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CERTIFICATE OF ANALYSIS N°
184567

BUPROPION HYDROCHLORIDE USP

CAS N. **31677-93-7** CODE **1019** BATCH **B210054** MAN. DATE **10/2021** RETEST DATE **10/2027**

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
· A) IR	positive			Complies
· B) HPLC	positive			Complies
· C) Chlorides	positive			Complies
Water (KF)		≤ 0.5	%	0.02
Assay (HPLC, on anhydrous basis)	≥ 98.0	≤ 102.0	%	99.7
Impurites (HPLC) - Limit of m-chlorobenzoic Acid				
· m-chlorobenzoic acid		≤ 0.10	%	<0.02 (LOQ)
		(USP spec.: NMT 0.2%)		
Impurities (HPLC) - Organic Impurities				
· RRT~0.38 (Deschloro bupropion)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.5%)		
· RRT~0.58 (Bupropion dione derivative)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.2%)		
· RRT~0.71 (o-Bupropion)		≤ 0.1	%	<0.05 (LOQ)
· RRT~0.78 (Chloropropiophenone)		≤ 0.1	%	<0.05 (LOQ)
· RRT~0.92 (USP Rel. Comp. A)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.2%)		
· RRT~1.14 (USP Rel. Comp. B)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.2%)		
· RRT~2.30 (4-Chlorobupropion)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.2%)		
· RRT~2.74 (5-Chlorobupropion)		≤ 0.1	%	<0.05 (LOQ)
		(USP spec.: NMT 0.2%)		
· any other impurity (highest)		≤ 0.10	%	<0.05 (LOQ)
		(USP spec.: NMT 0.1%)		
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)		≤ 0.5	%	<0.05 (LOQ)
		(USP spec.: NMT 1.0%)		
Additional specifications				
2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone)	NMT 3 ppm			Complies
Residual solvents (GC)				
· sec-butyl alcohol		≤ 300	ppm	<100 (LOQ)
· methanol		≤ 1000	ppm	<60 (LOQ)
Particle size (sieving)				
· more than 250 µm		≤ 10	%	2.8
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.52
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.77

OBSERVATIONS:
· Other residual solvents are unlikely to be present
· The impurity 2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone) is evaluated with the USP HPLC method slightly modified

Copies of this CoA are not valid

QUALITY CONTROL
Dr. S.Patroni

APPROVED
on Nov 05, 2021

1019-O

Jan 03, 2022