



ERREGIERRE

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CERTIFICATE OF ANALYSIS N°

38171

BUPROPION HYDROCHLORIDE USP

CAS N. 31677-93-7 CODE 1019

BATCH 0413A116

MAN. DATE 04/2013 RETEST DATE 04/2019

Description : White powder

TEST FOR	SPECIFICATIONS			RESULTS
Identification				
• IR	positive			Complies
• HPLC	positive			Complies
• Chlorides	positive			Complies
Water (KF)				
Assay (HPLC, on anhydrous basis)				
	≥ 98.0	≤ 102.0	%	0.04
Organic Impurity (HPLC) - Procedure 1				100.7
• m-chlorobenzoic acid		≤ 0.5	%	
Organic Impurity (HPLC) - Procedure 2				
• RRT~0.38 (2-(tert-Butylamino)propiofenone HCl)		≤ 0.2	%	Non quantifiable
		≤ 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'-chloropropiofenone HCl)		≤ 0.1	%	Non quantifiable
• RRT~0.78 (3'-chloropropiofenone)		≤ 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'-chloropropiofenone)		≤ 0.1	%	Non quantifiable
• RRT~2.30 (2-(tert-Butylamino)-3',4'-dichloropropiofenone HCl)		≤ 0.1	%	Non quantifiable
	(USP spec.: NMT 0.2%)			
• RRT~2.74 (2-(tert-Butylamino)-3',5'-dichloropropiofenone 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	38
Particle size (sieving)				
• more than 250 µm		≤ 10	%	3.1
Bulk density	≥ 0.40	≤ 0.60	g/ml	0.54
Tapped density (1250 taps)	≥ 0.60	≤ 0.86	g/ml	0.68
Optical rotation	≥ -0.1	≤ +0.1	°	+0.03

OBSERVATIONS:

- Other residual solvents are unlikely to be present

Copies of this CoA are not valid

APPROVED

on Apr 23, 2013

QUALITY CONTROL

D. J. Polj

May 02, 2013