

### **CERTIFICATE OF ANALYSIS**

### **QUALITY CONTROL DEPARTMENT**

**COA ISSUED DATE: 30/11/2024** 

Date of Manufacture: AUG, 2024

: JUL.2029

**Retest Date** Date of Analysis

: 06/09/2024

<b>Batch size</b>	•	131.00 KG
A.R. No.	:	FP-RF-064/24

Product : FUROSEMIDE EP Batch No.: RF-0824052

Specification No.: QC/SP/FP/FUR/014-07

Sr. Vo.	TESTS	SPECIFICATIONS	RESULTS					
01	Appearance	White or almost white Crystalline powder	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 alkali hydroxides	Complies					
	Identification: First Identifica	tion: B, Second identification: A	Lancon on account of the contract of the contr					
	A) Thin-layer chromatography							
03	Results-A	The principle spot in the chromatogram obtained with the test solution is similar in position and size to the principle spot in the chromatogram obtained with the reference solution.	Complies					
	Results-B	The principle spot in the chromatogram obtained with the test solution is similar in position, color and size to the principle spot in the chromatogram obtained with the reference solution.	Complies					
	B) Infra-red absorption spectrophotometry	Sample spectrum should be concordant with the standard spectrum	Complies					
04	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 (With BY5)	The test solution not more intensely colored than the reference solution BY5	Complies					
05	Chlorides	Not more than 200 ppm	Less than 200 ppm					
06	Sulphates	Not more than 300 ppm	Less than 300 ppm					
07	Loss on drying	Not more than 0.5%	0.1%					
08	Sulfated ash	Not more than 0.1%	0.03%					

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

Email: skg@srikrishnapharma.com

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

Tel: +91 8458 279296 / +91 8458 279295 Web: www.srikrishnapharma.com CIN No.: U24230TG1974PLC001790



Batch No.: RF-0824052

Batch size: 131.00 KG

Product

# METAPHARMACEUTICAL

N DE LOTE:

0171224

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: FUROSEMIDE EP

Sr. No.	TESTS	SPECIFICATIONS	RESULTS			
09	Related substances by HPLC (2.2.29)					
	Impurity-C [2-amino-4-chloro-5- sulfamoylbenzoic acid]	Not more than 0.2%	0.1%			
	Impurity-D [2,4-bis[(furan-2-ylmethyl) amino]- 5-sulfamoylbenzoic acid]	Not more than 0. 15%	0.03%			
	Unspecified impurity	Not more than 0.10%	Below Disregard Limit			
	Total Impurities	Not more than 0.5%	0.1%			
10	ASSAY by HPLC (On Dried Basis) [As per USP]	98.5% to 101.0%	100.0%			
11	Additional Tests					
	Residual solvents					
	Acetic acid (By Loss On Drying)	Not more than 0.5%	Less than 0.5%			

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 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 by:

SRI KRISHNA PHARMACEUTICALS LIMITED

Unit IV, Survey No. 296/7/10

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

Bollaram-502 325, Telangana, India.

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 Contract laboratory test details: NA

Issued to: M/s. META PHARMA, Qty.: 25.00 Kg

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