This Raw Material (3 Containers)
Client to bring Working Standard
7 Oct 2014

WRS-T8-4

Hetero Labs Limited

Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh, INDIA

Phone : 091-08458-277106

CERTIFICATE OF ANALYSIS

Product	: TERBINAFINE HYDROCHLORIDE	Reference STP No.	: TH-004-04
Batch No.	: TH1711211	Reference	: Ph.Eur
Dt. of Manufacture	December,2011	Batch Qty	: 140.15 Kg
Retest Date	November,2016	Dt. of Analysis	: 11/01/2012
Analytical Report No.	: TH0237/11	Status	: Initial Certification

S.No.	Test	Specifications	Results	Reference
1	Description	White or almost white powder.	A white powder	Visual Inspection
2	Solubility	Very slightly soluble in water, freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone.	Complies	Visual Inspection Ph.Eur 1.4
3	Identification by a) Infrared absorption	The infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Terbinafine Hydrochloride Working Standard.	Matches with working standard	Ph.Eur 2.2.24
	b) Chlorides	Should comply with the test for chlorides.	Complies	Ph.Eur 2.3.1
4	# Chloride Content	Between 10.7% w/w and 11.9% w/w	10.8% w/w	Ph.Eur 2.2.20
5	Loss on drying	Not more than 0.50% w/w	0.17% w/w	Ph.Eur 2.2.32
6	Sulphated Ash	Not more than 0.10% w/w	0.04% w/w	Ph.Eur 2.4.14
7	# Heavy Metals	Not more than 0.002%	Less than 0.002%	Ph.Eur 2.4.8
8	# Clarity and Colour of solution	Should be clear		
	Clarity of the solution		Complies	Ph.Eur 2.2.1
	Colour of the Solution	Maximum absorbance should not be more than 0.05Au between 400 to 700 nm	0.0260 Au	
9	# Melting point by DSC	Between 207.0°C and 211.0°C	207.5°C	Ph.Eur 2.2.34
10	Related substances by HPLC	(2Z)-N,6,6-Trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine (cis-Terbinafine) Impurity B : Not more than 0.10%	Below LOQ (LOQ -0.05%)	Ph.Eur 2.2.29
		(2E,4E)-4-(4,4-Dimethylpent-2-yn-1-ylidene)-N,N'-dimethyl-N,N'-bis(naphthalen-1-ylmethyl)pent-2-ene-1,5-diamine Impurity E : Not more than 0.05%	0.00%	

* No potential for any Class 1 solvents as specified by ICH to be present in the Terbinafine hydrochloride as they are not used in the manufacturing process. The material, if tested for these impurities, will comply with the established standards.

In-House tests Φ In-House impurity

The product CONFORMS to above specifications.

Compiled by : Leela.M Checked by : [signature] Authorised Signatory : [signature]

Date : 23/01/2012 Date : 23/01/2012 Date : 23/01/12

HETERO LABS LIMITED RELEASED 19/05/12 QUALITY ASSURANCE

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 07 OCT 2014 TEL: 2726963 / 3544523/30 FAX: 2718474 P.O. Box 29726 - 00202 NAIROBI

QC-TH-COA-002-05

Hetero Labs Limited

Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh, INDIA

Phone : 091-08458-277106

CERTIFICATE OF ANALYSIS

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Batch No.	: TH1711211	Reference	: Ph.Eur
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Retest Date	November,2016	Dt. of Analysis	: 11/01/2012
Analytical Report No.	:TH0237/11	Status	: Initial Certification

S.No.	Test	Specifications	Results	Reference
10	Related substances by HPLC	1-Bromo-6,6-dimethyl hept-2-ene-4-yne Φ Impurity I : Not more than 0.10%	Below LOQ (LOQ=0.02%)	Ph.Eur 2.2.29
		Maximum single unspecified Impurity : Not more than 0.10%	0.05%	
		Total impurities : Not more than 0.30%	0.05%	
11	Assay by Potentiometry (On dried basis)	Not less than 99.0% and not more than 101.0% w/w	100.2% w/w	Ph.Eur 2.2.20
12	*Residual solvents by GC	Acetone : Not more than 600 ppm	Below LOQ (LOQ= 60 ppm)	Ph.Eur 2.2.28,5.4 (In-House)
		Dichloromethane : Not more than 300 ppm	Below LOQ (LOQ=71 ppm)	
		Diisopropyl ether : Not more than 100 ppm	Below LOQ (LOQ=60 ppm)	
		Cyclohexane : Not more than 500 ppm	Below LOQ (LOQ=60 ppm)	
		N,N-Dimethyl formamide : Not more than 200 ppm	Below LOQ (LOQ=186 ppm)	
13	# Particle size by Laser diffraction	X(10) should be less than 5 microns.	2 microns	Ph.Eur 2.9.31 (In-House)
		X(50) should be less than 10 microns.	7 microns	
		X(90) should be less than 25 microns.	17 microns	

* No potential for any Class I solvents as specified by ICH to be present in the Terbinafine hydrochloride as they are not used in the manufacturing process. The material , if tested for these impurities, will comply with the established standards.

