	Hubei	Teyer Pharm	aceutical Co., L	td				
CERTIFICATE OF ANALYSIS								
Name of the product : VALACYCLOVIR HYDROCHLORIDE			Date of report	:Mar. 22, 2019				
Batch No.	: 20190302		Analytical Report Number	: V2019-0302				
Batch Size	: 100Kg		Retest Date	: Mar. 2022				
Mfg. Date	: Mar. 22, 2019		Page No.	:01 of 01				
Quality Standard	: USP40							

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	Conforms
		insoluble in trichlormethane	
3	Identification	IR: The IR spectrum is concordant with the reference spectrum of	Conforms
		valacyclovir hydrochloride;	
		UV: The UV spectrum of test solution in 0.01 M solution of	Conforms
		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	Conforms
		to the retention time of the major peak of reference solution.	
4	Water	Anhydrous: NMT 2.0%	
		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	- 8.5° ~ - 11.5°	-9.0°
	rotation [a]D25		
8	pН	4.0 ~ 6.0	pH 4.5
9	Specific absorption	From 336 to 372 at 254 nm (on anhydrous and organic solventless	Conforms
	index	basis)	
10	Organic impurities	Related Compound E: 0.2% max.	Conform
	by HPLC	Related Compound F: 0.1% max.	Conform
		Related Compound G: 0.05% max.	Conform
		Acyclovir Alaninate: 0.2% max.	Conform
		Related Compound C: 0.3% max.	Conform
		Related Compound D: 0.5% max.	Conform
		Acyclovir isoleucinate: 0.2% max.	Conform
		N-formyl valacyclovir: 0.8% max.	Conform
		Guaninyl Valacyclovir: 0.2% max.	Conform
		Bis valacviclovir:0.3% max.	Conform
		Any other individual impurity: 0.1% max.	Conform
		Total unspecified Impurities: 0.2% max.	Conform
		Guanine & Acyclovir: 2.0% max.	0.30%
		Related Compound A: 0.2% max.	Conform

		D-Valacyclovir: 3.0% max.	0.8%		
		Total Impurities:5.0% max.	1.2%		
11	Assay	I. By HPLC			
		Not less than 98.0 % and not more than 102.0 % (on anhydrous basis	98.9%		
		and organic solventless basis)			
		II.Titrimetry			
		Not less than 98.0 % and not more than 102.0 % (on anhydrous and			
		organic solventless basis)			
12	Residual solvents				
	Ethanol – Not more th	nan 5000 ppm	2680ppm		
	Dimethyl formamide -	Not detected			
Remarks: The product conforms to the USP40.					
Q.C. director: Gan Bin Checker: Wang xueping Analyst: Peng Guifang					