

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

CERTIFICATE OF ANALYSIS

Cisplatin

Batch No.: DR20140312	Piece: 25kg
Manufacture Date: 2014.03.12	Expiry Date: 2017.03.11
Inspection item: Total inspection	Package: polyethylene bag

TESTS:

Items	Specification	Results
Appearance	Yellow crystalline powder	Conforms
HPLC	HPLC the retention time of the major peak corresponds to that of the standard sample.	Conforms
IR	IR the infrared absorption spectrum exhibits maximum only at the same wavelengths as that of the standard sample.	Conforms
TLC	TLC the principle spot corresponds in appearance and Rf to that of the standard sample.	Conforms
Cystalline	Meets the requirements	Conforms
Water content	≤1.0%	0.2%
UV purity ratio	≥4.5	5.8
Trichloroamine-platinate	≤1.0%	0.05%
Transplatin	≤2.0%	Undetected
Platinum content	64.42%~65.22%	65.10%
Assay	98.0% ~ 102.0%	101.0%

Conclusion: The results conform with USP36.

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