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

CERTIFICATE OF ANALYSIS

Valaciclovir HCL(CAS 124832-27-5)

Batch No.: DR20120218	**Piece:** 450kg
Manufacture Date: 2012.02.18	**Expiry Date:** 2014.02.17

TESTS:

Items	Specification	Results
Characteristics	White or almost white powder	A white powder
Identification	Conforms	Conforms
Specific rotation	-8.5° ~ -11.5°	-9.0°
PH	4.0~6.0	4.4
Water	Anhydrous: ≤2.0% Hydrous: 5.0%~9.0%	3.1%
Heavy metals	≤10ppm	< 10ppm
Palladium	≤10ppm	< 10ppm
Palladium	≤10ppm	< 10ppm
Residue on ignition	≤0.1%	0.01%
Organic impurities	Related compound E: ≤0.2% Related compound F: ≤0.1% Related compound G: ≤0.05% Acyclovir alaninate: ≤0.2% Related compound C: ≤0.3% Related compound D: ≤0.5% Acyclovir isoleucinate: ≤0.2% N-formyl valacyclovir: ≤0.8% Guaninyl valacyclovir: ≤0.2% Bis valacyclovir: ≤0.3% Any other individual impurity:≤0.1% Total unspecified impurities: ≤0.2% Guanine & Acyclovir: ≤2.0% Related compound A: ≤0.2% D-valacyclovir: ≤3.0% Total impurities(1+2+3): ≤5.0%	Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms 0.84% Conforms 2.6% 4.0%
Assay(HPLC on anhydrous and solvent free basis)	95.0%~102.0%	97.2%
Conclusion: The results conform with USP34.		

Analyst:_____ **Checker:**_____ **QA.Manager:**_____

杭州东瑞医药科技有限公司 Hangzhou Dawn Ray Pharmaceutical Co. 质检专用章 QUALITY STAMP

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