METAPHARMACEUTICAL

N DE LOTE:
0191223

29/12/2023

Sri Krishna Pharma
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CERTIFICATE OF ANALYSIS

QUALITY CONTROL DEPARTMENT

COA ISSUED DATE: 14/12/2023

Product : **FUROSEMIDE EP**
Batch No. : RF-0823546
Batch size : 169.00 KG
A.R. No. : FP-RF-552/23
Specification No.: QC/SP/FP/FUR/014-06

Date of Manufacture: AUG.2023
Retest Date : JUL.2028
Date of Analysis : 11/09/2023

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	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
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 (BY5)	The test solution not more intensely colored than the reference solution BY5	Complies
05	Chlorides (2.4.4)	Not more than 200 ppm	Less than 200 ppm
06	Sulfates (2.4.13)	Not more than 300 ppm	Less than 300 ppm
07	Loss on drying (at 105°C) (2.2.32)	Not more than 0.5%	0.1%
08	Sulfated ash (2.4.14)	Not more than 0.1%	0.02%
09	Related substances by HPLC (2.2.29)		
A)	2-amino-4-chloro-5-sulfamoylbenzoic acid (Impurity-C)	Not more than 0.2%	0.03%
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%	0.1%

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

Unit - IV
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

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QUALITY CONTROL DEPARTMENT

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Sr. No.	TESTS	SPECIFICATIONS	RESULTS
10	ASSAY by HPLC (On Dried Basis) [As per USP]	98.5% to 101.0%	99.8%
11	ADDITIONAL TESTS		
A)	Residual solvent		
	Acetic acid (By Loss On Drying)(2.2.32)	Not more than 0.5%	Less than 0.5%

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

Contract laboratory test details: NA

14/12/23 — **COMPILED BY**

14/12/23 — **CHECKED BY**

14/12/23 — **APPROVED BY**

ISSUED TO: M/s. META PHARMA, Qty.: 25.00 Kg

Sri Krishna Pharmaceuticals Limited
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