



**Sri Krishna Pharma**  
Trusted partners for life's journey

## CERTIFICATE OF ANALYSIS

QUALITY CONTROL DEPARTMENT

COA RELEASE DATE: 14/04/2023

Product : **FUROSEMIDE EP**

Batch No. : RF-0323511

Batch size : 100.00 KG

A.R. No. : FP-RF-517/23

Specification No.: QC/SP/FP/FUR/014-05

Date of Manufacture: FEB.2023

Retest Date : JAN.2028

Date of Analysis : 23/03/2023

Sr. No.	TESTS	SPECIFICATIONS	RESULTS
01	Appearance	White or almost white, crystalline powder.	Almost white crystalline powder.
02	Solubility	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute solution of sodium hydroxide	Complies
03	Polymorphism	The XRD pattern of sample should comply with XRD pattern of furosemide standard	Complies
04	IDENTIFICATION (First Identification: B, Second identification: A)		
A)	By TLC Method (2.2.27)	The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution when examined under ultraviolet light at 254nm.	Complies
B)	By IR Spectroscopy (2.2.24)	Sample spectrum should be concordant with the standard spectrum	Complies
05	Appearance of solution (2.2.1 & 2.2.2 Method II)		
	a) Clarity test	The opalescence produced in test solution should be clear than the reference solution	Complies
	b) Colour test (BY5)	The test solution not more intensely colored than reference solution BY5	Complies
06	Chlorides (2.4.4)	Not more than 200 ppm	Less than 200 ppm
07	Sulfates (2.4.13)	Not more than 300 ppm	Less than 300 ppm
08	Loss on drying (at 105°C) (2.2.32)	Not more than 0.5%	0.1%
09	Sulfated ash (2.4.14)	Not more than 0.1%	0.02%

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### **Sri Krishna Pharmaceuticals Limited**

Corporate Office : C-4, Industrial Area, Uppal Khalsa (V), Uppal (M), Medchal-Malkajgiri (Dist.), Hyderabad - 500 039, Telangana, India.

Tel : +91 40 2720 1101-02/2720 0103-04/2720 4471-72

Fax : +91 40 2720 4470

Email : skg@srikrishnapharma.com

### **Unit - IV**

Factory : Survey No. 296/7/10, IDA Bollaram, Jinnaram Mandal, Sanga Reddy Dist. - 502 325. Telangana, India.

Tel : +91 8458 279296 Fax : +91 8458 279295

Web : www.srikrishnapharma.com

CIN No. : U24230 TG1974 PLC001790



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10	Related substances by HPLC (2.2.29)		
A)	2-amino-4-chloro-5-sulfamoylbenzoic acid (Impurity-C)	Not more than 0.2%	0.04%
B)	2,4-bis[(furan-2-ylmethyl)amino]-5-sulfamoylbenzoic acid (Impurity- D)	Not more than 0.15%	0.03%
C)	Unspecified impurities	Not more than 0.10%	Below disregard limit
D)	Total Impurities	Not more than 0.5%	0.06%
11	ASSAY by HPLC (On Dried Basis) [As per USP]	98.5% to 101.0%	99.4%
12	ADDITIONAL TESTS		
A)	Residual solvent		
	Acetic acid (By Loss On Drying)(2.2.32)	Not more than 0.5%	Less than 0.5%
B)	Microbiology Tests		
	Total Aerobic Microbial count	Not more than 100 cfu/g	Less than 10cfu/g
	Total Yeast & Mould Count	Not more than 10 cfu/g	Less than 10cfu/g
	E- Coli	Should be Absent	Absent
	Salmonella	Should be absent	Absent
	Pseudomonas aeruginosa	Should be absent	Absent
	S. Aureus	Should be absent	Absent

**Remarks:** The sample complies with the above specifications.

**Storage Conditions:** Preserve in well-closed, light resistant containers. Store at 25°C, excursions permitted between 15°C and 30°C.

### **Certificate of Suitability:**

Certificate of suitability:

Certificate No: R1-CEP 1999-137-Rev 08 granted by the European Directorate for the Quality of Medicines is renewed from 20 Aug 2021

Manufacturing Place:

**SRI KRISHNA PHARMACEUTICALS LIMITED**

Unit IV, Survey No. 296/7/10

I.D.A., Jinnaram Mandal, Sangareddy District

India-502 325 Bollaram, Telangana

Certified that the Quality is in accordance with the certificate of suitability of the monographs of the European Pharmacopoeia and the material manufactured is as per the process described in the COS

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**Contract laboratory test details:**

Test No	Test Name	Contract test lab details	AR No./Certificate number
03	XRD	STAR TECH LABS	ST/09/009/C/23
12 B)	Microbiology Tests	SKPL UNIT-I	NA

*URB*  
*14/04/23*  
**COMPILED BY**

*W*  
*14/04/23*  
**CHECKED BY**

*Det*  
*14/04/23*  
**APPROVED BY**

**ISSUED TO: M/s. NA Qty.: NA**

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