Control	Quality Control	Quality Assurance	Quality Assurance

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QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Type: Dispatch for Metapharmaceutical IND.S.L.	Page: 3 of 3
Product Name: FUROSEMIDE	Batch Number: AM20213004A
Compendia: EP	Quantity: 50 KG
Mfg. Date: JAN -2013	Retest Date: DEC-2017
Date of Sampling: 29/01/2013	Date of Analysis: 29/01/2013
Date of Release: 09/02/2013	A.R Number: FPF/13/039

Sr. No.	Test	Results	Specification
12.5	Particle size (By instrument method)	10 % particles less than 0.991 μm 50 % particles less than 2.372 μm 90 % particles less than 4.26 μm 100 % particles less than 10.93 μm	For Informative

*Additional tests determined as per in-house requirement.

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

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.: RI-CEP 1999-069-REV 05) of the monographs of the European Pharmacopoeia.

Prepared By / Date	Checked By / Date	Reviewed By / Date	Approved By / Date
 09/10/2014	 09/10/2014	 09/10/2014	 09/10/2014
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