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CERTIFICATE OF ANALYSIS N°

49004

BUPROPION HYDROCHLORIDE USP

CAS N. 31677-93-7

CODE 1019

BATCH 0614S074

MAN. DATE 06/2014 RETEST DATE 03/2020

Description : White powder

TEST FOR	SPECIFICATIONS	RESULTS
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
· Chlorides	positive	Complies
Water (KF)		0.04
Assay (HPLC, on anhydrous basis)	≥ 98.0 ≤ 102.0 %	101.5
Impurities (HPLC) - Limit of m-chlorobenzoic Acid		
· m-chlorobenzoic acid	≤ 0.2 %	Non quantifiable
Impurities (HPLC) - Organic Impurities		
· RRT~0.38 (Deschloro bupropion)	≤ 0.1 % (USP spec.: NMT 0.5%)	0.02
· RRT~0.58 (Bupropion dione derivative)	≤ 0.2 %	Non quantifiable
· RRT~0.71 (o-Bupropion)	≤ 0.1 %	Non quantifiable
· RRT~0.78 (Chloropropiophenone)	≤ 0.1 %	Non quantifiable
· RRT~0.92 (USP Rel. Comp. A)	≤ 0.1 % (USP spec.: NMT 0.2%)	Non quantifiable
· RRT~1.14 (USP Rel. Comp. B)	≤ 0.1 % (USP spec.: NMT 0.2%)	0.05
· RRT~1.63 (Bromochloropropionphenone)	≤ 0.1 %	Non quantifiable
· RRT~2.30 (4-Chlorobupropion)	≤ 0.1 % (USP spec.: NMT 0.2%)	Non quantifiable
· RRT~2.74 (5-Chlorobupropion)	≤ 0.1 % (USP spec.: NMT 0.2%)	Non quantifiable
· any other impurity	NMT 0.10% (USP spec.: NMT 0.1%)	Complies
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)	≤ 1.0 %	0.07
Additional specifications		
Residual solvents (GC)		
· sec-butyl alcohol	≤ 300 ppm	36
Particle size (sieving)		
· more than 250 µm	≤ 10 %	2.0
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.48
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.68

OBSERVATIONS:

- Other residual solvents are unlikely to be present

Copies of this CoA are not valid

APPROVED

QUALITY CONTROL