济南金达药化有限公司
Jinan Jinda Pharmaceutical Chemistry Co.,Ltd.

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Certificate of Analysis

COA No.: P-2-202201008

Product Name: Nitrofurantoin EP10/USP43

BATCH NUMBER	JD-P-2-20211203	TEST DATE	December 26, 2021
BATCH SIZE	1000Kg	MANUFACTURE DATE	December 14, 2021
QUANTITY	1000Kg	RETEST DATE	December 13, 2025

ANALYSIS	SPECIFICATION	RESULT
Appearance (Visual)	A yellow, crystalline powder or yellow crystals, very slightly soluble in water and in ethanol, soluble in dimethylformamide.	Yellow crystalline powder
Identification A (EP)	The solution should show two absorbance maxima at 266 and 367nm. The ratio of the absorbance at the maximum at 367nm to that at the maximum at 266nm should be 1.36 to 1.42.	Conforms
Identification B (EP)	A brown colour develops on reaction with specified reagents.	Conforms
Identification C (USP)	The infra red spectra of the sample should correspond to that of the reference standard.	Conforms
Loss on drying (EP)	Not more than 1.0%.	0.060%
Sulfated ash (EP)	Not more than 0.1%.	0.03%
Related Compounds (HPLC) (In-house)		
5-Nitrofurfural Diacetate	Not more than 0.15%	0.086%
Nitrofurazone	Not more than 0.01%	<0.003%
Individual biggest unknown impurity	Not more than 0.10%	<0.003%
Total impurities	Not more than 0.5%	0.09%
Assay (EP)	98.0 to 102.0% (Calculated on the dried basis)	100.3%
Residual solvent (GC) (In-house)		
Methanol	Not more than 500ppm	<58ppm
Acetone	Not more than 500ppm	<18ppm
Particle Size (By Malvin Laser Particle Size Analyzer)		
D (50)	Perform and report	32 μm
D (90)	Perform and report	81 μm
Storage	Storage protected from light, at a temperature below 25°C.	

Lara William
Digitally signed by Lara William
Date: 2022.01.24 09:03:16 +01'00'

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Conclusion: This batch of product complies with above specification.

Prepared by QA: Wang Huijun Signed/ Date: 王慧君/2022.01.07

Reviewed by QA: Sun Yingwen Signed/ Date: 孙英文/2022.01.07

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, at the above-mentioned site(s) in full compliance with Guidelines in ICH Q7. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person: Song Dairen Signed/ Date: 宋代仁/2022.01.07