



SUPRIYA LIFESCIENCE LTD.
Creating true values that bind global health

Certificate of analysis

Product	: Bupropion Hydrochloride USP	License No.	: KD-129
Batch No.	: SLL/BPH/0716008	Date of Manufacturing	: July -2016
Batch Qty.	: 650.0 kg	Date of re-test/Expiry	: June -2019
A. R. No.	: SLL/QC/FP/16/0574	Date of Release	: 25/07/2016

S.No.	Test	Specifications	Results
1.	Description	White powder	A white powder.
2.	Solubility	Soluble in water, in 0.1N hydrochloric acid and in alcohol.	Conforms
3.	Identification:		
	i. IR Absorption	The IR absorption spectrum should be concordant with that of Bupropion hydrochloride working standard.	Positive
	ii. Retention time in assay by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in assay.	Complies
	iii. Chloride	Its gives reaction of chlorides.	Positive
4.	Assay by HPLC on dry basis (% w/w)	98.0 to 102.0	100.02
5.	m-Chlorobenzoic acid by HPLC (%)	Not more than 0.2	BDL
6.	Organic Impurities by HPLC (%)		
	i. Deschlorobupropion	Not more than 0.5	0.05
	ii. Bupropion dione derivative	Not more than 0.2	BDL
	iii. o-Bupropion	Not more than 0.1	BDL
	iv. Chloropropiophenone	Not more than 0.1	BDL

QA/011/F03-02/Effective date 05/08/2015

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Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India
Tel : +91 22 40332727 / 66942507 | Fax : +91 22 26860011
CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory : A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal.- Khed, Dist.- Ratnagiri, Pin: 415 722, Maharashtra, India
Tel: +91 2356 272299 | Fax : +91 2356 272178 | E-Mail: factory@supriyalifescience.com

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S.No.	Test	Specifications	Results
	v. Bupropion hydrochloride related compound A	Not more than 0.2	BDL
	vi. Bupropion hydrochloride related compound B	Not more than 0.2	0.01
	vii. Bromochloropropion phenone	Not more than 0.1	BDL
	viii. 4-Chlorobupropion	Not more than 0.2	BDL
	xi. 5-Chlorobupropione	Not more than 0.2	BDL
	x. Any individual impurity	Not more than 0.1	BDL
	xi. Total impurities	Not more than 1.0	0.09
7.	Water by KF (%w/w)	Not more than 0.5	0.11
8.	Additional test:		
9.	Residual Solvents by GC-HS (ppm)		
	i. Acetone	Not more than 5000	BDL
	i. Isopropyl alcohol	Not more than 5000	660
	ii. Methylene chloride	Not more than 600	BDL

Remarks: The product is complies with respect to above mentioned test as per **USP38** specifications.

Storage: Preserve in well-closed, light resistant containers.

 Compiled by QC QC Chemist (M.M.Sawant)	 Checked by QC QC Dy. Sr Manager (S.U.Takale)	 Approved by QC QC Head (S.H.Kambale)
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