ERREGIERRE
Via F. Baracca, 19 - 24060 SAN PAOLO D'ARGON (BG) ITALY - Tel. +39-035-958383, Fax +39-035-958165
Man. Site: Via Valle delle Fontane, 2 - 24060 SOVERE (BG) ITALY - Tel. +39-035-981783, Fax +39-035-981769

CERTIFICATE OF ANALYSIS N°
247507

BUPROPION HYDROCHLORIDE USP

CAS N. **31677-93-7** CODE **1019** BATCH **B220036** MAN. DATE **06/2022** RETEST DATE **06/2028**

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
· A) IR	positive			Complies
· B) HPLC	positive			Complies
· C) Chlorides	positive			Complies
Water (KF)		≤ 0.5	%	0.03
Assay (HPLC, on anhydrous basis)	≥ 98.0	≤ 102.0	%	100.5
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
		(USP spec.: NMT 1.0%)		
Additional specifications				
n-Nitroso-Bupropion (UPLC)	NMT 3 ppm			<3 ppm
2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone) (HPLC)	NMT 3 ppm			<3 ppm
Residual solvents (GC)				
· sec-butyl alcohol		≤ 300	ppm	<100 (LOQ)
· methanol		≤ 1000	ppm	<60 (LOQ)
Particle size (sieving)				
· more than 250 µm		≤ 10	%	1.2
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.46
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.69

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

APPROVED
Electronically signed by
Resp. CQ SOV Stefano Patroni
on Apr 17, 2025 11:48:08

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