WRS-T11-5

Shasun®

Report of Evaluation & Standardization of Working Standard

Item	: Tenofovir Disoproxil Fumarate
Working Standard No.	: AWS-T03-05
Date of Starting Analysis	: 08/05/2015
Valid Upto	: 07/05/2016
Direction for Use	: Use as such
Storage Conditions	: Store in a tightly closed container at temperature of 2 to 8° C, Protect from light.
Source B. No.	: TF0421114 (Mfg.By: Hetero Labs Limited)

S.No.	Test	Acceptance Criteria	Results
1	Description	White to an off white crystalline powder.	White crystalline powder
2	Identification A.By Infrared absorption	The infrared absorption spectrum of the sample preparation should exhibit maxima only at the same wavelengths as that of a similar preparation of the Reference standard of Tenofovir Disoproxil Fumarate.	The infrared absorption spectrum of the sample preparation exhibits maxima only at the same wavelengths as that of a similar preparation of the Reference standard of Tenofovir Disoproxil Fumarate.
	B.By HPLC	The retention time of the principle peak in the chromatogram of the sample	The retention time of the principle peak in the chromatogram of the sample preparation corresponds to

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
Phone : 91-0413-2655946, 2655952, 2655697, 2655698
Fax : 0413-2655052

Shasun®

Report of Evaluation & Standardization of Working Standard

S.No.	Test	Acceptance Criteria	Results
		preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the test for assay.	that in the chromatogram of the standard preparation, as obtained in the test for assay.
3	Water content by KF	Not more than 1.0 % w/w	0.5
4	Assay by HPLC (on anhydrous and solvent free basis)	Not less than 98.0 %w/w and Not more than 101.0 %w/w	99.7
5	Potency (as is basis)	Report the value in %	99.2

REMARKS: The working standard AWS-T03-05 is standardized against USPRS LOT No: G0M335 and it is certified/ ~~not certified~~ for use

Prepared by	Checked by	Approved by
15/05/2015	15/05/2015	15/05/2015
Sign / Date	Sign / Date	Sign / Date
Quality Control	Quality Control	Quality Assurance

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
Phone : 91-0413-2655946, 2655952, 2655697, 2655698
Fax : 0413-2655052

WRS-S30-2.

MSN LABORATORIES PRIVATE LIMITED

FORMULATION DIVISION - BOLLARAM

Factory: Plot No.: 42, Anrich industrial Estate, Bollaram, Medak Dist, - 502325 A.P., India.

WORKING STANDARD CERTIFICATE OF ANALYSIS

Product : Silodosin — Evaluated with*:IH Lot No: SLD/C483/13H/26

W.STD B. No : SILWS1401 — Date of Analysis : 02.01.2015

Source Batch No : SL0201014 — Valid up to : September 2016

AR.No : GA1412046 — Specification No : RMS-059-02

Name of manufacture : MSN Laboratories Private Ltd. — Reference : IH

S. No.	TEST	SPECIFICATION	RESULT
1.0	Description	White to pale yellowish white powder.	White powder
2.0	Solubility	Freely soluble in acetic acid and alcohol and insoluble in water.	Freely soluble in acetic acid and alcohol and insoluble in water.
3.0 3.1	Identification Infrared absorption	Absorption peak at around 1166 ± 2 cm-1 and 1508± 2 cm-1 should be observed.	Meets the requirement
3.2	By HPLC	The Retention time of major peak in the chromatogram of assay preparation corresponding to that in the chromatogram of standard preparation, as obtained in the assay.	The retention time of major peak in the chromatogram of sample solution corresponds to that of standard solution obtained as directed in assay.
4.0	Specific optical rotation	Between (-1)11.0° and (-)17.0°	-15.9°
5.0	Loss on drying	NMT 1.0% w/w	0.189%w/w
6.0	Residue on ignition	NMT 0.20% w/w	0.06%w/w
7.0	Heavy metals	NMT 0.002%w/w	Less than 0.002% w/w

MSN LABORATORIES PRIVATE LIMITED-FORMULATION DIVISION ★ BOLLARAM ★ QA ISSUE Signature: Date: 02/01/2015

	Compiled By	Checked By	Approved By
Desi & Dept	Jr. Manager - QC	Asst. Manager - QC	Manager - QC
Name	R.N.D.Vara Prasad	Bhosale Dnyaneshwar	Yashwanth Gulatker
Signature			
Date	02/01/2015	02/01/2015	02/01/15

MSN LABORATORIES PRIVATE LIMITED

FORMULATION DIVISION - BOLLARAM

Factory: Plot No.: 42, Anrich industrial Estate, Bollaram, Medak Dist, - 502325 A.P., India.

WORKING STANDARD CERTIFICATE OF ANALYSIS

Product : Silodosin — Evaluated with*:IH Lot No: SLD/C483/13H/26

W.STD B. No : SILWS1401 — Date of Analysis : 02.01.2015

Source Batch No : SL0201014 — Valid up to : September 2016

AR.No : GA1412046 — Specification No : RMS-059-02

Name of manufacture : MSN Laboratories Private Ltd. — Reference : IH

S. No.	TEST	SPECIFICATION	RESULT
8.0	Related substances by HPLC		
8.1	Dehydro impurity	Not More than 0.50%	0.04%
8.2	Nitrile impurity	Not More than 0.50%	Not detected
8.3	Dimer impurity	Not more than 0.50%	Not detected
8.4	Highest individual unpecified Impurity	Not More than 0.30%	0.12%
8.5	Total impurities	Not More than 1.0%	0.29
9.0	Assay By HPLC (On dried basis)	NLT 98.0% and NMT 102.0%	99.54% w/w
10.0	Acetic acid content by HPLC	Not more than 5000ppm	Not detected
11.0	Residual solvents by GC (Method-I)		
11.1	Methanol	Not More than 3000ppm	BDL (9.0 ppm)
11.2	Ethanol	Not More than 5000ppm	BDL (15.0 ppm)
11.3	Dichloro methane	Not more than 600ppm	BDL (17.9 ppm)
11.4	Ethyl acetate	Not More than 5000ppm	379 ppm
11.5	Cyclohexane	Not More than 3880ppm	Less than LOQ (2.34 ppm)
11.6	Toulene	Not More than 890ppm	BDL (9.14 ppm)
12.0	Residual solvents by GC (Method-II)		
12.1	Dimethyl Sulphoxide	Not more than 5000ppm	BDL (43.4 ppm)
13.0	Potency	-	99.35% w/w

Note :*Assay and IR evaluated against with Silodosin In-house reference standard. This material can be used as Working standard for regular analysis.

