



CLOTRIMAZOLE USP - EP (micronized 10 microns)

CAS N. 23593-75-1

CODE 545M10

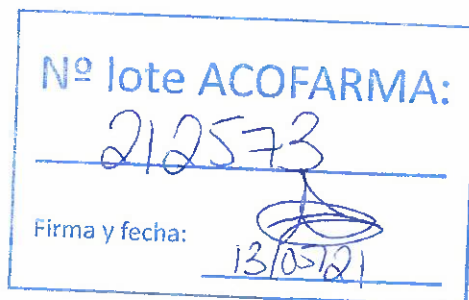
BATCH B200030

MAN. DATE 09/2020

RETEST DATE 09/2026

TEST FOR	SPECIFICATIONS	RESULTS
Description	white to pale yellow crystalline powder	Complies
Identification ✓		
· IR	positive	Complies
· HPLC	positive	Complies
Loss on drying ✓	≤ 0.5 %	0.04
Sulphated ash (Residue on ignition) ✓	≤ 0.1 %	0.00
Assay (HPLC, on dried basis)	≥ 98.5 ≤ 100.5 % (USP spec.: 98.0-102.0%)	99.7
Assay (volumetric, on dried basis) ✓	≥ 98.5 ≤ 100.5 %	100.2
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 %	Non quantifiable
· 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 %	Non quantifiable
· any other impurity	NMT 0.10%	Complies
· sum of any other impurity	≤ 0.2 % (in-house spec.)	0.01
· total ✓	≤ 0.5 %	0.01
Additional specifications		
Residual solvents (GC)		
· acetone ✓	≤ 2000 ppm	330
· benzene ✓	≤ 2 ppm	Non quantifiable
· methylene chloride ✓	≤ 600 ppm	35
Particle size (laser diffraction)		
· less than 10 µm	≥ 95 %	99.6

OBSERVATIONS:



Copies of this CoA are not valid

APPROVED

on Apr 29, 2021

QUALITY CONTROL
Dr. S. Patroni

Apr 30, 2021