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

CERTIFICATE OF ANALYSIS

Natural paclitaxel

Batch No.: DR20130325	**Piece:** 2.0kg
Manufacture Date: 2013.03.25	**Expiry Date:** 2016.02

TESTS:

Items	Specification	Results
Characteristics	White or almost white crystalline powder	white crystalline powder
Specific rotation	-49.0 ～-55º	-52.7º
Identification HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation,as obtained in the assay	Complies
Color and clarity of solution	Clear and colorless	Conforms
Identification IR	The infra-red absorption spectrum in potassium bromide dispersion of sample exhibits maximal at the same wave lengh as per that of similar preparation of paclitaxel working standard	Conforms
Related compounds	Baccatin III≤0.2%	ND
	10-deacetylpaclitaxel≤0.5%	ND
	7-xylosylpaclitaxel≤0.2%	ND
	Cephalomannine and 2,3-dihydrocephalomannine≤ 0.5%	0.1%
	10-deacetyl-7-epipaclitaxel≤0.5%	0.1%
	Benzyl analog and 3.4-dehydropaclitaxel C≤0.5%	ND
	7-epicephalomannine≤0.3%	ND
	7-Epipaclitaxel:≤0.5%	ND
	Other unspecified impurities≤0.1%	0.08%
	Total ≤2.0%	0.3%
Residual solvents	Acetone:≤0.5%	0.002%
	Acetic Ether:≤0.5%	N.D.
	N-Hexane:≤0.029%	0.0029%
	Dichloromethane:≤0.06%	0.01%
	Methanol:≤0.3%	0.005%
	2-methyl pentane:≤0.029%	N.D.
	3-methyl pentane:≤0.029%	N.D.
	Methylcyclopentane:≤0.029%	0.0028%
	N-butanol≤0.5%	0.04%

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	Chloroform≤0.006% 1，2-dichloroethane≤0.0005%	ND ND
Water	≤4.0%	0.5%
Residue on ignition	≤0.2%	0.1%
Heavy metals	≤20ppm	Conforms
Bacterial endotoxins	≤0.4EU/mg	Conforms
The total aerobic microbials	≤100CFU/g	10CFU/g
Staphylococcus aureus	Absence	N.D.
Pseudomonas aeruginosa	Absence	N.D.
Salmonella	Absence	N.D.
Escherichia coli	Absence	N.D.
Assay (calculated on the anhydrous,solvent-free basis)	97.0~102.0%	100.5%
Conclusion: The results conform with USP34-NF29.		

质检专用章

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