MSN LABORATORIES PRIVATE LIMITED-FORMULATIONS DIVISION ★ BOLLARAM ★ QA ISSUE Signature : Date : 02/02/2015

	Compiled By	Checked By	Approved By
Desi & Dept	Jr. Manager - QC	Asst. Manager - QC	Manager - QC
Name	R.N.D.Vara Prasad	Bhosale Dnyaneshwar	Yashwanth Gulatker
Signature			
Date	02/01/2015	02/01/2015	02/01/15

WRS-112-7.

NOVARTIS

Issued by :
Novartis Pharma AG

4002 Basel
Switzerland

Certificate of Analysis
No CH280100078255

Product Name:	INDACATEROL MALEATE/DS 04		
Global Material N°:	831045	**Batch No :**	C0026
Date of Manufacturing	18-JAN-2014		
Retest date	16-JAN-2018		
Testing Monograph:	DS_4001186_A_R_5	**Analysis No:**	4100219282

Tests	Requirements	Results
Appearance by visual examination	white to very slightly(greyish or Y-ish)	White
Appearance by visual examination	powder	Powder
Particle size by laser light diffraction X90	Max 5 µm	4 µm
Particle size by laser light diffraction X90	Min 2.6 µm	4.2 µm
Particle size by laser light diffraction X50	Max 2.5 µm	1.8 µm
Particle size by laser light diffraction X50	Min 1.2 µm	1.8 µm
Particle size by laser light diffraction X10	Min 0.5 µm	0.8 µm
Clarity of the solution	clear	Clear

This certificate has been automatically generated.
The data have been approved by an Authorized Person.

NOVARTIS

Issued by :
Novartis Pharma AG

4002 Basel
Switzerland

Certificate of Analysis
No CH280100078255

Product Name:	INDACATEROL MALEATE/DS 04		
Global Material N°:	831045	**Batch No :**	C0026

Tests	Requirements	Results
Colour of the solution	NMT B5, BY5, Y5, GY5	Corresponds to GY7 (Ph.Eur.)
Identity by IR	corresponds to the reference	Corresponds to the reference
Identity by X-ray diffraction	corresponds to the reference	Corresponds to the reference
Enantiomer by HPLC 529-00	Max 0.4 %	0.24 %
Residual solvents by GC Ethanol	Max 0.2 %	< 0.05 %
Residual solvents by GC Isopropanol	Max 0.2 %	< 0.05 %
Residual solvents by GC Tert. butyl methyl ether	Max 0.1 %	< 0.01 %
Residual solvents by GC Toluene	Max 0.08 %	< 0.01 %
Total residual solvents	Max 0.3 %	< 0.05 %

This certificate has been automatically generated.
The data have been approved by an Authorized Person.

NOVARTIS

Issued by :
Novartis Pharma AG

4002 Basel
Switzerland

Certificate of Analysis
No CH280100078255

Product Name:	INDACATEROL MALEATE/DS 04		
Global Material N°:	831045	**Batch No :**	C0026

Tests	Requirements	Results
Residual solvents by GC Diethylene glycol dimethyl ether	Max 100 ppm	< 50 ppm
Loss on drying by thermogravimetry	Max 0.5 %	< 0.05 %
Sulfated ash	Max 0.1 %	0.04 %
Heavy metals by ICP-OES: Ni	Max 2 ppm	< 1 ppm
Heavy metals by ICP-OES: Pb	Max 2 ppm	< 1 ppm
Heavy metals by ICP-OES: Pd	Max 2 ppm	< 1 ppm
Heavy metals by ICP-OES: Total (Fe, Ni, Cu, Zn, Pb, Pd)	Max 10 ppm	5 ppm
Amorphous content by microcalorimetry	Max 2.0 %	1.3 %

This certificate has been automatically generated.
The data have been approved by an Authorized Person.

NOVARTIS

Issued by :
Novartis Pharma AG

4002 Basel
Switzerland

Certificate of Analysis
No CH280100078255

Product Name:	INDACATEROL MALEATE/DS 04		
Global Material N°:	831045	**Batch No :**	C0026

Tests	Requirements	Results
Specified identified impurities 530-01 by HPLC	Max 0.2 %	< 0.05 %
Specified identified impurities 527-00 by HPLC	Max 0.4 %	0.23 %
Specified identified impurities 561-01 by HPLC	Max 0.3 %	0.13 %
Any unspecified impurities by HPLC	Max 0.10 %	< 0.05 %
Total unspecified impurities by HPLC	Max 0.3 %	< 0.05 %
Total impurities by HPLC	Max 0.8 %	0.35 %
Bacterial endotoxins test (BET)	< 70 EU/mg	< 1 EU/mg
Assay by titration, based on dried substance	99.0 - 101.0 %	99.8 %

This certificate has been automatically generated.
The data have been approved by an Authorized Person.

NOVARTIS

Issued by :
Novartis Pharma AG

4002 Basel
Switzerland

Certificate of Analysis
No CH280100078255

Product Name:	INDACATEROL MALEATE/DS 04		
Global Material N°:	831045	**Batch No :**	C0026

Tests	Requirements	Results
Assay of salt forming agent, calculated as maleic acid, based on dried substance	22.1 - 23.5 %	23.0 %
Content of drug	-	99.4 %
Assay by HPLC, based on dried substance	98.0 - 102.0 %	100.2 %

Conclusion
The batch complies with the testing monograph. It is hereby certified that the above information is authentic and accurate and that the analysis records have been reviewed and found to be in compliance with GMP.