In-House tests Φ In-House impurity

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Compiled by: [signature] Date : 23/01/2012

Checked by : [signature] Date : 23/01/2012

Authorised Signatory : [signature] Date : 23/01/12

Hetero Labs Limited

Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh. INDIA
Phone : 091-08458-277106

CERTIFICATE OF ANALYSIS

Product : TERBINAFINE HYDROCHLORIDE
Batch No. : TH1711211
Dt. of Manufacture : December,2011
Retest Date : November,2016
Analytical Report No. : TH0237/11
Reference STP No. : TH-004-04
Reference : Ph.Eur
Batch Qty : 140.15 Kg
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# In-House tests Φ In-House impurity
The product CONFORMS to above specifications.

Compiled by : [signature]
Date : 23/01/2012

Checked by : [signature]
Date : 25/01/12

Authorised Signatory : [signature]
Date : 07 OCT 2014

HETERO LABS LIMITED RELEASED QUALITY ASSURANCE

NATIONAL QUALITY CONTROL LABORATORY P.O. Box 29726 NAIROBI

Hetero Labs Limited

Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh, INDIA

Phone : 091-08458-277106

CERTIFICATE OF ANALYSIS

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Batch No.	: TH1711211	Reference	: Ph.Eur
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In-House tests Φ In-House impurity

The product CONFORMS to above specifications.

Compiled by : [signature] Checked by : [signature] Authorised Signatory : [signature]

Date : 23/01/2012 Date : 23/01/2012 Date : 23/01/12

HETERO LABS LIMITED RELEASED 19/05/12 QUALITY ASSURANCE

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 07 OCT 2014 P. O. Box 29726

Hetero Labs Limited

Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh. INDIA

Phone : 091-08458-277106

CERTIFICATE OF ANALYSIS

Product	: TERBINAFINE HYDROCHLORIDE	Reference STP No.	: TH-004-04
Batch No.	: TH1711211	Reference	: Ph.Eur
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Analytical Report No.	: TH0237/11	Status	: Initial Certification

S.No.	Test	Specifications	Results	Reference
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		Maximum single unspecified Impurity : Not more than 0.10%	0.05%	
		Total impurities : Not more than 0.30%	0.05%	
11	Assay by Potentiometry (On dried basis)	Not less than 99.0% and not more than 101.0% w/w	100.2% w/w	Ph.Eur 2.2.20
12	*Residual solvents by GC	Acetone : Not more than 600 ppm	Below LOQ (LOQ= 60 ppm)	Ph.Eur 2.2.28,5.4 (In-House)
		Dichloromethane : Not more than 300 ppm	Below LOQ (LOQ=71 ppm)	
		Diisopropyl ether : Not more than 100 ppm	Below LOQ (LOQ=60 ppm)	
		Cyclohexane : Not more than 500 ppm	Below LOQ (LOQ=60 ppm)	
		N,N-Dimethyl formamide : Not more than 200 ppm	Below LOQ (LOQ=180 ppm)	
13	# Particle size by Laser diffraction	X(10) should be less than 5 microns.	2 microns	Ph.Eur 2.9.31 (In-House)
		X(50) should be less than 10 microns.	7 microns	
		X(90) should be less than 25 microns.	17 microns	

* No potential for any Class I solvents as specified by ICH to be present in the Terbinafine hydrochloride as they are not used in the manufacturing process. The material , if tested for these impurities, will comply with the established standards.

In-House tests Φ In-House impurity

The product CONFORMS to above specifications.

