

GUANGZHOU HANPU PHARMACEUTICAL CO.LTD

ANALYTICAL REPORT

PRODUCT: Clotrimazole IP/BP/USP

RD-QF-7019-00

BATCH NO: 20150207

STANDARD: IP/BP/USP

PACKING: 25kg/Drum

MFG. DATE: 2015-02-14

QUANTITY: 1000kg

EXP. DATE: 2019-02-13

TEST ITEM		SPECIFICATION	RESULTS
1.Characteristics		A white or crystalline white powder	A white or crystalline white powder
2.Identification	Ir Spectrum	Similar To The Usp Clotrimazole Rs	Complies
	Tlc Test	Principal Spot Is Similar To The Reference Solution	Complies
3.Solubility		Practically insoluble in water, soluble in alcohol and in methylene chloride, slight soluble in ether	Complies
4. Related Compound A		(O-Chorophenyl)Diphenylmethanol $\leq 0.2\%$	Complies
		Each Known Impurity $\leq 0.2\%$	Complies
		Each Unknown Impurity $\leq 0.2\%$	Complies
		Sum Of All Impurities $\leq 0.5\%$	Complies
5.Imidazole		$\leq 0.2\%$	Less than 0.2%
6.Loss on drying		$\leq 0.5\%$	0.12%
7.Residue On Ignition		$\leq 0.1\%$	0.03%
8.Heavy Metals		$\leq 0.001\%$	Less than 0.001%
9.Assay		98.5%-100.5%(C ₂₂ H ₁₇ ClN ₂)	99.4%
10.Residual Solvent		Benzene $\leq 2\text{ppm}$	Complies
		Toluene $\leq 890\text{ppm}$	Complies
REMARK			
CONCLUSION: Conform With IP/BP/USP			

Q.M.Chief: 黄能章

Collator: 庾志敏

Analyst: 吴婷婷

黄能章

庾志敏

吴婷婷