Sun Pharmaceutical Industries Ltd.
Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk
Kancheepuram District, Tamil Nadu - 603 303, INDIA.
Tel. : 044 - 2756 7272, 2756 7432, 2756 7664, 2756 7878
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SUN PHARMA

Certificate of Analysis

Product	:	DIVALPROEX SODIUM USP					
Item Code	:	BD0129U0IA					
Mfg. Date	:	Nov/2012	Batch No.	:	PDLDVLFL275	AR. No.	: MKL1266
Exp. Date	:	Oct/2017	Batch Size	:	367 KGS	Release Date	: 30/11/2012

Sr.	Test	Observation/Results	Specification
1	Description	White Powder.	White to off white powder.
2	Solubility	Very soluble in Chloroform, Freely soluble in Methanol and in Diethyl ether,Soluble in Acetone,Insoluble in Acetonitrile.	Very soluble in Chloroform, freely soluble in Methanol and in Diethyl ether.Soluble in Acetone,practically insoluble in Acetonitrile.
3	Identification		
3.1	Identification by IR	Infra red spectrum of sample corresponds to that of Divalproex sodium working standard.	Infra red spectrum of sample should be corresponds to that of Divalrpoex sodium working standard.
3.2	Test for Sodium	Dense White Precipitate is Formed.	A dense white precipitate shall be formed.
4	Water content	Mean : 0.03 % w/w	Not more than 1.0%w/w
5	Heavy metals	Less than 0.002%	Not more than 0.002%
6	Assay (By HPLC)	99.4 % w/w	98.0% to 102.0%w/w(On anhydrous basis)
7	Loss on drying - 1g at 60°C under vacuum of 0.7kpa for 4 hrs	0.35 % w/w	Not more than 2.0%w/w.
8	Bulk Density - Sample weight : 25 - 30gm ; 100ml measuring cylinder		
8.1	Tapped Density	0.54 gm/ml	Between 0.45gm/ml and 0.65gm/ml
9	Related Substances by GC		
	Total Impurities	0.06 %	Not more than 0.4%
10	Sieve test	98.5 %	Not less than 80% should passes through 20mesh.
11	Residual Solvents		
	Methanol	Not Detected	Not more than 3000ppm
12	Assay by titrimetry		
12.1	Content of Valproic acid	46.5 % w/w	45.0% to 48.0%w/w(On anhydrous basis)
12.2	Content of Sodium Valproate	53.2 % w/w	

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Exp. Date	:	Oct/2017	Batch Size	:	367 KGS	Release Date	:	30/11/2012

Sr.	Test	Observation/Results	Specification
			anhydrous basis)

Remarks : The above sample complies with USP Specification and standards

Analysed By	Checked By	Approved By
S.Raju - E29241 30/11/2012	N.K.Elangovan - E08824 30/11/2012	P.Natesan - E07662 (30/11/2012)

Generated By D.Suresh
Date 30/11/2012

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CIN : L24230GJ1993PLC019050

SUN PHARMA

Customer ID: LI0193, Lifecare Neuro P. Ltd

Order No : 006SDG0458

CERTIFICATE OF ANALYSIS

PRODUCT	**: MIRTAZAPINE**		
BATCH No.	**: PNLMRTFL08**	**A.R. No.**	**: MO1511**
MFG. DT.	**: AUGUST 2012**	**RELEASE DATE**	**: 29.08.12**
EXP. DT.	**: JULY 2017**	**PAGE**	**: 01 OF 01**

Sr.#	TEST	SPECIFICATION	RESULT
1.	Description	White to creamy white, crystalline powder	Off-white crystalline powder.
2.	Solubility	Freely soluble in methanol, soluble in ethyl ether and toluene, sparingly soluble in n-Hexane and practically insoluble in water	Complies.
3.	Identification		
3.1.	By IR Spectrum	IR absorption spectrum of sample in KBr dispersion shall concordant with similarly recorded spectrum of Mirtazapine working standard.	Complies.
3.2.	By HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatograms of standard preparations as obtained in the assay	Complies.
4.	Water content (By KF)	Not more than 3.5% w/w	2.86% w/w.
5.	Specific optical rotation at 25°C (C=1% w/v in denatured alcohol)	Between +2° to -2°	1.4 °
6.	Residue on ignition	Not more than 0.1% w/w.	0.05% w/w.
7.	Heavy metals	Not more than 0.001%	Less than 0.001%
8.	Related substances (by HPLC)		
	a) Impurity A	Not more than 0.1%	BQL
	b) Impurity B	Not more than 0.1%	BQL
	c) Impurity C	Not more than 0.1%	BQL
	d) Impurity D	Not more than 0.1%	BQL
	e) Impurity E	Not more than 0.1%	BQL
	f) Impurity F	Not more than 0.1%	BQL
	g) Individual unspecified impurity	Not more than 0.10%	BQL
	h) Total impurities	Not more than 0.5%	BQL
9.	Organic Volatile Impurities (Residual Solvent–In house method)		
	a) Methanol	Not more than 1500 ppm.	Not detected
	b) n-Hexane	Not more than 150 ppm.	1 ppm
	c) Ethyl acetate	Not more than 1000 ppm.	Not detected
10.	Assay	Between 98.0% and 102.0 % w/w. (on anhydrous basis)	99.7% w/w.

