

安庆沃德化工有限公司

ANQING WORLD CHEMICAL COMPANY LIMITED

检验报告单

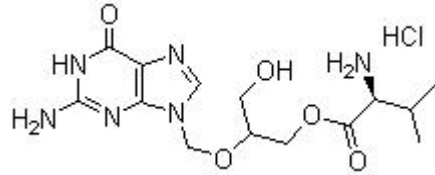
CERTIFICATE OF ANALYSIS

Product: Valganciclovir Hydrochloride

品名: 盐酸缬更昔洛韦

CAS: 175865-59-5

Molecular Structure:



Batch No. 批号	20160718	Manu. Date 生产日期	2016-07-18
Quantity 批量	20.0Kg	Rep. Date 报告日期	2018-07-20
Bource 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	USP36		

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 for Chloride		Complies
Isopropyl alcohol	≤1.0%		Complies
Water	≤8.0%		4.1%
Heavy metals	≤20ppm		<20ppm
Residue on ignition	≤0.1%		0.01%
Related impurities	Valganciclovir	—	—
	Ganciclovir	≤1.5%	0.40%
	Guanine	≤0.25%	0.01%
	Methoxymethylguanine	≤0.3%	Complies
	Isovalganciclovir	≤0.5%	Complies
	Monoacetoxyciclovir	≤0.15%	Complies

	Bis-valine ester 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).		46:54
Enantiomeric purity of valganciclovir	≥97.0%		99.1%
Residual solvents	Isopropanol≤5000ppm		1100ppm
	Methanol ≤3000ppm		800ppm
	Toluene≤890ppm		0ppm
	Methylene chloride≤600ppm		0ppm
	Acetone≤5000ppm		1200ppm
HPLC assay	97.0%~102.0%		99.4%
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 USP36 .			

ANALYST:WJ

CHECKER:WYH

Q.C.SUPERVISOR:YWD