ERREGIERRE
Via F. Baracca, 19 - 24060 SAN PAOLO D'ARGON (BG) ITALY - Tel. +39-035-958383, Fax +39-035-958165
Man. Site: Via F. Baracca, 19 - 24060 SAN PAOLO D'ARGON (BG) ITALY - Tel. +39-035-958383, Fax +39-035-958165

CERTIFICATE OF ANALYSIS N°
44767

BUPROPION HYDROCHLORIDE USP

CAS N. **31677-93-7** CODE **1019** BATCH **0114S015** MAN. DATE **01/2014** RETEST DATE **08/2019**

Description : White powder

TEST FOR	SPECIFICATIONS	RESULTS
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
· Chlorides	positive	Complies
Water (KF)	≤ 0.5 %	0.04
Assay (HPLC, on anhydrous basis)	≥ 98.0 ≤ 102.0 %	99.0
Impurites (HPLC) - Limit of m-chlorobenzoic Acid		
· m-chlorobenzoic acid	≤ 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)	≤ 0.2 %	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%)*	0.03
· RRT~1.63 (Bromochloropropionphenone)	≤ 0.1 %	Non quantifiable
· 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	NMT 0.10% *(USP spec.: NMT 0.1%)*	Complies
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)	≤ 1.0 %	0.05
Additional specifications		
Residual solvents (GC)		
· sec-butyl alcohol	≤ 300 ppm	32
Particle size (sieving)		
· more than 250 µm	≤ 10 %	2.5
Bulk density	≥ 0.40 ≤ 0.60 g/ml	0.53
Tapped density (1250 taps)	≥ 0.60 ≤ 0.86 g/ml	0.71

OBSERVATIONS:
· Other residual solvents are unlikely to be present

Copies of this CoA are not valid

APPROVED
on Jan 30, 2014

QUALITY CONTROL
Dr. R.Poli
Jan 31, 2014

1019-D