



BUPROPION HYDROCHLORIDE USP

M105

CAS N. 31677-93-7

CODE 1019

BATCH 0415A130

MAN. DATE 04/2015

RETEST DATE 04/2021

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 %	99.0
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%)	Non quantifiable
· 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%)	0.02
· RRT~1.14 (USP Rel. Comp. B)	≤ 0.1 % (USP spec.: NMT 0.2%)	Non quantifiable
· 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%)	0.02
Additional specifications		
Residual solvents (GC) · sec-butyl alcohol	≤ 300 ppm	32
· methanol	≤ 1000 ppm	Non quantifiable
Particle size (sieving) · more than 250 µm	≤ 10 %	2.5
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.51
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.74

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 Jun 10, 2015

QUALITY CONTROL

Dr. R. Poli

Jun 12, 2015