Authorized Person	Mensah ADZATIA	
Date and Time:	19-FEB-2014	11:49:34
Issuer of Certificate:	Mensah ADZATIA	
Function:	QA SPECIALIST	
Date and Time:	19-FEB-2014	11:49:34

This certificate has been automatically generated.
The data have been approved by an Authorized Person.

UNICHEM
LABORATORIES LTD.

WORKS : VILLAGE BHATAULI KALAN,
BADDI, DISTT. SOLAN (H.P.)-173 205
Tel. : (01795) 244507, 245322, 246702-06
Fax : (01795) 244508

OUR CIN NUMBER
L99999MH1962PLC012451

REGD. OFFICE :
8, PRABHAT ESTATE
S.V. ROAD, JOGESHWARI (WEST),
MUMBAI - 400 102

CERTIFICATE OF ANALYSIS – WORKING STANDARD

RAW MATERIAL

Working Standard	:	Clavulanate Potassium-Avicel (1:1)			
W.S.A.R. No.	:	BAWS15000004	Working Standard No.	:	CLAV-IH--13
Quantity.	:	90 g	Mfg. Date (Source Material)	:	Jul 10, 2014
SAP B.No. (Source Material)	:	1010000568	Exp. Date (Source Material)	:	Jun 27, 2018
Evaluated against Reference Lot No.	:	6.0	Manufacturer (Source Material)	:	Ckd Bio Corporation
Valid Upto	:	Aug 07, 2015	Specifcation ID	:	BA/WS/10000245/02
Storage condition	:	Store in amber coloured glass vial tightly.	STP No.	:	BA/WSSTP/10000245/00
	:			:	

Sr. No	TESTS	SPECIFICATIONS	RESULTS
1	Description	White to off -white powder	Off white powder
2	Identification - For Clavulanic acid (by HPLC)	In the test for 'Assay', the retention time of the peak due to Clavulanic acid in the sample preparation matches with that obtained in standard preparation	In the test for 'Assay', the retention time of the peak due to Clavulanic acid in the sample preparation matches with that obtained in standard preparation
	- For Avicel (Dispersion in Iodinated zinc chloride Solution)	The substance turns violet blue	The substance turns violet blue
3	Water	NMT 1.0 %	0.87 %
4	Assay (On anhydrous basis)	Between 39.5 % and 46.0 %	Average: 42.0 % Relative Std. Dev: 0.6 %
5	Potency (on as is Basis)	For reference only	41.65 %

REMARK: The material complies / ~~does not comply~~ with the prescribed standard of quality with respect to above tests and can be used as the working standard for specified period.

Checked By: Gulshan Sharma	Approved By: Vishant Mehta
Designation: Sr. Executive	Designation: Asst. Manager
Sign & Date: 29/04/15	Sign & Date: 29/4/15

COA Re-Issued for RA on 29.04.2015

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
29 MAY 2015
TEL: 2426963 / 3544525/30
FAX: 2718073
P. O. Box 29726 – 00202, NAIROBI

shelys pharmaceuticals ltd
an aspen group company
new bagamoyo road mwenge plot no.696 block no.32 dar es salaam
po box 32781 dar es salaam tanzania registration number 5914
tel +255 22 2771715/6/7 fax +255 22 2772417 info@tz.betashelys.com
www.aspenpharma.com www.shelysafrica.com www.betacare.co.ke

CERTIFICATE OF ANALYSIS
Working Standard

WRS-A20-4

Name of CRS used: Atenolol
Lot/Batch: no .10F032
Source: USP

Purity/Potency: 0.999mg/mg
Exp Date: Website information

Name of Working Standard: Atenolol
Raw Material Bno, used: MUM/2014-15/3156
Manufacturer: IPCA Laboratories
Date of Analysis: 09/01/2015
Validity of use: Use within one month after opening, valid up to 06/2019, when sealed.
Quantity: 5.0g

EWS No: 12/15
Mfg Date: 07/2014, **Exp Date:** 06/2019

RESULTS:

Sr. No.	Test Parameters	Limits	Observation
1	Description	A white or almost white powder	A white powder
2	Identification: A. Infra red absorption	The IR spectrum of test sample is concordant to the IR spectrum of chloramphenicol working standard	The IR spectrum of test sample is concordant to the IR spectrum of chloramphenicol working standard
3	Loss on drying	NMT 0.50 %	0.33%
4	Assay (On anhydrous basis)	99.0% - 102.0%	100.3%

Additional Remarks:

Storage conditions:

- Store in refrigerator at 2°C- 8° C, when not in use
- Use within 30 days after opening, kept at a temperature of below 25 °C
- Keep tightly closed and protect from light

Justification of the selection of raw material for qualification:

The Atenolol Raw material was taken from the current lot.

	Analysed by	Checked by	Approved by
Signature	Sm	[signature]	[signature]
Name	Sizford Mnaitonda	Lilian Mashirg	Codeue Obiorre
Date	31/03/2015	31/03/2015	31/03/2015
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control

NRS-Big-1

FINECURE PHARMACEUTICALS LIMITED

Quality Control Department

CERTIFICATE OF ANALYSIS

WORKING STANDARD

NAME OF MATERIAL	BROMHEXINE HCL BP	WORKING STD NO.	RWS/1BROM01
BATCH NO.	BH/201401001	ANALYSIS DATE	06/03/15
MFG. DATE	APR 2014	REPORT DATE	07/03/15
EXP.DATE	MAR 2017	EFFECTIVE DATE	09/03/15
MFG.BY	OREX PHARMA PVT LTD	VALID UPTO	08/03/16
STORAGE	STORE PROTECTED FROM LIGHT	NO.OF VIALS	14

TEST	SPECIFICATION	OBSERVATION
DESCRIPTION	White or almost white, crystalline powder.	White crystalline powder.
IDENTIFICATION	Shall comply	Complies
LOSS ON DRYING	Not more than 1.0 %w/w	0.12% w/w
ASSAY(ODB)	Between 98.5% to 101.5%	100.02% (ODB)

NATIONAL QUALITY CONTROL LABORATORY RECEIVED - 9 APR 2015

Remarks : The above material comply as per BP specification and can be used for working standard.

