

武义家园医药原料有限公司

Wuyi Jiayuan Pharmaceutical Materials CO.,Ltd

检验报告单

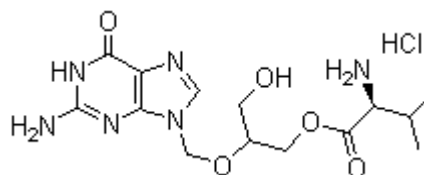
Certificate of Analysis

Product: Valganciclovir Hydrochloride

品名: 盐酸缬更昔洛韦

CAS: 175865-59-5

Molecular Structure:



Batch No. 批号	20110216	Manu. Date 生产日期	2011-02-16
Quantity 批量	500g	Rep. Date 报告日期	2011-02-21
Source 来源	Lab	Expiry Date 有效期	24 months
QCS 检验标准	USP32		

TETS 检验	STANDARD 标准	RESULTS 结果	
Appearance	White or almost white powder	white powder	
Identification	Infrared Absorption。	Complies	
	Ultraviolet Absorption	Complies	
	A solution in water (1 in 20) meets the requirements of the tests forChloride	Complies	
Isopropyl alcohol	≤1.0%	Complies	
Water	≤8.0%	4.5%	
Heavy metals	≤20ppm	<20ppm	
Residue on ignition	≤0.1%	0.01%	
Related impurities	Valganciclovir	—	
	Ganciclovir	≤1.5%	0.5%
	Guanine	≤0.25%	0.1%
	Methoxymethylguanine	≤0.3%	Complies
	Isovalganciclovir	≤0.5%	Complies

Asking for a Sample TEL:0086-579-87645148 13335996519 FAX: 0086-579-87646208

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	Monoacetoxyganciclovir	≤0.15%	Complies
	Bis-valine easter of ganciclovir	≤0.1%	Complies
	Homologue of valganciclovir	≤0.25%	Complies
	H	≤0.1%	Complies
	I	≤0.1%	Complies
	Ganciclovir monopropionate	≤0.15%	Complies
	Valganciclovir dimer (stereoisomer A)	≤0.1%	Complies
	Valganciclovir dimer (stereoisomer B)	≤0.1%	Complies
	Valganciclovir dimer (stereoisomer C)	≤0.1%	Complies
	Ganciclovir mono-N-methyl valinate	≤0.3%	Complies
	Other identified impurity	≤0.1 %individual ≤0.25 %total	Complies
	Unidentified impurity	≤0.1% individual ≤0.25% total	Complies
	Total of all impurities	≤3.0%	0.7%
Diastereomer ratio	he diastereomer ratio is (45:55) to (55:45).		49:51
Enantiomeric purity of valganciclovir	≥97.0%		98.1%
HPLC assay	97.0%~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 USP32 。			

ANAL.YIST:Chen.MH

CHECKER:Zhu.JD

Q.C.SUPEDRVISOR:Zhen.FZ

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