



**CERTIFICATE OF ANALYSIS**

QUALITY CONTROL DEPARTMENT

COA RELEASE DATE:24/07/2020

Product : **FUROSEMIDE USP 42**  
Batch No. : RF-0620020  
Batch size : 160.00 KG  
A.R. No. : FP-FM-094/20  
Specification No.: QC/SP/FP/FUR/003-01

Date of Manufacture : JUN.2020  
Expiry Date : MAY.2025  
Date of Analysis : 18/07/2020

Sr.No.	TESTS	SPECIFICATIONS	RESULTS
01	DESCRIPTION	white to slight yellow, odorless crystalline powder.	Almost white crystalline powder.
02	SOLUBILITY	Practically insoluble in water, freely soluble, in acetone, in Dimethyl formamide, and in solutions of alkali hydroxides. Soluble in methanol, sparingly soluble in alcohol, slightly soluble in ether, very slightly soluble in chloroform.	Complies
03	IDENTIFICATION		
A)	Infra-red spectroscopy	Sample spectrum should be concordant with the standard spectrum.	Complies
B)	By UV spectrum	The UV Spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	Complies
C)	By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies
04	LOSS ON DRYING (731)	Not more than 0.5%	0.12%
05	RESIDUE ON IGNITION(281)	Not more than 0.1%	0.02%
06	RELATED COMPOUNDS BY HPLC		
A)	Sum of the peak areas of the peaks eluting before Furosemide at 254nm:	Not more than the area of Furosemide Related Compound B Peak at 254 nm from Standard Solution (NMT 0.5%) Not more than 0.5%	0.03%
B)	Sum of the peak areas of the peaks eluting after the Furosemide at 272nm:	Not more than the area of Furosemide Related Compound A Peak at 272 nm from Standard Solution (NMT 0.5%) Not more than 0.5%	0.05%
07	Assay by HPLC (On Dried Basis)	98.0% to 102.0%	100.8%

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08	RESIDUAL SOLVENTS BY HSGC		
	Methylene chloride	Not more than 600ppm	27ppm
09	RELATED SUBSTANCE BY HPLC AS PER EP		
A)	<b>Impurity-C</b> (2-amino-4-chloro-5-sulfamoyl benzoic acid )	Not more than 0.2 %	0.03%
B)	<b>Impurity- D</b> (2,4-bis[(furan-2-ylmethyl)amino]5-sulfamoylbenzoic acid )	Not more than 0.15 %	0.03%
C)	<b>Unspecified impurities</b>	Not more than 0.10 %	Below Disregards Limit
D)	<b>Total Impurities</b>	Not more than 0.5 %	0.06%
10	MICROBIOLOGY TESTS		
a)	Total Aerobic Microbial Count	Not more than 100 cfu/g	10 cfu/g
b)	Total Yeast And Mould Count	Not more than 10 cfu/g	Less than 10 cfu/g
c)	Escherichia-Coli	Should be absent/g	Absent
d)	Salmonella	Should be absent/10 g	Absent
e)	Pseudomonas aeruginosa	Should be absent/g	Absent
f)	Staphylococcus aureus	Should be absent/g	Absent

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

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

**Certificate of Suitability:** NA

**Contract laboratory test details:**

Test No	Test Name	Contract test lab details	AR No./Certificate number
03(B)	By IR absorption	TEENA BIO LABS PVT.LTD	TLR/06/30005/20
10	Microbiology Tests	SKPL UNIT-I	NA

COMPILED BY

CHECKED BY

APPROVED BY

ISSUED TO: M/s. VENUS INTERNATIONAL INC Qty: 160 Kg

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