Analysed By	Checked By	Approved By
06/03-2015	09/03/2015	09/03/2015

FINECURE PHARMACEUTICALS LTD. QUALITY CONTROL

GULF PHARMACEUTICAL INDUSTRIES
Ras Al Khaimah, Post Box No. 997
Tel.: +9717-2461461, Fax: +9717-2462462
United Arab Emirates

Julphar
Quality Control Department

الخليج للصناعات الدوائية
ص.ب. ٩٩٧ رأس الخيمة
هاتف: ٢٤٦١٤٦١ +٩٧١٧٠ فاكس: ٢٤٦٢٤٦٢ +٩٧١٧٠
الإمارات العربية المتحدة

WRS-P29-2

Certificate of Analysis
Secondary Reference Standard

Name: Pantoprazole Sodium
Material No: 10000567

Batch No: 0000000903/II
Insp. Lot No: 10000001435

Test	Specification	Result
Description	White to off-white powder, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method	Conform
Water content	5.0% to 8.0%	6.50%
Related Compounds	1- Related Compound A: NMT 0.20%	0.089%
	2-Related Compound B: NMT 0.15%	0.00%
	3-Related Compound C: NMT 0.10%	0.00%
	4-Related Compound D and F: NMT 0.20%	0.00%
	5-Related Compound E: NMT 0.10%	0.064%
	6-Any other individual impurity: NMT 0.10%	0.052%
	7-Total impurities: NMT 0.50%	0.205%
Assay	NLT 98.0% and NMT 102.0% of $C_{16}H_{14}F_2N_3NaO_4S$, calculated with reference to the anhydrous basis.	93.04% (as is basis) 99.51% (anhydrous basis)

Standardization date: 16-12-2014

Standardized by: Anas

Exp. date: 12/2015

Weight per vial: 500mg

Standardized against: Pantoprazole Sodium USP Reference Standard (Lot No: H0L207)

Pensee

Checked by: Pensee Mohamed, B. S. Pharm
Quality Control Assistant Manager

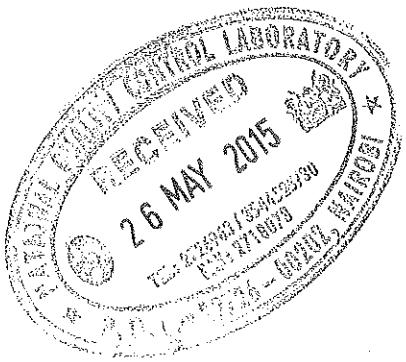
Head of Quality Control Department
Sheikha Khamis

WRS-73-C

ATOZ PHARMACEUTICALS PRIVATE LIMITED
CHENNAI

CERTIFICATE OF ANALYSIS FOR LABORATORY WORKING REFERENCE STANDARD

Name of the material	**TELMISARTAN**
Batch No	BTLS/1408064
Control No	A20/300
Mfg. Date	Aug-14
Exp. Date	Jul-17
Report Date	23/03/2015
Report No	WRS/K20/300
Mfgr's Name	VASUDHA PHARMA CHEM LTD.
Quantity	1.0 gm
Indented use	Working Reference Standard
Storage condition	STORE IN A WELL CLOSED CONTAINER



Description	A White colour powder		
Identification	BY IR		
Water	0.17%	Limit :	NMT 0.5%
Related Substances	Complies		
ASSAY(ODB):	100.31%	Limit:	99.0% - 101.0%
Material is sensitive to:	Heat Light Moisture		

The above material is qualified as Working Reference Standard.

Working Reference Standard is valid from: 23/03/2015 TO: 22/03/2016

Analysed by	Checked by	Approved by
N.Keerthika	T.Merlin	J.Sangeetha
(QC.Officer)	(QC.Sr.Executive)	(QA Manager)

WRS - E20 - 2

ATOZ PHARMACEUTICALS PRIVATE LIMITED
CHENNAI

CERTIFICATE OF ANALYSIS FOR LABORATORY WORKING REFERENCE STANDARD

Name of the material	**ESOMEPRAZOLE MAGNESIUM**
Batch No	ESM/1501021
Control No	A15/300
Mfg. Date	Jan-15
Exp. Date	Dec-18
Report Date	23/03/2015
Report No	WRS/K15/300
Mfgr's Name	METROCHEM API PRIVATE LIMITED
Quantity	1.0 gm
Indented use	Working Reference Standard
Storage condition	STORE IN A WELL CLOSED LIGHT RESISTANT CONTAINER

Description	A White colour powder		
Identification	BY IR		
Water	6.19%	Limit :	6.0% - 8.0%
Related Substances	Complies		
ASSAY(OAB):	100.31%	Limit:	98.0% - 102.0%
Material is sensitive to:	Heat Light* Moisture		

The above material is qualified as Working Reference Standard.

Working Reference Standard is valid from: 23/03/2015 TO: 22/03/2016

Analysed by	Checked by	Approved by
N.Keerthika (QC.Officer)	T.Merlin (QC.Sr.Executive)	J.Sangeetha (QA Manager)

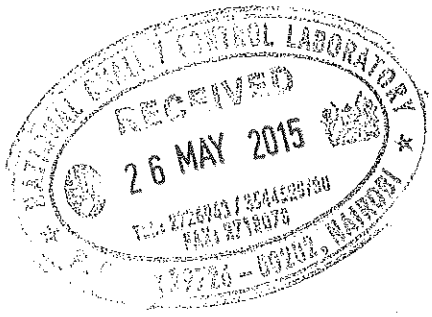
ATOZ PHARMACEUTICALS PVT. LTD. QA

WRS-H,-10

ATOZ PHARMACEUTICALS PRIVATE LIMITED
CHENNAI

CERTIFICATE OF ANALYSIS FOR LABORATORY WORKING REFERENCE STANDARD

Name of the material	**HYDROCHLOROTHIAZIDE**
Batch No	20140705
Control No	A22/067
Mfg. Date	Jul-14
Exp. Date	Jun-19
Report Date	23/03/2015
Report No	WRS/K22/067
Mfgr's Name	ZHEJIANG PVT. LTD
Quantity	1.0 gm
Indented use	Working Reference Standard
Storage condition	Store in a well closed container



Description	A white Powder		
Identification	BY IR		
LOD/WATER	0.21%	Limit :	NMT 0.5%
Related Substances	Complies		
ASSAY(ODB):	99.97%	Limit:	97.5 % - 102.0%
Material is sensitive to:	Heat Light Moisture		

The above material is qualified as Working Reference Standard.

