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CERTIFICATE OF ANALYSIS N° **52393**

BUPROPION HYDROCHLORIDE USP

CAS N. **31677-93-7** CODE **1019** BATCH **1114S182** MAN. DATE **11/2014** RETEST DATE **11/2020**

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 %	100.0
Impurites (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 (Bromochloropropionphenone)	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	55
· methanol	≤ 1000 ppm	Non quantifiable
Particle size (sieving)		
· more than 250 µm	≤ 10 %	1.0
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.55
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.72

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

QUALITY CONTROL
Dr. R.Poli
Dec 03, 2014

APPROVED
on Dec 02, 2014

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