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GUANGZHOU HANPU PHARMACEUTICAL CO.LTD

CERTIFICATE OF ANALYSIS

NO.9.JUFENG NORTH ROAD, AOTOU TOWN,CONGHUA CITY,GUANGZHOU,P.R.CHINA

PRODUCT:Clotrimazole RD-QF-7019-00

BATCH NO: 20171209	STANDARD: USP 40
PACKING: 25kg/Drum	MFG . DATE: 2017-12-17
QUANTITY: 1000 kg	EXP. DATE: 2019-12-16

TEST ITEM		SPECIFICATION	RESULTS
1.Characteristics		A white or crystalline white powder	A crystalline white powder
2.Identification	Ir Spectrum	Similar To The USP Clotrimazole Rs	Positive
	HPLC Test	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Positive
3.Related compound A		≤0.2%	<0.2%
4.Solubility		practically insoluble in water,soluble in ethanol(96%) ,it is also soluble in Chloroform and Acetone.	Complies
5.Melting poit		141°C to 145°C	143°C to 144°C
6.Imidazole		≤0.5%	<0.5%
7.Loss on drying		≤0.5%	0.12%
8.Residue On Ignition		≤0.1%	0.04%
9.Heavy Metals		≤0.001%	<0.001%
10.Assay		98%-102%($C_{22}H_{17}ClN_2$)	99.5%
11.Residual Solvent		Benzene≤2ppm	Complies
		Toluene≤890ppm	Complies
		Acetone≤5000ppm	Complies
		PETROLEUM ETHER≤200ppm	Complies
12.Microorganism		TPC<1000cfu/g	Complies
		Y and M <100cfu/g	Complies
		E-coli – absent	Complies
		PATHOGEN: ABSENT	Complies
Density		SPECIFY LOOSE 0.38g/ml and TAPPED DENSITY 0.56g/ml	
Remark		PARTICLE SIZE:98%<200MICRONS	

CONCLUSION: Conform With USP40

Quality Authorizer	陈亮辉	Report Date :	2017-12-31

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CERTIFICATE OF ANALYSIS

NO.9, JUFENG NORTH ROAD,AOTOU TOWN,CONGHUA CITY, GUANGZHOU,P.R.CHINA

PRODUCT: Clotrimazole

RD-QF-7019-00

BATCH NO: 20171209	STANDARD: BP2014
PACKING: 25kg/Drum	MFG . DATE: 2017-12-17
QUANTITY: 1000 kg	EXP. DATE: 2019-12-16

TEST ITEM	SPECIFICATION	RESULTS
Characteristics	A white or pale yellow, crystalline powder,practically insoluble in water,soluble in alcohol and in methylene choride.	A white crystalline powder,practically insoluble in water,soluble in alcohol and in methylene choride.
Identification	A. Melting point 141℃to145℃ B.Infrared absorption:Positive C.Thin-layerchromatograms:Positive	A.143℃ to 144℃ B. Positive C. Positive
Related substances	Impurities A:≤0.2%	0.02%
	Impurities B:≤0.2%	0.02%
	ImpuritiesD:≤0.2%	0.03%
	Impurities E:≤0.2%	0.01%
	Impurities F:≤0.1%	0.04%
	Unspecified Impurities:≤0.1%	0.01%
	Total Impurities :≤0.5%	0.17%
	Disregard limit:≤0.05%	0.01%
Appearance of solution	The solution is clear and not more intensely coloured than refe:ence solution BY6	Complies
Loss on drying	Not more than 0.5% ≤0. 5%	0.12%
Sulphated ash	Not more than 0.1% ≤0. 1 %	0.04%
Assay	98. 5%-100. 5% ($C_{22}H_{17}ClN_2$, on dried basis)	99.5%
Residual Solvent	Benzene≤2ppm	Complies
	Toluene≤890ppm	Complies
	Acetone≤5000ppm	Complies
	PETROLEUM ETHER≤200ppm	Complies
Microorganism	TPC<1000cfu/g	Complies
	Y and M <100cfu/g	Complies
	E-coli – absent	Complies
	PATHOGEN: ABSENT	Complies
Density	SPECIFY LOOSE 0.38g/ml and TAPPED DENSITY 0.56g/ml	
Remark	PARTICLE SIZE:98%<200MICRONS	
CONCLUSION: Conform With BP2014		

Quality Authorizer	陈亮辉	Report Date :	2017-12-31