



宁波泰达进出口有限公司

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## 质量检测报告单

### ANALYSIS CERTIFICATE FOR ACYCLOVIR

制造日期 MEG. DATE	2011/11/08	检验编号 ANALYSIS REGISTER	11228
批号 BATCH NO.	111109	检验日期 ANALYSIS DATE	2011/11/09
数量 QUANTITY	200KG	质量标准 QUALITY STANDARD	USP34
检验项目 Analysis Items	标准规定 Standard		检测结果 Results
性状 Characters	白色结晶性粉末 A white crystalline powder		白色结晶性粉末 A white crystalline powder 符合规定 conform
鉴别 Identification 1. 红外光谱 infrared absorption 2. 高效液相色谱 liquid chromatogram	红外光谱应与对照品的红外光谱一致 the infrared absorption spectrum of a potassium bromide dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Acyclovir RS		与对照品一致 Correspond to the standard preparation 符合规定 conform
	色谱图中供试品的主峰保留时间与对照品一致 the retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained under assay and limit for guanine		与对照品一致 Correspond to the standard preparation 符合规定 conform
有机易挥发性杂质 Organic volatile impurities	应符合规定 Meets the requirements		符合规定 conform
有关物质 Ordinary impurities	薄层色谱 $\leq 1\%$ examine by thin-layer chromatography $\leq 1\%$		符合规定 conform
鸟嘌呤限量 Limit for guanine	$\leq 0.7\%$		0.40%
干燥失重 Loss on drying	$\leq 6.0\%$		3.7%
含量 Assay	98.0% ~ 101.0%		100.3%
残留溶剂 Residual Solvent	Toluene	$\leq 890\text{ppm}$	Conform
	Methanol	$\leq 3000\text{ppm}$	Conform
	Ethanol	$\leq 5000\text{ppm}$	Conform
	Acetic Anhydride	$\leq 5000\text{ppm}$	Conform
	Anhydride	$\leq 5000\text{ppm}$	Conform
	Dimethyl Sulfoxide	N.D.	N.D.
		N.D.	N.D.
结论: 本品按规定标准检验符合规定 Result: Conform to the requirements of standard		有效期: 2013年11月07日 Expiry date: 2013/11/07	

THE DIRECTOR

OF THE QUALITY

LAB SECTION 黄林军

审核

EXAMINER 曹红

检验

ANALYST 李洞刚