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

CERTIFICATE OF ANALYSIS

Efavirenz

Batch No.: DR20140715	**Quantity:** 254kg
Manufacture Date: 2014.07.15	**Expiry Date:** 2016.07.14

TESTS:

Items	Specification	Results
Appearance	A White or almost white crystalline powder	Almost white crystalline powder
Identification	IR spectra of sample exhibit similar with standard spectra UV spectra of sample exhibit similar with standard spectra	Conforms
Completeness of solution	50mg/ML of efavirenz in methanol solvent ,clear	Conforms
Water	≤0.5%	0.1%
Residue on ignition	≤ 0.2%	0.04%
Heavy metals	≤20ppm	<20ppm
Enantiomer	≤0.5%	0.13%
Related substance	Impurity A ≤ 0.15% Impurity B ≤ 0.40% Impurity C、D、E ≤ 0.10% Impurity F ≤ 0.15% Impurity G ≤ 0.10% Impurity H ≤ 0.10% Impurity I ≤ 0.25% Impurity J ≤ 0.15% Impurity K ≤ 0.10% Impurity L ≤ 0.10% Impurity M ≤ 0.10% Impurity N ≤ 0.10% Impurity O ≤ 0.10% Impurity P ≤ 0.10% Any other individual impurity ≤ 0.10% Total impurities ≤ 1.0%	N,D N,D 0.06% N,D N,D N,D N,D N,D 0.03% N,D N,D N,D N,D N,D N,D 0.11%

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Assay （on the anhydrous，solvent-free basis）	98.0%~102.0%	99.7%
Residual organic sovents	Ethanol ≤ 5000PPM Tetrahydrofuran ≤720PPM Toluene ≤890PPM	N,D N,D N,D
Microbial limit	Bacteria ≤1000CFU/g Molds & yeasts ≤100CFU/g E.coli N,D	15CFU/g 55CFU/g N,D
Conclusion: The results conform to the USP.		

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