Working Reference Standard is valid from: 23/03/2015 TO: 22/03/2016

Analysed by	Checked by	Approved by
N.Keerthika	T.Merlin	J.Sangeetha
(QC.Officer)	(QC.Sr.Executive)	(QA Manager)

WRS - M19 - 9

ATOZ PHARMACEUTICALS PRIVATE LIMITED
CHENNAI

CERTIFICATE OF ANALYSIS FOR LABORATORY WORKING REFERENCE STANDARD

Name of the material	**METFORMIN HYDROCHLORIDE**
Batch No	MET/01/14101355
Control No	A18/200
Mfg. Date	Oct-14
Exp. Date	Sep-19
Report Date	23/03/2015
Report No	WRS/K18/200
Mfgr's Name	AVILASH CHEMICALS PVT LTD.
Quantity	1.0 gm
Indented use	Working Reference Standard
Storage condition	STORE IN A WELL CLOSED CONTAINER

Description	A white powder		
Identification	BY IR		
LOD/WATER	0.13%	Limit :	NMT 0.5%
Related Substances	Complies		
ASSAY(ODB):	99.85%	Limit:	98.5 % - 101.0%
Material is sensitive to:	Heat Light Moisture		

The above material is qualified as Working Reference Standard.

Working Reference Standard is valid from: 23/03/2015 TO: 22/03/2016

Analysed by	Checked by	Approved by
N.Keerthika QC Chemist	T.Merlin (QC.Sr.Executive)	J.Sangeetha (QA Manager)

WRS-E27-1

shelys pharmaceuticals ltd
an aspen group company

new bagamoyo road mwenge plot no.696 block no.32 dar es salaam
po box 32781 dar es salaam tanzania registration number 5914
tel +255 22 2771715/6/7 fax +255 22 2772417 info@tz.betashelys.com
www.aspenpharma.com www.shelysafrica.com www.betacare.co.ke

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 4 JUN 2015 P.O. Box 29726 - 00202, NAIROBI

CERTIFICATE OF ANALYSIS
Working Standard

Name of CRS used: Enalapril Maleate
Lot/Batch: no. JIC267
Source: USP
Purity/Potency: 0.992mg/mg
Exp Date: Website Information

Name of Working Standard: Enalapril Maleate
EWS No: 13/15
Raw Material Bno, used: EPFP 10005
Mfg Date: 10/2010, **Exp Date:** 09/2015
Manufacturer: Sri Krishna
Date of Analysis: 15 /05/2015
Validity of use: Use within one month after opening, valid up to 09/2015, when sealed.
Quantity: 2.0g

RESULTS:

Sr. No.	Test Parameters	Limits	Observation
1	Description	A white or almost white powder	A white crystallinepowder
2	Identification: A. Infra red absorption	The IR spectrum of test sample is concordant to the IR spectrum of Enalapril Maleate working standard	The IR spectrum of test sample is concordant to the IR spectrum of Enalapril Maleate working standard
3	Loss on drying	NMT 1.0 %	0.51%
4	Assay (On anhydrous basis)	98.5% - 101.5%	100.4%

Additional Remarks:

Storage conditions:

- Store in refrigerator at 2°C- 8° C, when not in use
- Use within 30 days after opening, kept at a temperature of below 25 °C
- Keep tightly closed and protect from light

Justification of the selection of raw material for qualification:

- The Enalapril Maleate Raw material was taken from the current lot.

QUALITY CONTROL MANAGER SHELYS PHARMACEUTICALS P. O. BOX 3016 DAR ES SALAAM

	Analysed by	Checked by	Approved by
Signature	[signature]	[signature]	[signature]
Name	Haford M.	Mwakatumbula	Codeu Obwago
Date	15/05/2015	15/05/2015	15/05/2015
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control

WRS-B20-1

MIDAS CARE PHARMACEUTICALS PVT. LTD.
P-76, MIDC , WALUJ , AURANGABAD , 431 136 , INDIA

WORKING STANDARD
Certificate of analysis

Quality Assurance Department	QARF No. : QA/QC/INH/WSWST - 002
Date of Preparation : 01/07/2012	Revision No. : 01
Specs No. : QA / QC / WS / SPECS-022	STP No. : QA / QC / WS / STP-022

Material: Budesonide BP

Manufacturer	: Coral drug's Pvt ltd.	A.R. No.	: WS|188
Batch No.	: 6102-B-14011	QC Reference No	: R416755
Mfg. Date	: 03|2014	Prepared on	: 22|06|2014
Exp. Date	: 02|2017	Used before	: 21|06|2015
Issued date	: 22|06|14	Issued by	:

Sr. #	Tests	Specification	Results
01.	Description	A White or almost white Crystalline powder	A white Crystalline powder.
02.	Identification by IR	IR Spectrum obtained with test specimen is to be concordant with that of reference standard or ws	IR Spectrum obtained with test specimen concordent with that of Reference standard.
03.	Loss on drying (% w/w) Determined on 1 g	NMT 0.50	0.24 %.
04.	Assay (% w/w) (By HPLC)	NLT 97.5% and NMT 102.0% (Anhydrous Substance)	99.42 %. on as is basis.
			99.66 %. on as anhydrous basis

Remark : The above sample complies as per In-House specification.

