

**ERREGIERRE**

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CERTIFICATE OF ANALYSIS N°
50871

BUPROPION HYDROCHLORIDE USP

CAS N. 31677-93-7

CODE 1019

BATCH 0914S121

MAN. DATE 09/2014 RETEST DATE 09/2020

Description : White powder

TEST FOR	SPECIFICATIONS	RESULTS
Identification • A) IR • B) HPLC • C) Chlorides	positive positive positive	Complies Complies Complies
Water (KF)	≤ 0.5 %	0.03
Assay (HPLC, on anhydrous basis)	≥ 98.0 ≤ 102.0 %	100.1
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%)	0.02
• 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%)	Non quantifiable
• RRT~1.14 (USP Rel. Comp. B)	≤ 0.1 % (USP spec.: NMT 0.2%)	0.04
• RRT~1.63 (Bromochloropropiophenone)	NMT 4 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%)	Non quantifiable
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)	≤ 0.5 % (USP spec.: NMT 1.0%)	0.06
Additional specifications		
Residual solvents (GC) • sec-butyl alcohol	≤ 300 ppm	45
• methanol	≤ 1000 ppm	26
Particle size (sieving) • more than 250 µm	≤ 10 %	0.4
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.46
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.63

OBSERVATIONS:

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

Copies of this CoA are not valid**APPROVED**

on Oct 10, 2014

QUALITY CONTROL

Oct 13, 2014