N DE LOTE: 0070323 10/03/2023

Mangalam Drugs and Organics Limited F&A PHARMA

Unit II: Plot No. 1203, 3rd Phase, G. I. D. C., VAPI, Dist Valsad - 396195 (Gujarat) ☎ 91 - 0260 - 2432669 / 07490052669
☎ 91 - 0260 2432669 / 2424970 ✉ mdol2@mangalamdrugs.com • CIN : L24230MH1972PLC116413

CERTIFICATE OF ANALYSIS

Name of the Material: Nitrofurantoin Ph. Eur.			
Mfg. License No.	G/1315	**CAS No.**	67-20-9
Batch No.	NTFA-2B-221003	**Batch Size**	365.00 Kg
Mfg. Date	October-2022	**Retest Date**	September-2025
Received Date	22/11/2022	**Release Date**	26/11/2022
A. R. No.	NTFA-22/04		
Storage Conditions	Store protected from light, at a temperature below 25°C		

RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
01	Description	A yellow crystalline powder	A yellow crystalline powder or yellow crystals.
02	Solubility	Complies	Very slightly soluble in water and in ethanol (96 per cent), soluble in dimethyl formamide.
03	Identification test:		
	A. By UV	Complies	The ratio of the absorbance at the maximum at 367 nm to that at the maximum at 266 nm is 1.36 to 1.42.
	B. Colour development	Complies	A brown colour develops.
04	Loss on drying (at 105°C)	0.35% w/w	Not more than 1.0 % w/w
05	Sulphated ash	0.04% w/w	Not more than 0.1 % w/w
06	Related substance (By TLC)	Complies	Any spot in the chromatogram obtained with the test solution, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with the reference solution (1.0 percent).
07	Assay (By UV)	99.5%	Not less than 98.0 per cent and not more than 102.0 per cent of $C_8H_6N_4O_5$, calculated on dried basis.
Additional In-House Tests:			
08	Nitrofurazone content (By HPLC)	Not Detected	Not more than 0.01 % w/w

Prepared by	**Checked by**	**Approved by**
01/02/2023	01/02/2023	01/02/2023
(Jr.Executive - Q.C.)	**(Sr.Manager - Q.C.)**	**(Sr.Manager - Q.A.)**
Ms.Krishna Patel	**Mr.Machindra Mungase**	**Mr.Chetan Sarda**

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RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
09	Related substance (By HPLC):		
	Single largest impurity	Below Disregard Limit	Not more than 0.10 %
	Total impurities	Below Disregard Limit	Not more than 1.0 %
10	Residual solvents:		
	A) By GCHS:		
	Isopropyl alcohol	322 ppm	Not more than 5000 ppm
	Isopropyl acetate	Not detected	Not more than 5000 ppm
	B) By HPLC:		
	Acetic acid	Not detected	Not more than 5000 ppm
11	Bulk Density:		
	Untapped density	0.63 g/ml	For Record
	Tapped density	0.77 g/ml	For Record
12	Particle size (By sieve)	100% passing through 40 mesh	For Record

Remark: The material **Complies** as per Ph. Eur. and In-House specification.
Note: This COA is generated for F & A Pharma.

METAPHARMACEUTICAL
N DE LOTE:
0070323

10/03/2023

COPY QA APPROVED
Date 06.03.23
Signature
F&A PHARMA-Handels GmbH

Prepared by	**Checked by**	**Approved by**
10/02/2023	01/02/2023	01/02/2023
(Jr.Executive - Q.C.)	**(Sr.Manager - Q.C.)**	**(Sr.Manager - Q.A.)**
Ms.Krishna Patel	**Mr.Machindra Mungase**	**Mr.Chetan Sarda**