This how Watero Chent to bony worky Standar (3 Conteines)

Hetero Labs Limited

Factory: Survey No. 10, 1.D.A., Gaddapotharam, Jinnaram Mandal, Medak District Andhra Pradesh, INDIA

Phone: 091-08458-277106

## CERTIFICATE OF ANALYSIS

Product

: TERBINAFINE HYDROCHLORIDE Reference STP No.

: 111-004-04

Batch No.

(TH1711211

Reference

: Ph.Eur

Dt. of Manufacture December 2011

Batch Qty

: <u>140</u>.15 Kg : 11/01/2012

Retest Date

November, 2016 Analytical Report No.: 11-10237/11

Dt. of Analysis Status

l	S.Ne	. Test	Status	: Initial Certific	ation
	1	Description	Specifications Specifications	Results	Reference
ļ.			White or almost white powder.	A white powder	Visual
]	2	Solubility	Very slightly religible in water # 37		Inspection
İ	1		Very slightly soluble in water, freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone.	Complies	Visual
	<u> </u>	1	as a standard soluble in accione.	1	Inspection
	3	Identification by	The infrared absorption spectrum of the finely ground sample in KBr		Ph.Eur 1.4
		a) infrared absorption	· Image and a control cost of the and the charter of the charter o		
			same wavelengths as that of a similar preparation of Terbinafine	working standard	IN. 11 35 44
			Hydrochloride Working Standard.		Ph.Eur 7.2.24
ļ		b) Chlorides	Should comply with the test for chlorides.		
-	4	# Chloride Content	<u>-L</u>	Complies	Ph.Hur 2,3,1
	٠,	a Culoride Content	Between 10.7% w/w and 11.9% w/w	10.8% w/w	
}	5	Loss on drying		10.075 42.4	Ph./Sur 2.2.20
1	_	Loss on drying	Not more than 0.50% w/w	0.17% w/w	<del> </del> -
t	6	Sulphated Ash	Not more than 0.10% w/w		Ph.Eur 2.2.32
1		Juniou / Call	riot more than 0.10% W/W	0.04% w/w	<del> </del>
Ī	7	# Heavy Metals	Not more than 0.002%		Ph.Janc 2,4,14
ŀ				Less than 0,002%	Ph.laur 2.4.8
	8	# Clarity and Colour	Should be clear	<del></del>	FILIAN 2.4.8
1		of solution			
1		Clarity of the solution		}	
1		0.1	<u> </u>	Complies	Ph.Eur 2.2.1
ĺ		Colour of the Solution	Maximum absorbance should not be more than 0.05Au between 400	0.0260 Au	
L	1		to 700 nm	U.U20() All	
١.	9	# Melting point by	Between 207.0°C and 211.0°C	,	
L		DSC	•	207.5°C	Ph.Eur 3.2.34
1	10	Related substances by	(2Z)-N,6,6-Trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-		FU.EUT .1.2.34
1		HPLC	wing (da-1 eminana)	Below, LOQ	
ı			Impurity B : Not more than 0.10%	(LOQ -0,05%)	11
	- 1	,			13h /
	- 1	· •	(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	0.00%	Ph.Eur 2.7,29
L	İ		Impurity E : Not more than 0.05%	ļ	
*	No po		solvente de consissad ha 1011 de	ĺ	11

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. Φ In-House impurity

The product CONFORMS to above specifications.

Compiled by: Jescu. 7

Cheeked by:

Authorised Signatory:

Date:

## 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. : 141-004-04 Batch No. (IH1711211) Reference : Ph.Eur Dt. of Manufacture December 2011 Batch Qty : ∐Q.15 Kg Retest Date November, 2016 Dt. of Analysis : 11/01/2012 Analytical Report No.: [110237/11 Status

