SUPRIYA LIFESCIENCE LTD.
(Formerly known as **Supriya Chemicals**)

Certificate of analysis

Product	:	Bupropion Hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/BPH/0815010	Date of Manufacturing	:	Aug , 2015
Batch Qty.	:	600.0 kg	Date of ~~re-test~~/Expiry	:	July, 2018
A. R. No.	:	SLL/QC/FP/15/0739	Date of Release	:	18/08/2015

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.	Conforms
	iii. Chloride	Its gives reaction of chlorides.	Positive
4.	Assay by HPLC on dry basis (%, w/w)	98.0 to 102.0	99.74
5.	m-Chlorobenzoic acid by HPLC (%)	Not more than 0.2	BDL
6.	Organic Impurities by HPLC (%)		
	i. Deschlorobupropion	Not more than 0.5	BDL
	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

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CIN : U51900MH2008PLC180452
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Factory : A 5/2, Lote Parshuram Industrial Area, M.I.D.C, Tal. - Khed, Dist.-Ratnagiri, 415 722, Maharashtra, India.
Tel. : +91 2356 272299 Fax : +91 2356 272178
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A. R. No.	:	SLL/QC/FP/15/0739	Date of Release	:	18/08/2015

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	BDL
	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	0.05
	xi. Total impurities	Not more than 1.0	0.08
7.	Water by KF (%,w/w)	Not more than 0.5	0.23
8.	**Additional test:**		
9.	Residual Solvents by GC-HS (ppm)		
	i. Acetone	Not more than 5000	BDL
	i. Isopropyl alcohol	Not more than 5000	359
	ii. Methylene chloride	Not more than 600	BDL

Remarks: The product is complies with respect to above mentioned test as per **USP 38** specifications.

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

Compiled by QC	Checked by QC	Approved by Head - QC
20/11/15	20/11/15	20/11/15

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Certificate of analysis

Product	:	Bupropion Hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/BPH/1115012	Date of Manufacturing	:	Nov - 2015
Batch Qty.	:	650.0 kg	Date of ~~re-test~~/Expiry	:	Oct - 2018
A. R. No.	:	SLL/QC/FP/15/0942	Date of Release	:	07/11/2015

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.	Conforms
	iii. Chloride	Its gives reaction of chlorides.	Positive
4.	Assay by HPLC on dry basis (%, w/w)	98.0 to 102.0	100.04
5.	m-Chlorobenzoic acid by HPLC (%)	Not more than 0.2	BDL
6.	Organic Impurities by HPLC (%)		
	i. Deschlorobupropion	Not more than 0.5	0.02
	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

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Certificate of analysis

Product	:	Bupropion Hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/BPH/1115012	Date of Manufacturing	:	Nov - 2015
Batch Qty.	:	650.0 kg	Date of ~~re-test~~/Expiry	:	Oct - 2018
A. R. No.	:	SLL/QC/FP/15/0942	Date of Release	:	07/11/2015

S.No.	Test	Specifications	Results
	v. Bupropion hydrochloride related compound A	Not more than 0.2	0.04
	vi. Bupropion hydrochloride related compound B	Not more than 0.2	BDL
	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	0.10
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	344
	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.*			

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Product	:	Bupropion Hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/BPH/0815011	Date of Manufacturing	:	July - 2015
Batch Qty.	:	600.0 kg	Date of ~~re-test~~/Expiry	:	June - 2018
A. R. No.	:	SLL/QC/FP/15/0761	Date of Release	:	26/08/2015

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.	Conforms
	iii. Chloride	Its gives reaction of chlorides.	Positive
4.	Assay by HPLC on dry basis (%, w/w)	98.0 to 102.0	99.37
5.	m-Chlorobenzoic acid by HPLC (%)	Not more than 0.2	BDL
6.	Organic Impurities by HPLC (%)		
	i. Deschlorobupropion	Not more than 0.5	BDL
	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

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Product	:	Bupropion Hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/BPH/0815011	Date of Manufacturing	:	July - 2015
Batch Qty.	:	600.0 kg	Date of ~~re-test~~/Expiry	:	June - 2018
A. R. No.	:	SLL/QC/FP/15/0761	Date of Release	:	26/08/2015

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	BDL
	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	0.06
	xi. Total impurities	Not more than 1.0	0.09
7.	Water by KF (%,w/w)	Not more than 0.5	0.06
8.	**Additional test:**		
9.	Residual Solvents by GC-HS (ppm)		
	i. Acetone	Not more than 5000	37
	i. Isopropyl alcohol	Not more than 5000	25
	ii. Methylene chloride	Not more than 600	132
Remarks: The product is complies with respect to above mentioned test as per **USP 38** specifications.			
Storage: *Preserve in well-closed, light resistant containers.*			

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