



A US FDA Accepted Company & WHO-GMP. ISO 9001, ISO 14001 & ISO 45001 Certified Company

CERTIFICATE OF ANALYSIS

Product Name: CLOTRIMAZOLE (Micronized)			Standards EP 10
Lot No.: HCZ20120	Mfg. Month.: DEC'2020	Exp Month.: NOV'2025	AR No.: HCZ20120/346
Mfg. Lic. No.: G/1223	Qty.: 480.10 Kg	Release Dt.: 28/12/2020	

Tests	Results	Specifications
CHARACTERS	Complies	A white or pale yellow crystalline powder
SOLUBILITY	Complies	Practically insoluble in water , soluble in ethanol and in dichloromethane .
IDENTIFICATION Test – B (By IR)	The IR spectrum of sample concordant with the IR spectrum of working standard of Clotrimazole.	The IR spectrum of sample concordant with the IR spectrum of working standard of Clotrimazole.
RELATED SUBSTANCES		
Impurity – A	0.02%	N.M.T. 0.20%
Impurity – B	0.02%	N.M.T. 0.20%
Impurity – D	0.02%	N.M.T. 0.20%
Impurity – E	Not Detected	N.M.T. 0.20%
Impurity – F	0.02%	N.M.T. 0.10%
Unspecified Impurity	0.02%	N.M.T. 0.10%
Total Impurities	0.13%	N.M.T. 0.50%
LOSS ON DRYING	0.29%	NMT. 0.50%
SULPHATED ASH	0.08%	NMT. 0.100%
ASSAY	99.65%	98.5 % TO 100.50%.*
RESIDUAL SOLVENT ACETONE (BY LOD)	Complies	NMT 5000 PPM

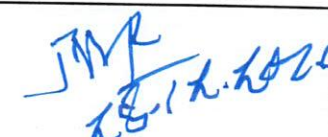


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ADDITIONAL IN- HOUSE TEST AS PER CUSTOMER REQUIREMENT

PARTICLE SIZE	Complies	90 % < 10 µm	
	Complies	100 % < 20 µm	
Material Complies / Does not comply as per above specification.			
* as C ₂₂ H ₁₇ ClN ₂ On dried basis reference to standard			
	PREPARED BY	REVIEWED BY	APPROVED BY
Sign. & Date	 28/12/2020	 28/12/2020	 28/12/2020
Name & Designation	Mr. Ravi Lakhani (QC Officer)	Mr. Shailesh Patel (Manager- Quality)	Mr. Janak Patel (AGM- Quality)

This product is not offered or for sale in countries where valid patent exist. Purchase is at buyer's risk though developmental quantities are permissible as per normal regulations to carried out R & D activities

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For, HALCYON LABS PVT. LTD.


(JANAK PATEL)
AGM-(QUALITY)