

**BUPROPION HYDROCHLORIDE USP**

CAS N. 31677-93-7

CODE 1019

BATCH 0913S081

MAN. DATE 09/2013

RETEST DATE 05/2019

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
· IR	positive			Complies
· HPLC	positive			Complies
· Chlorides	positive			Complies
Water (KF)		≤ 0.5	%	0.02
Assay (HPLC, on anhydrous basis)	≥ 98.0	≤ 102.0	%	98.4
Impurities (HPLC) - Limit of m-chlorobenzoic Acid		≤ 0.2	%	Non quantifiable
· m-chlorobenzoic acid		≤ 0.1	%	Non quantifiable
Impurities (HPLC) - Organic Impurities				
· RRT~0.38 (Deschloro bupropion)	(USP spec.: NMT 0.5%)	≤ 0.2	%	Non quantifiable
· RRT~0.58 (Bupropion dione derivative)		≤ 0.1	%	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)	(USP spec.: NMT 0.2%)	≤ 0.1	%	0.01
· RRT~1.14 (USP Rel. Comp. B)	(USP spec.: NMT 0.2%)	≤ 0.1	%	Non quantifiable
· RRT~1.63 (Bromochloropropiophenone)		≤ 0.1	%	Non quantifiable
· RRT~2.30 (4-Chlorobupropion)	(USP spec.: NMT 0.2%)	≤ 0.1	%	Non quantifiable
· RRT~2.74 (5-Chlorobupropion)	(USP spec.: NMT 0.2%)	≤ 0.1	%	Non quantifiable
· any other impurity	(USP spec.: NMT 0.2%)	NMT 0.10%		Complies
	(USP spec.: NMT 0.1%)			
Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities)		≤ 1.0	%	0.02
Additional specifications				
Residual solvents (GC)				
· sec-butyl alcohol		≤ 300	ppm	34
Particle size (sieving)				
· more than 250 µm		≤ 10	%	1.3
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.54
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.68

OBSERVATIONS:

- Other residual solvents are unlikely to be present

Copies of this CoA are not valid

APPROVED

on Sep 17, 2013

QUALITY CONTROL

D. R. Poli

Oct 07, 2013