RPK 22|06|14	22|06|14	22|06|14
Analyst	Checked by	Approved by

WRS-F7-2

MIDAS CARE PHARMACEUTICALS PVT. LTD.
B-16, MIDC, WALUJ, AURANGABAD, 431 136, INDIA

WORKING STANDARD
Certificate of analysis

Quality Assurance Department	QARF No. :QA/QC/INH/WSWST - 001
Date of Effective : 01/07/2012	Revision No. : 01
Specs No. : QA / QC / WS / SPECS-023	STP No. : QA / QC / WS / STP-023

Material: Formoterol Fumarate Dihydrate

Manufacturer :	Coral Drugs pvt Ltd.	A.R. No. :	CDS/195
Batch No. :	7000-14002	QC Reference No :	R416579
Mfg. Date :	03/12/14.	Prepared on :	29/12/14.
Exp. Date :	02/12/16.	Used before :	28/12/15
Issued date :	29/12/14.	Issued by :	

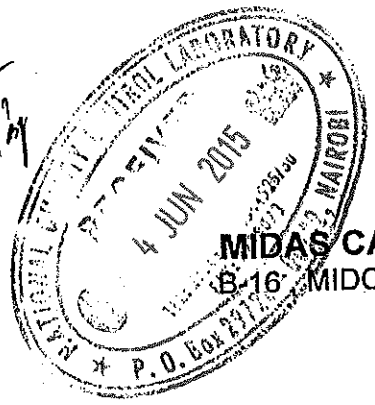
Sr. #	Tests	Specification	Results
01.	Description	A White or almost white or slightly yellow powder	A white powder.
02.	Identification by IR	IR Spectrum obtained with test specimen is to be concordant With that of reference standard or ws	IR spectrum obtained with test specimen is concordant with that of reference standard.
03.	Water (% w/w)	Between 4.0 & 5.0	4.71 %
04.	Assay (By HPLC)	NLT 98.5 % and NMT 101.5% (Anhydrous Substance)	95.19 % (on as 'is basis)
			99.90 % (on as. Anhydrous basis)

Remark: The above sample complies as per In-House specification.

MIDAS CARE PHARMACEUTICALS PVT. LTD. MUMBAI

29.12.14	29/12/14	29/12/14
Analyst	Checked by	Approved by (mam)

WRS-FL-2



MIDAS CARE PHARMACEUTICALS PVT. LTD.
B-16, MIDC, WALUJ, AURANGABAD, 431 136, INDIA

WORKING STANDARD
Certificate of analysis

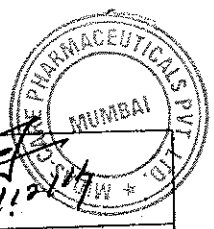
Quality Assurance Department	QARF No. : QA/QC/INH/WSWST - 007
Date of Preparation : 01/07/2012	Revision No. : 01
Specs No. : QA / QC / WS / SPECS-001	STP No. : QA / QC / WS / STP-001

Material: Fluticasone Propionate BP — Page 1 of 1

Manufacturer :	Coral Drugs. Pvt. Ltd	A.R. No. :	WS/194
Batch No. :	5503-B-14075	QC Reference No :	R417918
Mfg. Date :	11/2014	Prepared on :	28/12/2014
Exp. Date :	10/2017	Used before :	27/12/2015
Issued date :	28/12/2014	Issued by :	

Sr. #	Tests	Specification	Results
01.	Description	A White Crystalline powder	A white ceystaline powder
02.	Identification by IR	IR Spectrum obtained with test specimen is to be concordant with that of reference standard or ws	IR Spectrum obtained with test speciman is concordant with that of reference standard
03.	Water (%w/w) (By KF) Determined on 250 mg	NMT 0.5 %	0.13%.
04.	Assay (By HPLC)	NLT 97.0% and NMT 102.0% (Anhydrous Substance)	98.68%. (on as basis) 98.81 (on as anhydrous basis).

Remark : The above sample complies as per In-House specification.



28/12/14	28/12/14	28/12/14
Analyst	Checked by	Approved by

WRS-R13-1

FINECURE PHARMACEUTICALS LIMITED

Quality Control Department

CERTIFICATE OF ANALYSIS

WORKING STANDARD

NAME OF MATERIAL	RIBOFLAVIN BP	WORKING STD NO.	RWS/1RIBO01
BATCH NO.	H201410011FM	ANALYSIS DATE	11/03/15
MFG. DATE	OCT 2014	REPORT DATE	12/03/15
EXP.DATE	OCT 2017	EFFECTIVE DATE	13/03/15
STORAGE	STORE PROTECTED FROM LIGHT.	VALID UPTO	12/03/16
		NO.OF VIALS	14

TEST	SPECIFICATION	OBSERVATION
DESCRIPTION	Yellow to orange-yellow, crystalline powder.	Orange-yellow, crystalline powder.
IDENTIFICATION	Shall comply	Complies
LOSS ON DRYING	Not more than 1.5 %w/w	0.30% w/w
ASSAY(ODB)	Between 97.0% to 103.0%	99.26% (ODB)

Finecure Pharmaceuticals Ltd.

Remarks :The above material comply as per BP specification and can used for working standard.

Analysed By	Checked By	Approved By
12-03-2015	12/3/2015	

FINECURE PHARMACEUTICALS LTD. QUALITY CONTROL

KIRS - N11-1

FINECURE PHARMACEUTICALS LIMITED

Quality Control Department

CERTIFICATE OF ANALYSIS

WORKING STANDARD

NAME OF MATERIAL	NICOTINAMIDE BP	WORKING STD NO.	RWS/1NIAC01
BATCH NO.	14-0468	ANALYSIS DATE	10/03/15
MFG. DATE	AUG-2014	REPORT DATE	11/03/15
EXP.DATE	JUL-2019	EFFECTIVE DATE	11/03/15
MFG.BY	LASONS LIMITED	VALID UPTO	10/03/16
STORAGE	STORE PROTECTED FROM LIGHT AND MOISTURE	NO.OF VIALS	14

TEST	SPECIFICATION	OBSERVATION
DESCRIPTION	A white or almost white, crystalline powder or colourless crystals.	A white, crystalline powder.
IDENTIFICATION	Shall comply	Complies
LOSS ON DRYING	Not more than 0.5 %w/w	0.24% w/w
ASSAY(ODB)	Between 99.0% to 101.0%	99.41% (ODB)

Remarks: The above material comply as per BP specification and can used for working standard.

