

**BUPROPION HYDROCHLORIDE USP**

CAS N. 31677-93-7 CODE 1019

BATCH B210030

MAN. DATE 05/2021 RETEST DATE 05/2027

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
· A) IR	positive			Complies
· B) HPLC	positive			Complies
· C) Chlorides	positive			Complies
Water (KF)		≤ 0.5	%	0.04
Assay (HPLC, on anhydrous basis)	≥ 98.0	≤ 102.0	%	100.4
Impurities (HPLC) - Limit of m-chlorobenzoic Acid				
· m-chlorobenzoic acid		≤ 0.10	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
Impurities (HPLC) - Organic Impurities				
· RRT~0.38 (Deschloro bupropion)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.5%)			
· RRT~0.58 (Bupropion dione derivative)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· 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	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~1.14 (USP Rel. Comp. B)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~1.63 (Bromochloropropiophenone)		NMT 3 ppm		Complies
	(USP spec.: NMT 0.1%)			
· RRT~2.30 (4-Chlorobupropion)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~2.74 (5-Chlorobupropion)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· any other impurity (highest)		≤ 0.10	%	Non quantifiable
	(USP spec.: NMT 0.1%)			
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)		≤ 0.5	%	Non quantifiable
	(USP spec.: NMT 1.0%)			
Additional specifications				
Residual solvents (GC)				
· sec-butyl alcohol		≤ 300	ppm	Non quantifiable
· methanol		≤ 1000	ppm	Non quantifiable
Particle size (sieving)				
· more than 250 µm		≤ 10	%	1.2
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.44
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.68

OBSERVATIONS:

- Other residual solvents are unlikely to be present
- The impurity at RRT 1.63 Bromochloropropiophenone also called 2-Bromo-3'-chloropropiophenone is evaluated with the USP HPLC method slightly modified

Copies of this CoA are not valid

APPROVED

on Jun 21, 2021

QUALITY CONTROL

Dr. S. Patroni

Sep 02, 2021