

**ERREGIERRE**

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Lote Accettato: 151553
CERTIFICATE OF ANALYSIS N°

61295**CLOTRIMAZOLE USP - EP (micronized 100 microns)**CAS N. **23593-75-1**CODE **545M100**BATCH **B15027M**MAN. DATE **07/2015** RETEST DATE **05/2021**

TEST FOR	SPECIFICATIONS	RESULTS
Description	white to pale yellow crystalline powder	Complies
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
Loss on drying	≤ 0.5 %	0.03
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.00
Heavy metals	NMT 10 ppm	Complies
Assay (HPLC, on dried basis)	≥ 98.5 ≤ 100.5 % (USP spec.: 98.0-102.0%)	99.0
Assay (volumetric, on dried basis)	≥ 98.5 ≤ 100.5 %	100.3
Related substances (HPLC)		
· A) (2-chlorophenyl)diphenylmethanol - USP imp. A	≤ 0.2 % (USP spec.: NMT 0.5%)	Non quantifiable
· B) 1-[(4-chlorophenyl)diphenylmethyl]-1H-imidazole	≤ 0.2 %	0.01
· D) imidazole	≤ 0.2 % (USP spec.: NMT 0.5%)	Non quantifiable
· E) (2-chlorophenyl)phenylmethanone - (2-chlorobenzophenone)	≤ 0.1 % (EP spec.: NMT 0.2%)	Non quantifiable
· F) 1-(triphenylmethyl)-1H-imidazole - (deschloroclotrimazole)	≤ 0.1 %	0.02
· any other impurity	NMT 0.10%	Complies
· sum of any other impurity	≤ 0.2 % (in-house spec.)	0.03
· total	≤ 0.5 %	0.06
Additional specifications		
Residual solvents (GC)		
· acetone	≤ 2000 ppm	1303
· benzene	≤ 2 ppm	Non quantifiable
· methylene chloride	≤ 600 ppm	Non quantifiable

OBSERVATIONS:

Copies of this CoA are not valid**APPROVED**

on Oct 09, 2015

QUALITY CONTROL

Dr. G. Lorenzi

Oct 09, 2015