Bo5000188

Certificate of Analysis

Zhejiang Charioteer Pharmaceutical Co., Ltd.

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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℃ 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	Lv Xinghua	**Release Date**	2018.04.14

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