

**CLOTRIMAZOLE USP - EP (micronized 100 microns)**

CAS N. 23593-75-1 CODE 545M100 BATCH S0713028M MAN. DATE 07/2013 RETEST DATE 04/2019

TEST FOR	SPECIFICATIONS	RESULTS
Description	white to pale yellow crystalline powder	Complies
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
Loss on drying	≤ 0.5 %	0.01
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.03
Heavy metals	NMT 10 ppm	Complies
Assay (HPLC, on dried basis)	≥ 98.5 ≤ 100.5 % (USP spec.: 98.0-102.0%)	99.5
Assay (volumetric, on dried basis)	≥ 98.5 ≤ 100.5 %	99.4
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 %	0.02
· 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 %	0.03
· any other impurity	NMT 0.10%	Complies
· sum of any other impurity	≤ 0.2 % (in-house spec.)	0.04
· total	≤ 0.5 %	0.09
Additional specifications		
Residual solvents (GC)		
· acetone	≤ 2000 ppm	1362
· benzene	≤ 2 ppm	Non quantifiable
· methylene chloride	≤ 600 ppm	36

OBSERVATIONS:

Copies of this CoA are not valid

APPROVED

on Sep 06, 2013

QUALITY CONTROL
✓ Dr. G. Lorenzi

Nov 25, 2014