武 义 家 园 医 药 原 料 有 限 公 司

WUYI JIAYUAN PHARMACEUTJICAL MATERIALS COMPANY LIMITED

CERTIFICATE OF ANALYSIS

PRODUCT: GANCICLOVIR SODIUM	**QUALITY STANDARD:USP32**
MFG DATE:2012.12.01	**ANALYSIS DATE:2012.12.01**
LOT NO.:20121201	**REPORT DATE:2012.12.03**
PACKAGE:10.0KG/DRUM	**QUANTITY:30KG**
EXP.DATE: 12.01, 2014	

TEST	METHOD	LIMITS	RESULTS
DESCRIPTION	EYES MEASURE	WHITE ODOURLESS POWDER	COMPLIES
SOLUBILITY	USP 32	VERY EASILY SOLUBLE IN WATER	COMPLIES
IDENTIFICATION	ULTRAVIOLET ABSORPTION BETWEEN 200 AND 400nm HPLC	SHOULD HAVE BIGGEST ABSORPTION AT 222-252NM; IR SHOULD BE CONSISTENT WITH THAT OF THE REFERENCE STANDARE; SHOULD BE SODIUM REACTION. RETENTION TIME SIMILIAR	COMPLIES COMPLIES
ASSAY	HPLC	IT CONTAINS NOT LESS THAN 90.0 PERCENT AND NOT MORE THAN 110.0 PERCENT OF THE LABELED AMOUNT OF GANCICLOVIR(C9H13N5O4),CALCULATED ON THE ANHYDROUS BASIS	98.5%
RELATED SUBSTANCES	HPLC	NO MORE THAN 0.5% GANCICLOVIR RELATED COMPOUND A NO MORE THAN 0.5%GUANINE NO MORE THAN 1.5% FOR TOTAL IMPURITIES	 0.11% 0.27% 0.43%
WATER	USP32 METHOD	NO MORE THAN 6.0%	1.6%
PH	USP32	BETWEEN 10.8 AND 11.4	11.3
ORGANIC REMAIN		NO MORE THAN0.5%ACETONE	COMPLIES
BACTERIAL ENDOTOXINS	USP32	0.84 ENDOTOXIN UNIT PER mg	<0.25EU/mg
HEAVY METALS	USP32	NO MORE THAN0.002%	COMPLIES
RESULT	CONFORM TO THE REQUIREMENTS OF USP32		