

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

CERTIFICATE OF ANALYSIS

Oxaliplatin

Batch No.: DR20140707	Piece: 25kg
Manufacture Date: 2014.07.07	Expiry Date: 2017.07.06
Inspection item: Total inspection	Package: polyethylene bag

TESTS:

Items	Specification	Results
Appearance	White or almost white,crystalline powder.	White , crystalline powder.
Identification IR	The positions and relative sizes of the bands in the spectrum of the sample are concordant with those in the spectrum of the Reference spectrum	Conforms
Identification Specific optical rotation	It conforms with the test for specific optical rotation.	Conforms
Appearance of solution	Clear and colorless	Conforms
Acidity	$\leq 0.6\text{ml}$ of 0.01M NaOH is required to change the color of the indicator to pink	0.35ml
Specific optical rotation	$+74.5^{\circ} \sim +78.0^{\circ}$	$+76.1^{\circ}$
Related substances	Impurity A $\leq 0.15\%$ Impurity B $\leq 0.15\%$ Impurity C $\leq 0.15\%$ Unspecified impurities $\leq 0.10\%$ sum of Unspecified impurities $\leq 0.15\%$ um of impurities other than D $\leq 0.30\%$	0.0033% 0.012% 0.0054% Undetected Undetected 0.021%
Silver	$\leq 5\text{ppm}$	1ppm
Loss on drying	$\leq 0.5\%$	0.02%
Bacteria endotoxins	$\leq 1.0\text{IU/mg}$	$< 1.0\text{IU/mg}$
Assay	98.0% \sim 102.0%	100.1%

Conclusion: The results conform with EP8.0

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/>