

**BUPROPION HYDROCHLORIDE USP**

CAS N. **31677-93-7** CODE **1019** BATCH **A170058** MAN. DATE **09/2017** RETEST DATE **09/2023**

Description : White powder

TEST FOR	SPECIFICATIONS	RESULTS
Identification A) IR B) HPLC C) Chlorides	positive positive positive	Complies Complies Complies
Water (KF)	≤ 0.5 %	0.02
Assay (HPLC, on anhydrous basis)	≥ 98.0 ≤ 102.0 %	100.3
Impurities (HPLC) - Limit of m-chlorobenzoic Acid m-chlorobenzoic acid	≤ 0.10 % (USP spec.: NMT 0.2%)	Non quantifiable
Impurities (HPLC) - Organic Impurities RRT~0.38 (Deschloro bupropion)	≤ 0.1 % (USP spec.: NMT 0.5%)	0.05
RRT~0.58 (Bupropion dione derivative)	≤ 0.1 % (USP spec.: NMT 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%)	0.03
RRT~1.14 (USP Rel. Comp. B)	≤ 0.1 % (USP spec.: NMT 0.2%)	Non quantifiable
RRT~1.63 (Bromochloropropiophenone)	NMT 3 ppm (USP spec.: NMT 0.1%)	Complies
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 (highest)	≤ 0.10 % (USP spec.: NMT 0.1%)	0.01
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)	≤ 0.5 % (USP spec.: NMT 1.0%)	0.10
<u>Additional specifications</u>		
Residual solvents (GC) - sec-butyl alcohol - methanol	≤ 300 ppm ≤ 1000 ppm	36 48
Particle size (sieving) more than 250 µm	≤ 10 %	1.2
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.47
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.67

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 Sep 20, 2017

QUALITY CONTROL
Dr. R. Roli

Sep 26, 2017