BQL = Below Quantification Limit

REMARKS : The product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per USP & In-house specification.

Note : DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 19.08.15

PREPARED BY :

DATE : 19.08.15

VERIFIED BY :

DATE : 19.08.15

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Certificate of Analysis

Product	:	SODIUM VALPROATE IP/BP						
Item Code	:	BD0397IBAA						
Mfg. Date	:	Sep/2015	Batch No.	:	PDOSDMFL237	AR. No.	:	MKO1006
Exp. Date	:	Aug/2020				Release Date	:	16/09/2015

Sr.	Test	Observation/Results	Specification
11	Assay by titrimetry	99.5% w/w	Not less than 98.5% and not more than 101.0% of Sodium valproate, calculated on the dried basis.
12	Residual Solvents		
	Toluene	111ppm	Not more than 890ppm
13	Bulk Density		
	Tapped Density	0.59 gm/ml	0.40gm/ml to 0.60 gm/ml
14	Sieve Test	89.8 % passes through 60 mesh	Not less than 85% passes through 60mesh.

BQL = Below Quantification Limit

Note : Impurity D, E, F, G, H, I , J, K & L as per BP/Ph.Eur are not possible as per our route of synthesis of sodium valproate

Remarks : The Sample Complies with IP/BP/Inhouse Specification and Standards

Date of issue : **16/09/2015**

Prepared by : V. Sasikumar 16/09/15 **Checked by :** 16/09/15 **Approved by :** 16/09/15

Note: REPRODUCED FROM ORIGINAL REPORT

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RM/506/10/1536

SUN PHARMA

CERTIFICATE OF ANALYSIS

Product	**Fluvoxamine Maleate IP**	**A.R.NO.**	QFP / 41691
Batch No.	AHNFLVFL052	**Mfg. Date**	August 2014
Release Date	11.09.15	**Exp. Date**	July 2019

Specification No. : BD0187I0AA **Rev. No. : 1.0**

Sr.	*Test*	*Results*	*Specification*
1	Description	White, crystalline powder.	A white to off - white, crystalline powder.
2	Solubility	Freely soluble in ethanol (95%) and in methanol, Sparingly soluble in water	Freely soluble in ethanol (95%) and in methanol, Sparingly soluble in water
3	Identification - by IR	The infra red absorption spectrum of sample in Potassium bromide dispersion is concordant with that of Fluvoxamine maleate working standard.	The infra red absorption spectrum of sample in Potassium bromide dispersion should be concordant with that of Fluvoxamine maleate working standard.
4	Related Substances (By HPLC)		
	Known Impurities		
	Impurity B	0.136 %	Not more than 0.5%
	Impurity C	0.043 %	Not more than 0.3%
	Impurity A	BQL	Not more than 0.2%
	Impurity D	BQL	Not more than 0.15%
	Impurity F & G	BQL	Not more than 0.3%
	UnKnown Impurities		
	Any other secondary impurity	0.1 %	Not more than 0.1 %
5	Heavy metals	Less than 20 ppm	Not more than 20 ppm
6	Sulphated Ash	0.04 %	Not more than 0.1%
7	Loss on drying	0.21 %	Not more than 0.5 %
8	Assay by titrimetric	99.8% w/w	Between 99.0 % and 101.0 % w/w (On dried basis)
9	Clarity	A 5% w/v solution in methanol is clear and free from extraneous matter	A 5% w/v solution in methanol should be clear and free from extraneous matter
10	colour index	0.009 abs	Absorbance at 420 nm with 1 cm path length, of a 5% w/v solution in methanol should not more than 0.05 .
11	Residual Solvents (By GC)		
	Toluene	BQL	Not more than 100ppm
	Methanol	BQL	Not more than 3000ppm
	n-Hexane	Not Detected	Not more than 290ppm

Conclusion : Product complies with the quality standard as per **IP & In-house** specifications.

Date of Issue : 11.09.15

Prepared by 11.09.15 Checked by 11.09.15 Approved by 11.09.15

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Certificate of Analysis

Product	:	VALPROIC ACID IP						
Item Code	:	BD0447I0AA						
Mfg. Date	:	Sep/2015	Batch No.	:	PDOVALFL146	AR. No.	:	MKO1054
Exp. Date	:	Aug/2020				Release Date	:	29/09/2015

