

METAPHARMACEUTICAL

N DE LOTE:

0080724

09/07/2024

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 @ mdpl2@mangalamdrugs.com • CIN : L24230MH1972PLC116413



CERTIFICATE OF ANALYSIS

Page No. 1 of 3

Name of the Material: Nitrofurantoin Macrocrystals Ph. Eur.			
Mfg. License No.	G/1315	CAS No.	67-20-9
Batch No.	NTFM-2B-241001	Batch Size	310.00 Kg
Mfg. Date	May-2024	Retest Date	April-2028
Received Date	19/05/2024	Release Date	31/05/2024
A. R. No.	NTFM-24/02		
Storage Conditions	Store protected from light, at 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:		
	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.
	Test-B: Colour development	Complies	A brown colour develops
04	Loss on drying (At 105°C)	0.36% w/w	Not more than 1.0 % w/w
05	Sulfated 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)	100.3%	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.

Prepared by (Jr.Executive - Q.C.) Ms.Krishna Patel	Checked by (Sr.Manager - Q.C.) Mr.Hemant Patel	Approved by (Sr.Manager - Q.A.) Mr.Chetan Sarda
--	--	---



CERTIFICATE OF ANALYSIS

Page No. 2 of 3

Name of the Material: Nitrofurantoin Macrocrystals Ph. Eur.			
Mfg. License No.	G/1315	CAS No.	67-20-9
Batch No.	NTFM-2B-241001	Batch Size	310.00 Kg
Mfg. Date	May-2024	Retest Date	April-2028
Received Date	19/05/2024	Release Date	31/05/2024
A. R. No.	NTFM-24/02		
Storage Conditions	Store protected from light, at temperature below 25°C		

RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
Additional In-House Tests:			
08	Limit of Nitrofurazone (By HPLC)	Below Quantification Limit	Not more than 0.01 % w/w
09	Related substance (By HPLC):		
	Single largest Impurity	Below Disregard Limit	Not more than 0.10 % w/w
	Total impurities	Below Disregard Limit	Not more than 1.0 % w/w
10	Residual solvent:		
	Method-A: By GCHS:		
	Methanol	Not Detected	Not more than 3000 ppm
	Isopropyl alcohol	Not Detected	Not more than 5000 ppm
	Isopropyl acetate	Not Detected	Not more than 5000 ppm
	N,N-Dimethyl formamide	Not Detected	Not more than 880 ppm
	Method-B: By HPLC:		
	Acetic acid	Below Quantification Limit	Not more than 5000 ppm
11	Specific Surface Area	0.17 m ² /g	Between 0.045 and 0.20 m ² /g

Prepared by (Jr. Executive - Q.C.) Ms. Krishna Patel	Checked by (Sr. Manager - Q.C.) Mr. Hemant Patel	Approved by (Sr. Manager - Q.A.) Mr. Chetan Sarda
--	--	---



CERTIFICATE OF ANALYSIS

Page No. 3 of 3

Name of the Material: Nitrofurantoin Macrocrystals Ph. Eur.			
Mfg. License No.	G/1315	CAS No.	67-20-9
Batch No.	NTFM-2B-241001	Batch Size	310.00 Kg
Mfg. Date	May-2024	Retest Date	April-2028
Received Date	19/05/2024	Release Date	31/05/2024
A. R. No.	NTFM-24/02		
Storage Conditions	Store protected from light, at temperature below 25°C		

RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
12	Bulk density:		
	Untapped density	0.67 g/ml	For Record
	Tapped density	0.84 g/ml	For Record
13	Particle size (By sieve)	100% passing through 40 mesh	For Record
Additional test as per customer requirement:			
14	Particle Size (By Malvern)*	199 μ m	> 90% > 75 μ m

Remark: The material **Complies** as per Ph. Eur. and In-House specification.

Note: This COA is generated for F & A Pharma.

*: Test performed on 07/06/2024.



Prepared by (Jr. Executive - Q.C.) Ms. Krishna Patel	Checked by (Sr. Manager - Q.C.) Mr. Hemant Patel	Approved by 07/06/2024 (Sr. Manager - Q.A.) Mr. Chetan Sarda
--	--	---