S.No		<u> </u>	Status	: Initial Certific	ation
10	Related substances by	Specification Specification	ons	Results	Reference
	HPLC -	Φ Impurity I : Not more than 0.	10%	Below LOQ (LOQ=0.02%)	
		Maximum single unspecified Impurity :	Not more than 0.10%	0.05%	Ph.Pan 2 2,39
		Total impurities : Not more than 0.3	30%	Ü (15 <sup>4</sup> 8	
11	(On dried basis)	Not less than 99.0% and not more than	101.0% w/w	100.2% w/w	Ph.Eur 3.2,20
12	by GC	Acetone	: Not more than 600 ppm	Below LOQ (LOQ= 60 ppm)	-
		Dichloromethane	; Not more than 300 ppm	Below LOQ (LOQ : 71 ppm)	
		Diisopropyl ether	: Not more than 100 ppm	Below I.OQ (LOQ=60 ppm;	Ph.Eur 2.2.28,5,4
		Cyclohexane	: Not more than 500 ppm	Below LOQ (LOQ=60 ppm)	(In-House)
	<u> </u>	N.N-Dimethyl formamide	: Not more than 200 ppm	Below LOQ (LOQ -186 ppm)	-
13	Laser diffraction	K(10) should be less than 5 microns.		2.microns	
	L	K(50) should be less than 10 microns.	•	7 microns	Ph.Eur 2 9.31 (In-House)
		(90) should be less than 25 microns.		17 microns	(m-notiae)

\* No potential for any Class 1 solvents as specified by ICH to be present in the Terbinaline 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 

# Un-House tests 

# Un-House tests 

# Un-House impurity

The product CONFORMS to above specifications.

Compiled by: Lescu.

Date : 23 01 2012

Checked by :

necked by: (KE)

Date:

Authorised Signatory:

natory: 1-VL

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 : TERBINAPINE HYDROCHLORIDE Reference STP No. Batch No. Dt. of Manufacture December 2011 : TII-004-04 Reference Retest Date : Ph.Eur November, 2016 Batch Qty Analytical Report No. (11/0237/11 : <u>140</u>.15 Kg Dt. of Analysis

7	,	ort No. (11-10237/11	Dt. of Analysis	. Tuncto Kñ	
5.1	7'001		Status	: <u>11/01/2</u> 01:	2
	Description .	White or almost white pour		! Initial Cert	iliant.
- L_		White or almost white powder.	Ations		
1 2	Solubility			Results	Refere
1	1	Very slightly soluble in water, freely and in methanol, slightly soluble in ac	<u></u>	A white powde	r C
1	1	and in methanol all the water, freely	soluble in antivita		1
13		and in methanol, slightly soluble in ac	elone.	Complies	Inspect
13	Identification by	The information		1	Visua
l	a) Infrared absorpt	on dienamina absorption spectrum of the	ne filmala	1	Inspecti
l		The infrared absorption spectrum of the dispersion compressed into a disc short same wavelength.	to thely ground sample in KB	r Matet	Ph.Jar J
1	į.		ard exhibit maxima only at the		
	b) Chlorides	_ I I I I I I I I I I I I I I I I I I I	F WIOH OL I PIRMAGE	working standard	៨ ∫
_	-1 Cinorides	Should comply with a		1	Ph.Bur 2.2
. 4	# Chloride Content	Should comply with the test for chlorid	es.	_ {	1
	- Content	Between 10.7% w/w and 11.9% w/w		Complies	
5	100	11.9% W/W		<u></u>	Ph.Eur 2,3,
٠	Loss on drying	Not more than 0.50% w/w		10.8% w/w	
<del></del>		11an 0.50% w/w			Ph. liur 2,23
6	Sulphated Ash	Not my		0.17% w/w	
$-\bot$		Not more than 0.10% w/w			DL C
7 /	Heavy Metals	<u>L.</u>		0.04% w/w	Ph.Eur 2.2.3
1		Not more than 0.002%	<del></del>	0.04% W/W	131
8 #	Clarity and Colour	Should be clear			Ph.Jpic 2,4,17
D.	f solution	onobio se clear		Loss than 0.062%	·
	larity of the solution				Ph.lar 2.4.8
	of the solution		1	, - <del>-</del>	
100	ala.		j		<b>[</b>
100	plour of the	Maximum about	1		1
30	lution	Maximum absorbance should not be more o 700 nm	than 0.05 t	Complies	Ph.Eur 2.2.1
# N	velting point by	- 7 OD 1181	than 0.03 Au between 400 0	.0260 Au	
	DSC:	Setween 207.0°C and 211.0°C	-	.020() A(I)	
Rel	030	c and 211.00C		_ '	
IKC	lated substances by	2%)-N,6,6-Trimethyl-N-(naphthalon-1-ylm nine (cis-Terbinafine )	20	77.5°C	,
Jun	f.C	wing this is the thyl-N-(naphthalon-1-vim	pelvodat		Ph.Eur 2.2.34
1	[i.	(cis- (erbinafine)	emytinept-2-cn-4-yn-1- Be	low.LOQ	
1	4	NO more de	1	TOW FOLD	
1	(2			OQ-0.05%)	- 11
1	bi	annhthalas I meinylpent-2-yn-1-yliden	aball by as		11
<u></u>	l <sub>lm</sub>	E.4E)-4-(4.4-Dimethylpent-2-yn-1-ylidene (naphthalen-1-ylmethyl)pent-2-ene-1.5-di purity E : Not more than a gene-1.5-di	Driver of methyl-N.N-	0% P	h.Eur 2, 2, 20
potent	ial for any Classic	purity E: Not more than 0.05% Ivents as specified by ICH to be present in The material if tested for the	amine   5.0		
e man	ufactoria	ivents as specified by tou	[	1	. 11
House	amounting process,	he material if leated s	n the Terbination		- 11

