

# 武义家园医药原料有限公司

Wuyi Jiayuan Pharmaceutical Materials CO.,Ltd

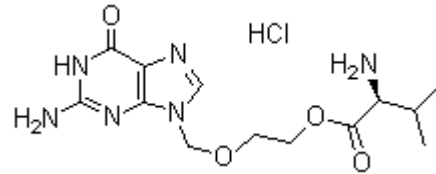
## 检验报告单

Certificate of Analysis

**Product:** Valaciclovir Hydrochloride

品名: 盐酸伐昔洛韦(盐酸万乃洛韦)

**CAS:** 124832-27-5



### Molecular Structure:

Batch No. 批号	20110312	Manu. Date 生产日期	2011-03-12
Quantity 批量	100kg	Rep. Date 报告日期	2011-03-14
Bource 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	2010 of Chinese Pharmacopoeia 中国药典 2010 版		

TETS 检验	STANDARD 标准	RESULTS 结果
Appearance 外观	White or almost white powder 白色或类白色粉末	white powder 白色粉末
Specific rotation 比旋度	-8.5° ~ -11.5°	-8.6°
pH 酸碱度	4.0 ~ 6.0	4.1
Water 水分	≤ 8.0%	4.0%
Heavy metals 重金属	≤ 20ppm	< 20ppm
Residue on ignition 灼烧残渣	≤ 0.1%	0.02%
Related impurities 有关物质	Other impurities ≤ 0.5% Aciclovir ≤ 1.5% (external standard method) No more than 2.0% for total impurities	Other impurities: 0.24% Aciclovir: 0.77% 1.0%
HPLC assay 液相色谱含量	98.0% ~ 102.0%	99.2%
Package: Closed packing with moisture-proof plastic bag inside, packing with paper-plate boxes outside. (3kg-25Kg), moisture-proof plastic bag inside, packing with aluminum foil bag outside. (<3kg)		
Conclusion: Complies With ChP2010 经检验符合中国药典 2010 版。		

ANALYST: Chen.MH

CHECKER: Zhu.JD

Q.C.SUPERVISOR: Zhen.FZ

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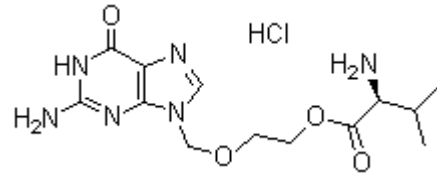
Certificate of Analysis

**Product:** Valaciclovir Hydrochloride

品名: 盐酸伐昔洛韦(盐酸万乃洛韦)

**CAS:** 124832-27-5

**Molecular Structure:**



Batch No. 批号	20110219	Manu. Date 生产日期	2011-02-19
Quantity 批量	100kg	Rep. Date 报告日期	2011-02-21
Source 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	2010 of Chinese Pharmacopoeia and USP33		

TETS 检验	STANDARD 标准	RESULTS 结果
Appearance 外观	White or almost white powder 白色或类白色粉末	white powder 白色粉末
Specific rotation 比旋度	-8.5° ~ -11.5°	-9.0°
pH 酸碱度	4.0~6.0	4.4
Water 水分	≤8.0%	4.1%
Heavy metals 重金属	≤20ppm	<20ppm
Residue on ignition 灼烧残渣	≤0.1%	0.01%
Related impurities 有关物质	USP impurities ≤0.2% Aciclovir ≤1.5%(external standard method) D-Valaciclovir ≤3.0%	All impurities ≤0.2% Aciclovir: 0.75% 2.5%
HPLC assay 液相色谱含量	96.0%~102.0%	99.0%
Package: Closed packing with moisture-proof plastic bag inside, packing with paper-plate boxes outside. (3kg-25Kg), moisture-proof plastic bag inside, packing with aluminum foil bag outside. (<3kg)		
Conclusion: Complies With ChP2010 and USP33 .		

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