ERREGIERRE

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CERTIFICATE OF ANALYSIS N°
25456

BUPROPION HYDROCHLORIDE USP

CAS N. **31677-93-7** CODE **1019** BATCH **S1011A216** MAN. DATE **10/2011** RETEST DATE **09/2017**

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
· IR	positive			Complies
· HPLC	positive			Complies
· Chlorides	positive			Complies
Water (KF)		≤ 0.5	%	0.01
Assay (HPLC, on anhydrous basis)	≥ 98.0	≤ 102.0	%	100.2
Organic Impurity (HPLC) - Procedure 1				
· m-chlorobenzoic acid		≤ 0.2	%	Non quantifiable
Organic Impurity (HPLC) - Procedure 2				
· RRT~0.38 (2-(tert-Butylamino)propiophenone HCl)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.5%)			
· RRT~0.58 (1-(3-Chlorophenyl)-1,2-propanedione)		≤ 0.2	%	Non quantifiable
· RRT~0.71 (2-(tert-Butylamino)-2'-chloropropiophenone HCl)		≤ 0.1	%	Non quantifiable
· RRT~0.78 (3'-chloropropiophenone)		≤ 0.1	%	Non quantifiable
· RRT~0.92 (USP Rel. Comp. A)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~1.14 (USP Rel. Comp. B)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~1.63 (2-Bromo-3'-chloropropiophenone)		≤ 0.1	%	Non quantifiable
· RRT~2.30 (2-(tert-Butylamino)-3',4'-dichloropropiophenone HCl)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· RRT~2.74 (2-(tert-Butylamino)-3',5'-dichloropropiophenone HCl)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
· any other impurity	NMT 0.10%			Complies
	(USP spec.: NMT 0.1%)			
· sum of any other impurity		≤ 0.3	%	Non quantifiable
Total impurities (Procedure 1 + Procedure 2)		≤ 1.0	%	Non quantifiable
Additional specifications				
Residual solvents (GC)				
· sec-butyl alcohol		≤ 300	ppm	55
Particle size (sieving)				
· more than 250 µm		≤ 10	%	3.7
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.54
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.74
Optical rotation	≥ -0.1	≤ +0.1	°	0.00

OBSERVATIONS:
· Other residual solvents are unlikely to be present

Copies of this CoA are not valid

QUALITY CONTROL
Dr. G.Lorenzi

APPROVED
on Oct 26, 2011

Oct 27, 2011

1019-G