\* 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.

The product CONFORMS to above specifications.

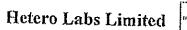
Compiled by: Jesley. 7

Checked by

Date

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Page1 of 2 Ellarina 28/11/2000



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

Phone: 091-08458-277106

#### CERTIFICATE OF ANALYSIS

Product

: TERBINAFINE HYDROCHLORIDE Reference STP No.

: 111-004-04

Batch No.

TH1711211

Reference

: Ph.Eur

Dt. of Manufacture December 2011

Batch Qty

: <u>140</u>.15 Kg

Retest Date Analytical Report No.:(110237/11

November, 2016

Dt. of Analysis Status

: 11/01/2012 : Initial Certification

			50005	: Initial Certifica	llon -
	S.No.		Specifications	Results	Reference
	, ,	Description	White or almost white powder.	A white powder	Visual
ľ	2	Solubility	Voice to the second of the sec		Inspection
ı	-	Somonits	Very slightly soluble in water, freely soluble in anhydrous ethanol	Complies	Visual
			and in methanol, slightly soluble in acetone.		Inspection
-	3	Identification by	The infrared absorption spectrum of the finely ground sample in KBr		Phdiur Ld
ļ	-		dispersion compressed into a disc should exhibit maxima only at the	Matches with	i
ŀ		,	same wavelengths as that of a similar preparation of Terbinafine	working standard	Ph.Eur 7.2.24
1		•	Hydrochloride Working Standard.	•	, mode and of
-	;	b) Chlorides	Should comply with the test for chlorides.	<u> </u>	
-			<u> </u>	Complies	Ph.Eur 2,3,1
	4	# Chloride Content	Between 10.7% w/w and 11.9% w/w	10.8% w/w	·
ŀ	5	1 1 1 1			Ph.Bur 2,2,20
1	ט	Loss on drying	Not more than 0.50% w/w	0.17% w/w	DV 51 5 5 5 5 5
ŀ	6	Sulphated Ash	Ned months (1.1704)	<u> </u>	Ph.Eur 2.2.32
-	``	addumenta tran	Not more than 0.10% w/w	0.04% w/w	Ph.lan 2,4,14
ı	7	# Heavy Metals	Not more than 0.002%		1 0.5 501 -,21, 5-1
ļ				Less than 0.002%	Ph.bair 2.4.8
			Should be clear	<del> </del>	<del> </del>
1	J	of solution			
İ	[	Clarity of the solution			
1	I			Complies	Ph.Dar 2.2.1
١		Colour of the	Maximum absorbance should not be more than 0.05Au between 400	0.0260 Au	1
L		Solution '	to 700 nm		
$\cdot$	9	# Melting point by	Between 207.0°C and 211.0°C	207.5°C	
١		DSC ·	•	207.5 (	Ph.Eur 2.2.34
-	10	Related substances by	(2Z)-N,6,6-Trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-	Below LOO	<u> </u>
1	ľ	HPLC	amine (cis-Terbinafine )	(LOQ -0.05%)	1
1			Impurity B : Not more than 0.10%	(150 4 170 7 4)	i i
		,	(2E,4E)-4-(4,4-Dimethylpent-2-yn-1-ylidene)-N,N-dimethyl-N,N'-	0.00%	Ph.Eur 2.3.29
1		·	bis(naphthalen-1-ylmethyl)pent-2-ene-1,5-diamine	ν.υ <b>ψ</b> νου το σ	
L			Impurity E: Not more than 0.05%		
	* No.n	ofential for any Class	adjusting a second of the control of		

\* 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 | | Ф In-House impurity

The product CONFORMS to above specifications.

