

 Yichang Tianren Pharmaceutical Co., Ltd	CERTIFICATE OF ANALYSIS	No.: A-QC-0009-12.02
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		Effective Day: 2020.11.15

COA No.OM-YF-210023

Product Name	Valacyclovir Hydrochloride	Inspection Basis	EP and In-house
Batch No.	210710	Batch Quantity	502.75kg
Packing	20.00kg/ Drum 2.69kg/ Drum		
Manu Date	2021.07.19	Retest Date	2023 .07.18

ITEMS	SPECIFICATION: EP and In-house		REAULTS
Characteristics	A white to off white crystalline powder, hygroscopic		Complies
Solubility	Freely soluble in water, very slightly soluble in ethanol, practically insoluble in acetonitrile.		Complies
Identification	A: IR - The spectrum of the sample is consistent with spectrum obtained with anhydrous valacyclovir hydrochloride CRS.		Complies
	B: It gives reaction (a) of chlorides		Complies
Tests	TLC	Impurity G: NMT 0.05% Impurity S: NMT 0.05%	Complies Complies
	HPLC	Method A: Impurity A & B : NMT 2.0 % Impurity R : NMT 3.0 %	0.30% 0.93%
		Method B: Impurity M: NMT 0.6% Impurity D: NMT 0.3% Impurity C: NMT 0.2% Impurity H: NMT 0.1% Impurity P: NMT 0.1% Any unspecified impurity: NMT 0.05%	0.05% 0.02% 0.03% 0.04% Not detected Not detected
		Total organic impurities: NMT 4.0 %	1.36%
	Water: 4.5% - 11.0%		7.2%
	Palladium : Not more than 10 ppm		Complies
	Heavy metals: Not more than 20 ppm		Complies
	Sulfated ash: Not more than 0.1%		0.05%
	Residual Solvents : Ethanol ≤0.5% Acetone ≤0.5% DMF ≤ 0.088%		0.01% 0.002% Not detected
Assay	95.0%-102.0% on the anhydrous and free from any organic solvent basis		99.7%
Conclusion	Complies with the standard EP and In-house		

Analysed by: Zhang Da

Reviewer by: Wang Xuejie

Approved by: Du Sheng