

# Hubei Teyer Pharmaceutical Co., Ltd

## CERTIFICATE OF ANALYSIS

Name of the product : <b>VALACYCLOVIR HYDROCHLORIDE</b>	Date of report : July 16,2021
Batch No. : <b>20210702</b>	Analytical Report Number : V2021-0702
Batch Size : 400kg	Retest Date : July , 2024
Mfg. Date : July 16,2021	Page No. : 01 of 01
Quality Standard : USP42	

No.	Test	Specification	Observation
1	Description	A white or almost white crystalline powder, hygroscopic.	White crystalline powder
2	Solubility	Freely soluble in water; very slightly soluble in ethanol; practically insoluble in trichlormethane	Conforms
3	Identification	IR: The IR spectrum is concordant with the reference spectrum of valacyclovir hydrochloride; UV: The UV spectrum of test solution in 0.01 M solution of hydrochloric acid in range from 210 to 340 nm has the absorption maximum at 254 nm $\pm$ 2 nm, absorption minimum at 224 nm $\pm$ 2 nm and shoulder in range from 266 to 286 nm; chlorides reaction:The aqueous solution yields the reactions characteristic of chlorides; HPLC: According to the chromatogram recorded in the Assay item, the retention time of the major peak of test solution is corresponding to the retention time of the major peak of reference solution.	Conforms  Conforms  Conforms
4	Water	Hydrous: 5.0~9.0% max	6.2%
5	Residue on ignition	Not more than 0.10 %	0.02%
6	Heavy Metals	Not more than 20 ppm	Conforms
7	Specific optical rotation $[\alpha]_{D25}$	- 8.5° ~ - 11.5°	-9.0°
8	pH	4.0 ~ 6.0	pH 4.5
9	Specific absorption index	From 336 to 372 at 254 nm (on anhydrous and organic solventless basis)	Conforms
10	Organic impurities by HPLC	Any other individual impurity: 0.1% max. Total unspecified Impurities: 0.2% max. Guanine & Acyclovir: 2.0% max. Related Compound A: 0.2% max. D-Valacyclovir: 3.0% max. Total Impurities:5.0% max.	Conform Conform 0.3% Conform 0.8% 1.5%
11	Assay	By HPLC Not less than 98.0 % and not more than 102.0 % (on anhydrous basis and organic solventless basis)	99.1%
12	Residual solvents Ethanol – Not more than 5000 ppm Dimethyl formamide – Not more than 880 ppm		2790ppm Not detected

Remarks: The product conforms to the USP42.

Q.C. director: Gan Bin

Checker: Huang Mei

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