



## 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
<b>Identification</b>				
· A) IR	positive			Complies
· B) HPLC	positive			Complies
· C) Chlorides	positive			Complies
<b>Water (KF)</b>		≤ 0.5	%	0.03
<b>Assay (HPLC, on anhydrous basis)</b>	≥ 98.0	≤ 102.0	%	100.5
<b>Impurities (HPLC) - Limit of m-chlorobenzoic Acid</b>				
· m-chlorobenzoic acid		≤ 0.10	%	<0.02 (LOQ)
	<i>(USP spec.: NMT 0.2%)</i>			
<b>Impurities (HPLC) - Organic Impurities</b>				
· RRT~0.38 (Deschloro bupropion)		≤ 0.1	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.5%)</i>			
· RRT~0.58 (Bupropion dione derivative)		≤ 0.1	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.2%)</i>			
· 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)
	<i>(USP spec.: NMT 0.2%)</i>			
· RRT~1.14 (USP Rel. Comp. B)		≤ 0.1	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.2%)</i>			
· RRT~2.30 (4-Chlorobupropion)		≤ 0.1	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.2%)</i>			
· RRT~2.74 (5-Chlorobupropion)		≤ 0.1	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.2%)</i>			
· any other impurity (highest)		≤ 0.10	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 0.1%)</i>			
<b>Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)</b>		≤ 0.5	%	<0.05 (LOQ)
	<i>(USP spec.: NMT 1.0%)</i>			
<b>Additional specifications</b>				
<b>2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone)</b>	NMT 3 ppm			Complies
<b>Residual solvents (GC)</b>				
· sec-butyl alcohol		≤ 300	ppm	<100 (LOQ)
· methanol		≤ 1000	ppm	<60 (LOQ)
<b>Particle size (sieving)</b>				
· more than 250 µm		≤ 10	%	1.2
<b>Bulk density</b>	≥ 0.40	≤ 0.60	g/ml	0.46
<b>Tapped density (1250 taps)</b>	≥ 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

Copies of this CoA are not valid

APPROVED

on Sep 26, 2022

QUALITY CONTROL

Dr. S.Patroni

Oct 12, 2022