

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

CERTIFICATE OF ANALYSIS

Nifedipine

Batch No.: DR20131113	Quantity : 1000kg
measure of packing: height 35cm, diameter 40cm	Specification of packing: 25Kg cardboard drum
Manufacture Date: 2013.11.13	Expiry Date: 2017.11.12

TESTS:

Items	Specification	Results
Description	Yellow crystalline powder	Complies
Melting point	171°C~175°C	172.5°C~173.50°C
Heavy metals	≤0.001%	Complies
Sulphate ash	≤0.05%	0.034%
Chloride	≤0.02%	Complies
Loss on dry	≤0.5%	0.19%
Residue on ignition	≤0.1%	0.036%
Related compounds	Impurity A: ≤0.2% Impurity B: ≤0.2% Total impurities: ≤0.5%	Complies
Perchloric acid titration	≤0.12ml/g	0.10ml/g
Organic volatile impurities	Meets the requirements	Conforms
Assay(Dry)	98.0%~102.0%	99.85%

Conclusion: The results conform with USP32.

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