



ALIVIRA

**ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS**

FLUNIXIN MEGLUMINE USP

Batch No.	ASA000700A	Quantity	50.00 Kg
Manufacturing Date	July-2018	Retest / Expiry Date	June- 2022
A.R.NO.	ALIV-FP-180363	Lot No.	40000016582
Storage Condition	Preserve in well closed containers, store at 25°C, excursions permitted between 15°C - 30°C.		
Customer Name	LGM PHARMA,LLC		

S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
1	Description	White or almost white crystalline powder.	White crystalline powder
2	Solubility	Freely soluble in water and in Methanol.	Complies
3	Identification by IR	The infrared absorption spectrum of sample matches with spectrum obtained from	Complies
4	Identification by HPLC	The retention time of the major peak of the sample solution should correspond to that of the standard solution as obtained in the Assay.	Complies
5	Specific Optical rotation	-9.0° - 12.0° (Dried substance)	-9.8°
6	Appearance of solution	Test solution should be clear and not more intensely coloured than Y7	Complies
7	pH	7.0 - 9.0 (5.0% w/v solution in water)	8.2
8	Related substance by HPLC Impurity A Impurity B Impurity C Impurity D Unspecified impurity Total impurities	Not more than 0.20% Not more than 0.20% Not more than 0.20% Not more than 0.20% Not more than 0.20% Not more than 0.50%	Not detected Not detected Not detected Not detected 0.03% 0.03%
9	Chromatographic purity by TLC Individual impurity Total impurities	Not more than 0.2% Not more than 0.5%	Less than 0.2% Less than 0.5%
10	Loss on drying	Not more than 0.5% w/w	0.20% w/w
11	Sulphated ash	Not more than 0.10% w/w	0.04% w/w

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Executive-QC	Head-QC	Head-QA
SIGNATURE			
DATE	08/08/2018	08/08/2018	08/08/2018

Format No.: QA/039/FMT-002/R1

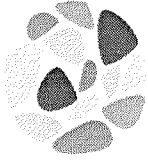
Alivira Animal Health Ltd.

Corporate off & Regd.Off: 301, 3rd Floor, Dosti Pinnacle, Plot No.E7, Road No.22, Wagle Indl. Estate, Thane (W), Mumbai-400604. India. T +91 22 41114777 F +91 22 41114754

Factory : Plot No. 104 to 109, Part of 112 & 113, JNPC – SEZ, Parawada Mandal, Visakhapatnam-531 019. A.P., India. Tel.: +91 08924 – 660888

Plot No.A-68, M.I.D.C., Additional Ambarnath, Ambarnath (EAST)-421 506, Tel.: +91 0251 – 2621155, 2621159

Email : info@alivira.in www.alivira.in CIN : U74120MH2013PLC248708



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S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
12	Assay by titration ODB	99.0% to 101.0%	100.2%
13	Assay by HPLC on as is basis	98.0% to 102.0%	99.5%
14	Residual solvents Methanol Methylene chloride Isopropyl alcohol	Not more than 3000 ppm Not more than 600 ppm Not more than 5000 ppm	50 ppm Not detected 259 ppm
15	Palladium Content by AAS	Not more than 1 ppm	BDL(LOD:0.007ppm)
Remarks : The above batch Complies as per the Specification No: FLMF/01A/FP/R3			

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