Compiled by: Jesten. 7

Checked by

Date :

# Hetero Labs Limited

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

Phone: 091-08458-277106

#### CERTIFICATE OF ANALYSIS

Product : TERBINAFINE HYDROCHLORIDE Reference STP No. : PH-004-04 Batch No. :111711211 Reference : Ph.Eur Dt. of Manufacture December 2011 Batch Qty : [ქ0,15 €ւք

Retest Date November, 2016 Dt. of Analysis : 11/01/3013

Analytical Report No.: [110237/]] : Initial Certification

S.No.		Specification	S	Results	Reference
10	Related substances by	I-Bromo-6,6-dimethyl hept-2-ene-4-ync		Below LOQ	
}	HPLC -	o Impurity I : Not more than 0.10		(1.OQ=0.02%)	
1	1	Maximum single unspecified Impurity:	Not more than 0.10%	0.05%	1
					Ph.Eu 2 2.39
	,	Total impurities : Not more than 0.30	%	0 05%	
11		Not less than 99.0% and not more than I	01.0% w/w	100.2% w/w	, <u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>
	Potentiometry (On dried basis)				Pb.Eur 2.2,20
12		Acctone	: Not more than 600 ppm	Below LOQ	
	by GC			(F.OQ= 60 ppm)	
		Dichloromethane	: Not more than 300 ppm	Below LOQ	
				(LOQ -71 ppm)	
	i I	Diisopropyl ether	: Not more than 100 ppm	Below LOQ	Pla.Eur
	j			(LOQ=60 թթա։	2.2.28.5.4 [In-House]
		Cyclohexane	: Not more than 500 ppm	Below LOQ	(vii-i (heze)
				(LOQ−60 թրm)	
	,	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	
					•
		X(50) should be less than 10 microns.	•	7 microns	Ph.Eur 2 9.31
		X(90) should be less than 25 microns.		17 microns	(In-House)
					}.

\* No potential for any Class 1 solvents as specified by ICH to be present in the Terbinaline 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.

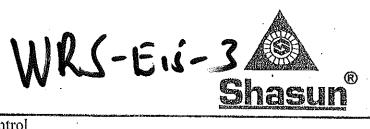
Compiled by: \$804.77

Date: 23/01/2012

Checked by

Date:

Authorised-Signatory

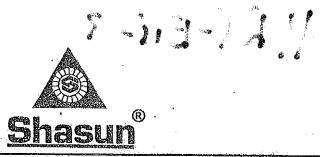


CERTIFICATE OF ANALYSIS							
Material Name	:	Efavirenz (WHO)					
Manufactured by	:	Laurus Labs Private Limited			,		
Batch / Lot No.	;	ELT301VSP19320813(M)	A.R.No.	: ;	RF1729		
Item Code	:	010002537	Specification No.	;	SPEC-SFQC-1526	Rev. No.: 0	
Manufacturing date	:	August 2013	Manufacturer's Expire / 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	fre fre	ans	0:-
Date	14/02/0015	17/02/2015	12/02/2015

SOP-FCQA-024/A-01/00	Shasun	Pharmaceuticals	Limited	,
		nown as Shasun Chemicals and di		-
and the second s		Unit II,		intercontaining and third properties the part of the p
The state of the s	R.S No. 32	2, 33 & 34, Shasun Road, Periya	kalapet,	



CERTIFICATE OF ANALYSIS							
Material Name	•	Efavirenz (WHO)				Committee of the state of the s	**************************************
Manufactured by	:	Laurus Labs Private Limited					
Batch/ Lot-No.	;	ELT301VSP19320813(M)	A.R.No.		;	RF1729	<del>-,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</del>
Item Code	:	010002537	Specification	on No.	:	SPEC-SFQC-1526	Rev. No.: 03
Manufacturing date		August 2013	Manufactu Expira/ Re		:	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	Are	ant	8:
Date	1402/2015	17/07/2015	13/02/2015

