

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

CERTIFICATE OF ANALYSIS

Secnidazole

Batch No.: DR20130226	Quantity: 1000.0kg
Manufacture Date: 2013.02.26	Expiry Date: 2015.02.25

TESTS:

Items	Specification	Results
Description	A almost white or slightly yellowish crystalline powder	Conforms
Solubility	Freely soluble in ethanol,chloroform,methanol,glacial acetic acid,Soluble in 0.1N diluted hydrochloric acid,0.1N sodium hydroxide,sparingly soluble in water.	Conforms
Melting point	74~78°C	75.5~76.0°C
Identification	A:Chemical reaction:The solution to be examined gives positive chemical reactions. B:UV(water) Max 320nm,min 263nm UV(0.1mol/HCL) Max 276nm C:Infrared absorption: The spectrum obtained with the substance to be examined corresponds to that of the reference standard of secnidazole.	Conforms
Clarity and color of solution	The solution should be clear and colorless,if turbid,It should be not more intense than 0.5 reference turbidity solution;if coloration,it should be not more than reference solution GY3.	Conforms
Acidity and Alkalinity	5.5~7.5	6.8
Loss on drying	4.0%~6.0%	4.7%
Related substances(HPLC)	≤ 1.0%	0.4%
Heavy metals	≤ 10ppm	< 10ppm
Residue on ignition	≤ 0.1%	< 0.1%
Assay	≥98.5%(on dried basis)	99.8%

Conclusion: The results conform to In-house standard



Analyst: _____

Checker: _____

QA.Manager: _____

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