上药康丽(常州)药业有限公司

SHANGHAI PHARMA GROUP CHANGZHOU KONY PHARMACEUTICAL CO., LTD.

Certificate of Analysis (Export)

Intention of issuing this COA: COA of Sample

Product Name	Valacyclovir Hydrochloride			
Batch No.	**Released Date**	**Quantity**	**Mfg. Date**	**Retest Date**
VCV20210601	2021.06.08	kg	2021.05.15	2023.05.14

Items	Acceptance Criteria (USP43)	Results
Appearance	White to off- white powder	White powder
Identification		
A: Infrared absorption	Corresponds to reference spectrum	Complies
B: HPLC retention time	Corresponds to that of reference standard	Complies
C: General, chloride	Positive	Complies
Assay	NLT 95.0% and NMT 102.0% of $C_{13}H_{20}N_6O_4 \cdot HCl$, calculated on the anhydrous and solvent-free basis	100.1%
Impurities		
Residue on ignition	NMT 0.1%	0.02%
Heavy metals	NMT 20 ppm	Complies
Limit of Palladium	NMT 10ppm	Complies
Organic impurities		
Valacyclovir related compound E	NMT 0.2%	Not detected
Valacyclovir related compound F	NMT 0.1%	Not detected
Valacyclovir related compound G	NMT 0.05%	Not detected
Acyclovir alaninate	NMT 0.2%	0.02%
Valacyclovir related compound C	NMT 0.3%	0.004%
Valacyclovir related compound D	NMT 0.5%	Not detected
Acyclovir isoleucinate	NMT 0.2%	0.03%
N-Formyl valacyclovir	NMT 0.8%	Not detected
Guaninyl valacyclovir	NMT 0.2%	Not detected
Bis Valacyclovir	NMT 0.3%	Not detected
Any unspecified impurity	NMT 0.1%	Max 0.01%
Guanine and acyclovir	NMT 2.0%	0.29%
Acyclovir related compound A	NMT 0.2%	0.02%
D-Valacyclovir	NMT 3.0%	0.75%
Total organic impurities	NMT 5.0%	1.2%
Specific tests		
Water determination	5.0%~11.0%	6.5%
Residual Solvents		
Ethanol	NMT 5000 ppm	1636ppm
Acetone	NMT 5000 ppm	21ppm
Methanol	NMT 3000 ppm	11ppm
Toluene	NMT 890 ppm	1ppm

Conclusion Complies with the specifications of Valacyclovir Hydrochloride Monograph in USP 43

Drafted by: 俞颖 **Quality Assurance Department:** 朱勇

Date: 2021年6月24日 **Date:** 2021年6月24日

产品合格章

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