Finecure Pharmaceuticals Ltd.

Analysed By	Checked By	Approved By
10-03-2015	11/03/2015	

KRS-F13-1

FINECURE PHARMACEUTICALS LIMITED

Quality Control Department

CERTIFICATE OF ANALYSIS

WORKING STANDARD

NAME OF MATERIAL	FERROUS GLUCONATE BP	WORKING STD NO.	RWS/1FER01
BATCH NO.	FG-14076	ANALYSIS DATE	06/03/15
MFG. DATE	JAN 2015	REPORT DATE	08/03/15
EXP.DATE	DEC 2019	EFFECTIVE DATE	09/03/15
MFG. BY	GLUCO CHEM INDUSTRIES	VALID UPTO	08/03/16
STORAGE	STORE PROTECTED FROM LIGHT.	NO.OF VIALS	14

TEST	SPECIFICATION	OBSERVATION
DESCRIPTION	Greenish-yellow or grey powder or granules.	Greenish-yellow powder.
IDENTIFICATION	Shall comply	Complies
LOSS ON DRYING	5.0 %w/w to 10.5 % w/w	6.30% w/w
ASSAY(ODB)	Between 11.8% to 12.5%	11.99% (ODB)

Finecure Pharmaceuticals Ltd

Remarks :The above material comply as per BP specification and can used for working standard.

Analysed By	Checked By	Approved By
08-03-2015	09/03/2015	09/03/2015

FINECURE PHARMACEUTICALS LTD. QUALITY CONTROL

WRS-540-1

01/07/12 commn? dated by

MIDAS CARE PHARMACEUTICALS PVT. LTD.

B-16, MIDC, WALUJ, AURANGABAD, 431 136, INDIA

Midas Care - Quality Assurance. Issued By & Date 01/07/2012

RECEIVED 4 JUN 2016

WORKING STANDARD
Certificate of analysis

Quality Assurance Department	QARF No. : QA/QC/INH/WSWST - 004
Date of Preparation : 01/07/2012	Revision No. : 01
Specs No. : QA / QC / WS / SPECS-030	STP No. : QA / QC / WS / STP-030

Material:	**Salmeterol Xinafoate BP**	**Page 1 of 1**	
Manufacturer :	Coral Drugs Pvt. Ltd	A.R. No. :	WS/193
Batch No. :	6601-B-14003	QC Reference No :	R417520
Mfg. Date :	07/2014	Prepared on :	25/12/2014
Exp. Date :	06/2016	Used before :	24/12/2015
Issued date :	25/12/2014	Issued by :	[signature]

Sr. #	Tests	Specification	Results
01.	Description	White or almost white powder	White powder.
02.	Identification by IR	IR Spectrum obtained with test specimen is to be concordant with that of reference standard or ws	IR spectrum obtained with test specimen is concordant with that of reference standard
03.	Water (% w/w) (By KF)	NMT 0.5 %	0.19%
04.	Assay (%w/w) (By HPLC)	NLT 97.0% and NMT 102.0% (Anhydrous substance)	99.09% (on as basis) 99.28% (on anhydrous basis)

Remark : The above sample complies as per In-House specification.

MIDAS CARE PHARMACEUTICALS PVT. LTD. MUMBAI

[signature] 25/12/14	[signature] 25/12/14	[signature] 25/12/14
Analyst	Checked by	Approved by

PRS-C62-3

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 01/2008:51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) - Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet : http://www.edqm.eu

Name	Lithium clavulanate
Catalogue code	L0720000
Batch number*	6
Assigned value	97.0%
Validity	Batch 6 is valid at the printing date: 2014-8-22
Storage conditions	The standard is intended for immediate use. Recommended EDQM storage conditions for unopened containers : +5° C ± 3° C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, **if available** (Adobe Acrobat Reader version 5 or higher, or the corresponding browser plug-in is needed to open the file) click to download the leaflet

PNS-C62-3

Sub-batches 1.1, 1.2,1.3, etc., are obtained from the same batch of bulk material.
Notice: the previous classification of the sub-batches 1a,1b, 1c will be gradually replaced with 1.1, 1.2, 1.3 etc.

This statement is valid at the date of printing : 2014-8-22

KRS-43-1

FINECURE PHARMACEUTICALS LTD

Unit Village Simlapistaur, Rudrapur, Dist. Udhamsingh Nagar (U.A.)

CERTIFICATE OF ANALYSIS

Product Name : - 4-AMINOPHENOL EXTRA PURE
Formula : - C_6H_7NO
Mol. Weight : - 109.13
Code no. : - 01070
CAS no. : - 123-30-8
Lot no. : - S44301504
Mfg date : - APR-2015
Exp date : - MAR-2018

Analyzed on: - 07/04/15 Mol.

Sr. no.	Tests	Specifications	Results
1	Description	White/Off white crystalline powder	Off white crystalline powder
2	Assay	Min 98.0%	98.7%
3	Melting range	185 - 189°C	185°C

*This above product complies as per the specifications of **FINECURE PHARMACEUTICALS LIMITED.***

Finecure Pharmaceuticals Ltd.

This document has been produced electronically and it is valid without signature.

KRS – 21 – 1.

FINECURE PHARMACEUTICALS LTD

Unit Village Simlapistaur, Rudrapur, Dist. Udhamsingh Nagar (U.A.)