Compiled by: [signature] Date : 23/01/2012

Checked by : [signature] Date : 23/01/2012

Authorised Signatory : [signature] Date : 23/01/12

HETERO LABS LIMITED (UNIT-I) QUALITY ASSURANCE

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 07 OCT 2014 P. O. Box 2726 – 500027, MALAKPET

WRS-Eli-3

Shasun®

Quality Control

CERTIFICATE OF ANALYSIS

Material Name	:	Efavirenz (WHO)			
Manufactured by	:	Laurus Labs Private Limited			
Batch / ~~Lot~~ No.	:	ELT301VSP19320813(M)	A.R.No.	:	RF1729
Item Code	:	010002537	Specification No.	:	SPEC-SFQC-1526 Rev. No.: 03
Manufacturing date	:	August 2013	Manufacturer's Expiry / ~~Retest~~ date	:	July 2018
Date of Analysis	:	10/02/2015	Page No.	:	3 of 11
Date of Approval	:	17/02/2015	Retest date	:	16/02/2016
Quantity Approved	:	22.390 Kg			

S.No.	Test	Specification	Result
7	Heavy metals*	Not more than 0.002 % w/w	Less than 0.002
8	Water By KF	Not more than 0.5 % w/w	0.1
9	Limit of Efavirenz Enantiomer (By HPLC)	Not more than 0.2 % w/w	BLD (LOD : 0.016)
10	Organic Impurities By HPLC **Procedure - 1**		
	Efavirenzaminoalcohol (Impurity I)	Not more than 0.1 % w/w	Not detected
	Quinoline analog (Impurity II)	Not more than 0.10 % w/w	Not detected

	Prepared by	Reviewed by	Approved by
Signature			
Date	17/02/2015	17/02/2015	17/02/2015

Shasun Pharmaceuticals Limited
(Formerly known as Shasun Chemicals and drugs Ltd.)
Unit II,
R.S No. 32, 33 & 34, Shasun Road, Periyakalapet,
Puducherry - 605 014. India

Shasun®

Quality Control

CERTIFICATE OF ANALYSIS

Material Name	:	Efavirenz (WHO)			
Manufactured by	:	Laurus Labs Private Limited			
Batch/ ~~Lot~~ No.	:	ELT301VSP19320813(M)	A.R.No.	:	RF1729
Item Code	:	010002537	Specification No.	:	SPEC-SFQC-1526 Rev. No.: 03
Manufacturing date	:	August 2013	Manufacturer's Expiry/ ~~Retest~~ date	:	July 2018
Date of Analysis	:	10/02/2015	Page No.	:	4 of 11
Date of Approval	:	17/02/2015	Retest date	:	16/02/2016
Quantity Approved	:	22.390 Kg			

S.No.	Test	Specification	Result
	Efavirenzethene analog (efavirenz related compound B) (Impurity III)	Not more than 0.1 % w/w	0.003
	Efavirenzpentyne analog (Impurity IV)	Not more than 0.1 % w/w	0.02
	Efavirenz pent-3-ene-1-yne (cis)**	Not more than 0.10 % w/w	Not detected
	Efavirenz pent-3-ene-1-yne (trans)**	Not more than 0.10 % w/w	Not detected
	Efavirenzpenteneyne**	Not more than 0.10 % w/w	Not detected
	Methyl efavirenz	Not more than 0.10 % w/w	Not detected

	Prepared by	Reviewed by	Approved by
Signature			
Date	16/02/2015	17/02/2015	17/02/2015

SOP-FCQA-024/F-06/01 WEF : 25/05/2013

Shasun Pharmaceuticals Limited
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Puducherry - 605 014, India.

Shasun®

Quality Control

CERTIFICATE OF ANALYSIS

Material Name	: Efavirenz (WHO)				
Manufactured by	: Laurus Labs Private Limited				
Batch / ~~Lot~~ No.	: ELT301VSP19320813(M)	A.R.No.	: RF1729		
Item Code	: 010002537	Specification No.	: SPEC-SFQC-1526	Rev. No.:	03
Manufacturing date	: August 2013	Manufacturer's Expiry / ~~Retest~~ date	: July 2018		
Date of Analysis	: 10/02/2015	Page No.	: 5 of 11		
Date of Approval	: 17/02/2015	Retest date	: 16/02/2016		
Quantity Approved	: 22.390 Kg				

S.No.	Test	Specification	Result
	Efavirenz amino alcohol methyl carbamate	Not more than 0.10 % w/w	Not detected
	N-Benzylefavirenz	Not more than 0.25 % w/w	Not detected
	Efavirenzbenzoylamino alcohol	Not more than 0.15 % w/w	Not detected
	Efavirenz amino alcohol ethyl carbamate	Not more than 0.10 % w/w	Not detected
	Unidentified impurity (RRT ~ 1.60)	Not more than 0.10 % w/w	Not detected
	Efavirenz amino alcohol bis (ethoxycarbonyl)	Not more than 0.10 % w/w	Not detected
	Unidentified impurity	Not more than 0.10 % w/w	Not detected

