

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

CERTIFICATE OF ANALYSIS

Clarithromycin

<b>Batch No.:</b> DR20120805	<b>Piece:</b> 25kg
<b>Manufacture Date:</b> 2012.08.05	<b>Expiry Date:</b> 2015.08.04

**TESTS:**

Items	Specification	Results
Characteristics	White or almost white crystalline powder	Conforms
Identification	IR spectrum of the sample corresponds to that of the reference standard.	Conforms
Specific optical rotation(levo-compound)	-85° ~ -95°	-92.5°
Crystallinity	Meets the requirements	Conforms
PH	7.5~10.0	8.05
Water	≤ 2.0%	0.52%
Residue on ignition	≤ 0.3%	0.10%
Heavy metals	≤ 0.002%	Conforms
Residual solvents	Methanol: ≤3000ppm Ethanol: ≤5000ppm Methylene chloride: ≤600ppm	37ppm 13ppm 55ppm
Assay(HPLC)	96.0%~104.0%	96.68%

Conclusion: The results conform with USP28.



Analyst: \_\_\_\_\_

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