Sr.	Test	Observation/Results	Specification
1	Description	Colourless liquid, slightly viscous.	A colourless or very slightly yellow liquid, slightly viscous.
2	Solubility	Very soluble in organic solvents, slightly soluble in water.	Very soluble in organic solvents, slightly soluble in water.
3	Identification		
	By IR	Infra red spectrum of the sample is concordant with the spectrum of valproic acid working standard.	Infra red spectrum of the sample should be concordant with the spectrum of valproic acid working standard.
	Thin Layer Chromatography	The principal spot in the chromatogram obtained with test solution is similar in position colour and size to the principal spot in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with test solution should be similar in position colour and size to the principal spot in the chromatogram obtained with the reference solution.
	Reaction with Cobalt Nitrate	Violet precipitate is formed , filter; the precipitate dissolved in methylene chloride.	A violet precipitate is formed ,filter; the precipitate dissolves in methylene chloride.
4	Appearance of solution	The solution is clear and less intensely coloured than reference solution YS5.	The solution should be clear and not more intensely coloured than reference solution YS5.
5	Refractive index	1.425	1.422 to 1.425
6	Related Substances by GC		
	UnKnown Impurities		
	Any individual impurity	0.037%	Not more than 0.1 %
	Total Impurity	0.037%	Not more than 0.3%
7	Heavy metals	Less than 20ppm.	Not more than 20ppm.
8	Sulphated Ash	0.03% w/w	Not more than 0.1%w/w.
9	Assay	99.7% w/w	99.0% to 101.0%w/w(On as is basis)

Remarks : The above sample Complies with IP/Inhouse Specification and Standards

Date of issue : **08/10/2015**

Prepared by : D.Sv 08/10/15 **Checked by :** 08/10/15 **Approved by :** 08/10/15

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SUN PHARMA

Customer ID : LI0193, M/s. Lifecare Neuro Products Ltd.
Order No : 006SDG0563, 10 Kg

CERTIFICATE OF ANALYSIS

PRODUCT	**: CLOMIPRAMINE HYDROCHLORIDE IP**		
BATCH No.	**: PNOCLMFL021**	**A. R. No.**	**: MO1659**
MFG. DT.	**: MARCH 2015**	**RELEASE DATE**	**: 31.03.15**
EXP. DT.	**: FEBRUARY 2020**	**PAGE NO.**	**: 01 OF 01**

Sr.#	TEST	SPECIFICATION	RESULT
1.	Characteristics	White or slightly yellow crystalline powder, Slightly hygroscopic	White crystalline powder, Slightly hygroscopic
2.	Solubility	Freely soluble in water and in methylene chloride, soluble in ethanol (95%).	Complies
3.	Identification		
3.1.	By IR	The infrared (IR) absorption spectrum of sample should concordant with the IR absorption spectrum obtained from Clomipramine Hydrochloride working standard.	Complies.
3.2.	By TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	Complies.
3.3.	By colour reaction	An instance blue colour develops	Complies.
3.4.	By chloride	A curdy white precipitate is formed	Complies.
4.	Appearance of solution	The solution A should be clear and not more intensely coloured than reference solution Y5.	Complies.
5.	pH	Between 3.5 and 5.0	3.74
6.	Heavy Metals	Not more than 10 ppm.	Less than 10 ppm.
7.	Loss on Drying	Not more than 0.50% w/w.	0.33%
8.	Sulphated Ash	Not more than 0.10% w/w.	0.04%
9.	Assay by Titrimetry	Between 99.0% to 101.0% (on dried basis)	99.9%
10	Related substances by HPLC		
	a) Highest unknown impurity	Not more than 0.5%	0.084%
	b) Total impurities	Not more than 1.0%	0.209%

REMARKS: The above product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per IP specification.

Note: DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 21.09.15

PREPARED BY :

DATE : 21/09/15

VERIFIED BY :

DATE : 21/09/15

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Customer ID : **LI0193, M/s. Lifecare Neuro Products Ltd.**
Order No : **006SDG0563, 10 Kg**

CERTIFICATE OF ANALYSIS

PRODUCT	**: CLOMIPRAMINE HYDROCHLORIDE IP**			
BATCH No.	**: PNOCLMFL021**		**A. R. No.**	**: MO1659**
MFG. DT.	**: MARCH**	**2015**	**RELEASE DATE**	**: 31.03.15**
EXP. DT.	**: FEBRUARY**	**2020**	**PAGE NO.**	**: 01 OF 01**

Sr.#	TEST	SPECIFICATION	RESULT
1.	Characteristics	White or slightly yellow crystalline powder, Slightly hygroscopic	White crystalline powder, Slightly hygroscopic
2.	Solubility	Freely soluble in water and in methylene chloride, soluble in ethanol (95%).	Complies
3.	Identification		
3.1.	By IR	The infrared (IR) absorption spectrum of sample should concordant with the IR absorption spectrum obtained from Clomipramine Hydrochloride working standard.	Complies.
3.2.	By TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	Complies.
3.3.	By colour reaction	An instance blue colour develops	Complies.
3.4.	By chloride	A curdy white precipitate is formed	Complies.
4.	Appearance of solution	The solution A should be clear and not more intensely coloured than reference solution Y5.	Complies.
5.	pH	Between 3.5 and 5.0	3.74
6.	Heavy Metals	Not more than 10 ppm.	Less than 10 ppm.
7.	Loss on Drying	Not more than 0.50% w/w.	0.33%
8.	Sulphated Ash	Not more than 0.10% w/w.	0.04%
9.	Assay by Titrimetry	Between 99.0% to 101.0% (on dried basis)	99.9%
10	Related substances by HPLC		
	a) Highest unknown impurity	Not more than 0.5%	0.084%
	b) Total impurities	Not more than 1.0%	0.209%

REMARKS: The above product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per IP specification.

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