

B05000188

Certificate of Analysis

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The product name	Acyclovir		
Batch No.	186461438(W)	Inspection Basis	USP40
Manufacturing Date	2018.04.02	Retest Date	2022.04.01
Packing	25kg/drum	Amount	1100kg
The items and results of inspection			
Items	Test results	Specification	
[Appearance]	White crystalline powder	White to off-white, crystalline powder	
[Solubility]	Conform	Soluble in diluted hydrochloric acid; slightly soluble in water; insoluble in alcohol.	
[Identification]			
Infrared absorption	Conform	Positive	
Retention time (HPLC)	Conform	Positive	
Melting point	Conform	About 250°C with decomposition	
[Ordinary Impurities]			
Total impurities (TLC)	<0.5%	(≤1%)	
[Water]	5.0%	(≤6.0%)	
[Residue on ignition]	0.06%	(≤0.1%)	
[Residual solvent](GC)			
Toluene	<1ppm	(≤45ppm)	
[Assay and limit for guanine] (HPLC)			
Assay: (on the anhydrous basis)	100.5%	(98.0—101.0%)	
Guanine	0.16%	(≤0.7%)	
[Particle size]			
	99%=13.16microns 90%=6.68microns	(99% < 24microns, 90% < 12microns)	
[Bulk density]	0.22g/ml	(0.15-0.30g/ml)	
[Tapped density]	0.39g/ml	(0.30-0.50g/ml)	
[Microbial test]			
Total aerobic microbial count	<10 cfu /g	(NMT 1000 cfu /g)	
Total combined yeast and mold count	<10 cfu /g	(NMT 100 cfu /g)	
E.Coli	Conform	(Absent/g)	
Conclusion	Analysis according to USP40, Conform		
QA Manager	(s) Xiangjun	Release Date	2018.04.18

Packaging and Storage: Preserve in tight containers. Store at room temperature. Protect from light and moisture.