

杭州东瑞医药科技有限公司  
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Nitrofurantoin Macrocrystals

<b>Batch No.:</b> DR20140112	<b>Quantity:</b> 500kg
<b>Manufacture Date:</b> 2014.01.12	<b>Expiry Date:</b> 2017.01.11

**TESTS:**

Items	Specification	Results
Characteristics	Yellow crystalline Powder	Conforms
Identification	A. Infrared Absorption:Previously dried at 140°C for 30minutes. B. B.The retention time of the major peak in the chromatogmm of the Assay preparation conesponds to that in the chromatogram of the standard preparation, as obtained in the Assay.	Conforms Conforms
Loss on drying	≤1.0%	0.18%
Limit of Nitrofurfural Diacetate	≤1.0%	Conforms
Limit of Nitrofurazone	≤0.01%	Conforms
Assay	98.0%-102.0%.	99.52%.
Specific surface area	0.045 -0.20 m <sup>2</sup> /g	0.151 m <sup>2</sup> /g

Conclusion: The results conform with the USP35

Analyst: Joe Yu      Checker: Agnes Zhong      QA.Manager: Sun Wenhui



Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China  
Tel:+86-571- 85335020  
E-mail:agnes@dawnraypharma.com

Fax: +86-571- 85335020  
Website: <http://www.dawnraypharma.com/>