	Prepared by	Reviewed by	Approved by
Signature			
Date	17/02/2015	17/02/2015	17/02/2015

SOP-FCQA-024/F-06/01 WEF : 25/05/2013

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Shasun®

Quality Control

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Manufacturing date	: August 2013	Manufacturer's Expiry / Retest date	: July 2018		
Date of Analysis	: 10/02/2015	Page No.	: 7 of 11		
Date of Approval	: 17/02/2015	Retest date	: 16/02/2016		
Quantity Approved	: 22.390 Kg				

S.No.	Test	Specification	Result
11	Assay by HPLC (on anhydrous basis)	Not less than 98.0 % w/w and Not more than 102.0 % w/w	99.3
12	Residual solvents (By GC)*		
	Toluene	Not more than 200 ppm	2 (LOQ : 10.739 µg/g)
	Tetrahydrofuran	Not more than 200 ppm	Not detected
	Cyclohexane	Not more than 3880 ppm	Not detected
	Methanol	Not more than 1000 ppm	Not detected
	Isopropyl acetate	Not more than 5000 ppm	Not detected

	Prepared by	Reviewed by	Approved by
Signature			
Date	17/02/2015	17/02/2015	17/02/2015

SOP-FCQA-024/F-06/01 WEF : 25/05/2013

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Shasun®

Quality Control

CERTIFICATE OF ANALYSIS

Material Name	: Efavirenz (WHO)				
Manufactured by	: Laurus Labs Private Limited				
~~Batch~~ / ~~Lot~~ No.	: ELT301VSP19320813(M)	A.R.No.	: RF1729		
Item Code	: 010002537	Specification No.	: SPEC-SFQC-1526	Rev. No.:	03
Manufacturing date	: August 2013	Manufacturer's ~~Expiry~~ / ~~Retest~~ date	: July 2018		
Date of Analysis	: 10/02/2015	Page No.	: 9 of 11		
Date of Approval	: 17/02/2015	Retest date	: 16/02/2016		
Quantity Approved	: 22.390 Kg				

Chemical Names of the Organic Impurities:

Efavirenzaminoalcohol(Impurity I) : (S)-2-(2-Amino-5-chlorophenyl)-4-cyclopropyl-1,1,1-trifluorobut-3-yn-2-ol

Quinolineanalog (Impurity II) : 6-Chloro-2-cyclopropyl-4-(trifluoromethyl)quinoline.

Efavirenz ethane analog

2H-(efavirenz related compound B) : (S,E)-6-Chloro-4-(2-cyclopropylvinyl)-4-(trifluoromethyl)-3,1-benzoxazin-2-one (Impurity III)

Efavirenzpentyneanalog : (S)-6-Chloro-4-(pent-1-ynyl)-4-(trifluoromethyl)-2H-3,1- benzoxazin-2-one. (Impurity IV)

Efavirenz pent-3-ene-1-yne (cis) : (S,E)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one

Efavirenz pent-3-ene-1-yne (trans) : (S,Z)-6-Chloro-4-(pent-3-en-1-ynyl)-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one.

Efavirenzpenteneyne : (S)-6-Chloro-4-(3-methylbut-3-en-1-ynyl)-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one.

Methyl Efavirenz : (S)-6-Chloro-4-{[(2RS,2RS)-2-methylcyclopropyl]ethynyl}-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one.

Efavirenz amino alcohol methyl carbamate : (S)-Methyl 4-chloro-2-(4-cyclopropyl-1,1,1-trifluoro-2- hydroxybut-3-yn-2-yl)phenylcarbamat

	Prepared by	Reviewed by	Approved by
Signature			
Date	17/02/2015	17/02/2015	17/02/2015

SOP-FCQA-024/F-06/01 WEF : 25/05/2013

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Date of Analysis	: 10/02/2015	Page No.	: 11 of 11		
Date of Approval	: 17/02/2015	Retest date	: 16/02/2016		
Quantity Approved	: 22.390 Kg				

Note: Index of USP 37, Suppl. 1 has been referred for the references of General chapters for this specification which is a combin index of USP 37 and NF 32 including first supplement.

The Material conforms / ~~does not conform~~ to the Specification.

	Prepared by	Reviewed by	Approved by
Signature			
Date	16/02/2015	17/02/2015	17/02/2015

SOP-FCQA-024/F-06/01 WEF : 25/05/2013

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