

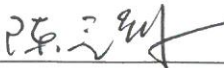
GUANGZHOU HANPU PHARMACEUTICAL CO.LTD

CERTIFICATE OF ANALYSIS

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

PRODUCT: Clotrimazole Micronized

RD-QF-7019-03

BATCH NO: H20230401		STANDARD: USP43	
PACKING: 25kg/Drum		MFG . DATE: 2023-04-03	
QUANTITY: 1000 kg		RETEST DATE: 2026-04-02	
TEST ITEM	SPECIFICATION	RESULTS	
1.Characteristics	White topale yellow,crystalline powder.Melts at about 142,with decomposition.Practically insoluble inwater;freely soluble in methanol,in acetone,in chloroform,and in alcohol.	A crystalline white powder	
2.Identification	Infrared Absorption <197>	Positive	
	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. (HPLC)	Positive	
3.Related compound A	≤0.5%	0.12%	
4.Imidazole	≤0.5%	0.02%	
5.Loss on drying	≤0.5%	0.23%	
6.Residue On Ignition	≤0.1%	0.05%	
7.Heavy Metals	≤0.001%	<0.001%	
8.Assay	98%-102%(C ₂₂ H ₁₇ ClN ₂) Calculated on dried basis	99.8%	
9.Residual Solvent	Benzene≤2ppm	Absent	
	Acetonitrile≤410ppm	7.2ppm	
10.Microorganism	TPC<1000cfu/g	< 10cfu/g	
	Y and M <100cfu/g	< 10cfu/g	
	E-coli – absent	Absent	
	Staphylococcus Aureus-Absent	absent	
	Pseudomonas Aeruginosa-Absent	absent	
	Albicans Saccharomyces-Absent	absent	
REMARK	Particle Size: 90% pass 10 micron		
CONCLUSION: Conform With USP43			
Quality Authorizer		Report Date :	2023-04-12

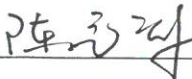
GUANGZHOU HANPU PHARMACEUTICAL CO.LTD

CERTIFICATE OF ANALYSIS

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

PRODUCT: Clotrimazole Micronized

RD-QF-7019-03

BATCH NO: H20230401		STANDARD: BP2022	
PACKING: 25kg/Drum		MFG . DATE: 2023-04-03	
QUANTITY: 1000 kg		RETEST DATE: 2026-04-02	
TEST ITEM	SPECIFICATION	RESULTS	
Characteristics	White or pale yellow, crystalline powder.	White crystalline powder.	
Solubility	Practically insoluble in water, soluble in ethanol (96 per cent) and in methylene chloride.	Complies	
Identification	A. Melting point 141℃to145℃ B.Infrared absorption:Positive C.Thin-layerchromatograms:Positive	A.142℃ to 144℃ B. Positive C. Positive	
Related substances	Impurities A:≤0.2%	0.12%	
	Impurities B:≤0.2%	Not detected	
	ImpuritiesD:≤0.2%	0.02%	
	Impurities E:≤0.2%	Not detected	
	Impurities F:≤0.1%	Not detected	
	Unspecified Impurities:≤0.1%	Not detected	
	Total Impurities :≤0.5%	0.14%	
	Disregard limit:≤0.05%	Not detected	
Loss on drying	Not more than 0.5% ≤0. 5%	0.23%	
Sulphated ash	Not more than 0.1% ≤0. 1 %	0.05%	
Assay	98.5%-100.5%(C ₂₂ H ₁₇ ClN ₂ ,on dried basis)	99.8%	
Residual Solvent	Benzene≤2ppm	Absent	
	Acetonitrile≤410ppm	7.2ppm	
Microorganism	TPC<1000cfu/g	< 10cfu/g	
	Y and M <100cfu/g	< 10cfu/g	
	E-coli – absent	Absent	
	Staphylococcus Aureus-Absent	absent	
	Pseudomonas Aeruginosa-Absent	absent	
	Albicans Saccharomyces-Absent	absent	
REMARK	Particle Size: 90% Pass 10 micron		
CONCLUSION: Conform With BP2022			
Quality Authorizer			Report Date : 2023.04.12



UniFarma s.a.

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CERTIFICADO DE ANÁLISIS

Fecha :

9/1/2024

Nº Análisis

24010427

Producto :

CLOTRIMAZOL MICRONIZADO

Código :

PH001457

Lote :

H20230401

Fabricante y Dirección :

Guangzhou Hanpu Pharmaceutical Co. Ltd.

#9 Jufeng North Road, Aotou Town, Conghua City, Guangzhou - CHINA

Vto :

Retesteo :

02/04/2026

Referencia : USP 36

Ensayo	Especificación	Resultado
(*)Aspecto	Polvo cristalino blanco o casi blanco.	CUMPLE
(*)Identificación (IR)	Cumple contra estándar	CUMPLE

(*) Estos ensayos son realizados por UNIFARMA S.A., al mismo se adjunta el Certificado de Origen, el cual incluye el resto de las pruebas analíticas realizadas por el Fabricante de la materia prima.

Observaciones :

Laboratorio C.C

Fecha:

UNIFARMA S.A.
D. FORTAVO H. DARTAYET
LAB. CONTROL DE CALIDAD

Dirección Técnica
UNIFARMA S.A.
NORBERTO CEBALLOS
FARMACEUTICO
DIRECTOR TECNICO
M.N. 17453

Fecha:

24/01/2024