COR COM A COME OF THE		the state of the same of the s
SOP-FCQA-024/A-01/00		
	Shasun Pharmaceuticals Limited	•
Demonstrative account of the first of the fi	(Formerly known as Shasun Chemicals and drugs Ltd.)	-
Control of the Laborate Springer of the Control of	Unit II.	ALEXANDER OF THE PROPERTY OF T
	R.S No. 32, 33 & 34, Shasun Road, Periyakalapet,	
	Dradical annex CAC A1 A Tat At a	Age parameters and the second



	lity		

# CERTIFICATE OF ANALYSIS

Material Name	:	Efavirenz (WHO)		·		
Manufactured by	:	Laurus Labs Private Limited	ŧ			
Batch/ Let No.	;	ELT301VSP19320813(M)	A.R.No.		RF1729	<del>i</del>
Item Code	:	010002537	Specification No.		SPEC-SFQC-1526	Rev. No.:
Manufacturing date		August 2013	Manufacturer's Expurs/ 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	11.
Quantity Approved	:	22.390 Kg				i

S.No.	Test	Specification	Result
<u> </u>	Bfavirenz 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	412_	aux	0-
Date	17/02/2015	17/02/2015	12/02/2015

SOP-FCQA-024/A-01/00	Shasun Pharmaceuticals Limited	•
- A state of the same and the same of the	(Formerly known as Shasun Chemicals and drugs Ltd.)	for highlighten from the commission of the commi
	Unit II,	$\\ = \frac{1}{2} d^2 d^2 d^2 d^2 d^2 d^2 d^2 d^2 d^2 d^2 $
	R S No. 32, 33 & 34. Shasun Road, Perivakalapet.	



Quality Control

CERTIFICATE	OF	'ANALYSIS
		and the second s

			OZZZZZ OZ ZZZ		A CAC		
Material Name	;	Efavirenz (WHO)					
Manufactured by	:	Laurus Labs Private Limited					
Batch/Lot No.	;	ELT301VSP19320813(M)	A.R.No.	:	RF1729	, part 10 - 10 - 10 - 10 - 10 - 10 - 10 - 10	
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.	•	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	Not less than 98.0 % w/w and Not more than	99.3
	anhydrous basis)	102.0 % w/w	
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
	Cyclonexane	Not more than 3000 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	42	pour !	84
Date	14/02/2015	17/02/2015	13/02/2015.

The State of the Control of the Cont		Edwinian de des des des des Californias de la Company de l
SOP-FCQA-024/A-01/00	Shasun Pharmaceuticals Limited	
ngine di namahah na salam namah di padapan panjang anjang angang ilihip kanan mana di nangsing nagan pangan panda 1999.	(Formerly known as Shasun Chemicals and drugs Ltd.)	Mary year growing for the first and public complete and the complete and support and any particular section of the complete and the complete a
	Unit II, R S No. 32, 33 & 34 Shasun Road, Periyakalapet.	Participation (Charles Andrews Miles of Transfer Charles and Andrews Associated Association (Charles Andrews Associated A



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### CERTIFICATE OF ANALYSIS

Material Name	:	Efavirenz (WHO)					
Manufactured by	;	Laurus Labs Private Limited	:				1
Batchy 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 (Expire) / 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

: (S)-Methyl 4-chloro-2-(4-cyclopropyl-1,1,1-trifluoro-2- hydroxybut-3-yn-2-yl)phenylcarbamat

carbamate

	Prepared by	Reviewed by	Approved by
Signature	. tr_	Aut	·. 0:-
Date	14/02/2015	17/02/2015	12/02/2015

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

SOP-FCQA-024/A-01/00 Shasun Pharmaceuticals (Formerly known as Shasun Chemicals and drugs Ltd.) Unit II, R S No 32 33 & 34 Shasun Road Perivakalanet.



Quality Control

#### CERTIFICATE OF ANALYSIS

Material Name	:	Efavirenz (WHO)	· · · · · · · · · · · · · · · · · · ·				
Manufactured by	4	Laurus Labs Private Limited					
Batch/Lot No.	:	ELT301VSP19320813(M)	A.R.No.	:	RF1729		
Item Code		010002537	Specification No.	:	SPEC-SFQC-1526	Rev. No.:	03
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Date of Analysis	<u>:</u>	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	dre	Bust	AY
Date	14/02/0015	17/02/1015	12/02/2015

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SOP-FCQA-024/A-01/00	Shasun Pharmaceuticals Limited	
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:	R.S No. 32, 33 & 34, Shasun Road, Periyakalapet,	