CERTIFICATE OF ANALYSIS

Product Name : - 2, 6-DICHLOROQUINONE-4-CHLORIMIDE AR
Analyzed on: - 23/04/14
Mol. Formula : - $C_6H_2Cl_3NO$
Mol. Wt. : - 210.45
Code no. : - 03310
CAS No. : - 101-38-2
Lot no. : - A125941404
Mfg date : - APR-2014
Exp date : - MAR-2019

Sr. no.	Tests	Specifications	Results
1	Description	Brownish yellow coloured crystalline powder	Brownish crystalline powder
2	Assay	Min. 98.0%	99.75%
3	Melting point	65.0 – 68.0°C	65°C
4	Spec. Absorptivity A1%/1cm (312 nm; 0.001%; ethanol)	Min. 800	843.33

This above product compiles as per the specifications of FINECURE PHARMACEUTICALS LIMITED.

Finecure pharmaceuticals Ltd.

This document has been produced electronically and it is valid without signature.

BAROQUE PHARMACEUTICALS PVT.LTD

WRS - A47 - 1

CERTIFICATE OF ANALYSIS

NAME OF WORKING STANDARD : Ammonium Ferrous Sulfate Hexahydrate (Working Standard)

BATCH NO : WS/AFS/05 **A.R. NO.** : WL/15/04/05

MFG. DATE : APR-2015 **QTY. GIVEN** : 5 GM

EXP. DATE : MAR-2017 **REPORT DATE** : 15.04.2015

Sr. No	Test	Specifications	Results
1	Description	Pale Bluish –green crystals.	Pale Bluish –green crystals.
2	Solubility	Soluble in water. Solubility in Water: 26.9 g/100 ml water at 20 deg. C; 73 g/100 ml water at 80 deg. C. Insoluble in Ethanol.	Soluble in water. Solubility in Water: 26.9 g/100 ml water at 20 deg. C; 73 g/100 ml water at 80 deg. C. Insoluble in Ethanol.
3	Melting Point	99℃ to 102˚C	100˚C
4	Identity: NH_4 Fe	 To meet the test To meet the test	 Complies Complies
5	Assay	NLT 99.0 %	99.6 %

The product meets specification of **Ammonium Ferrous Sulfate Hexahydrate (Working Standard)** and hence is of standard quality.

Q. C. Manager

Sign.

Baroque Pharmaceuticals Pvt. Ltd.

WRS-A48-1

Mylan

MYLAN LABORATORIES LIMITED
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik - 422 113, Maharashtra, India.

CERTIFICATE OF ANALYSIS
(WORKING STANDARD)

Name: Atazanavir Sulfate

Source Batch No.	50032679	**W.S. A.R. No.**	MLNWSD14000118
Date Of Standardization	Dec 23 2014 11:37AM	**Standardized against**	Atazanavir Sulfate RS B.No.RFS-GVS(A-860)053
Storage Condition	NMT 25°C	**Validity**	Dec 20, 2015
STP No.	RMPATS019-09	**Ref. Specification**	RMSATS019-10

S. No.	TEST	SPECIFICATION	RESULTS
1	**Description**	White to pale yellow powder which may contains lumps.	Pale yellow powder.
2	**Identification (By Infrared Absorption)**	The absorption maxima in the spectrum obtained with the substance to be examined corresponds in position and relative intensity to those in the spectrum obtained with the working standard.	The absorption maxima in the spectrum obtained with the test substance is corresponds in position and relative intensity to those in the spectrum obtained with the Atazanavir RS B.No.RFS-GVS(A-860)053
3	**Water (By KF)**	Not more than 1.0% w/w	0.34 % w/w
4	**Assay (By HPLC)**	Not less than 97.5% w/w and not more than 102.0% w/w.	Assay of Atazanavir 'corrected for water and sulfuric acid':99.6 % w/w Assay of Atazanavir 'corrected for water, sulfuric acid and total residual solvents':99.6 % w/w Assay on 'as is basis' as atazanavir sulfate:99.3 % w/w on 'as is basis':87.6 % w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Bhushan.Amrutkar	Approved By	Jadhav.Sanjay
Checked On	Dec 23 2014 11:26AM	Approved On	Dec 23 2014 11:37AM

Printed by: Bhushan.Amrutkar	**Printed on: Dec 23 2014 11:55AM**	**Copy No.: 1** **Page No.: 1 of 1**

Note : This document has been generated electronically and is valid without signature.

Format No.N/A

Plot No. 564/A/22, Road No. 92, Jubliee Hills, Hyderabad - 500 034, Telangana, India
Tel: 91-40-30866666, 23550543, Fax: 30866699
www.mylanlabs.in

WLS-C28-6

apdl

Abacus Parenteral Drugs Ltd.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF WORKING STANDARD

Name	Ciprofloxacin Hydrochloride U.S.P
Batch No	HB00N130199
Description	Pale yellow, slightly hygroscopic powder.
Water %	5.92 %
Assay (Anhydrous basis)	99.71 %
Preparation Date	29/07/2014
Expiry Date	28/07/2016

Storage: Store in a cool and dry place below 30°C.

Sign			
Name	EVANS C		Margaret
Date	30/07/14	30/07/14	30/07/14
	Q.C Chemist	Q.C In-charge	Q.C Manager

WRS-014-C

ATOZ PHARMACEUTICALS PRIVATE LIMITED
CHENNAI

CERTIFICATE OF ANALYSIS FOR LABORATORY WORKING REFERENCE STANDARD

Name of the material	**OMEPRAZOLE**
Batch No	OMP/P/2/2014101214
Control No	A25/280
Mfg. Date	Oct-14
Exp. Date	Sep-17
Report Date	23/03/2015
Report No	WRS/K25/280
Mfgr's Name	METROCHEM PRIVATE LIMITED
Quantity	1.0 gm
Indented use	Working Reference Standard
Storage condition	STORE IN A WELL CLOSED LIGHT RESISTANT CONTAINER

Description	A White Pellets		
Identification	BY IR		
Water	0.12%	Limit :	NMT 0.5%
Related Substances	Complies		
ASSAY(ODB):	99.84%	Limit:	98.0% - 102.0%
Material is sensitive to:	Heat *Light Moisture		

The above material is qualified as Working Reference Standard.

Working Reference Standard is valid from: 23/03/2015 TO: 22/03/2016

Analysed by	Checked by	Approved by
N.Keerthika	T.Merlin	J.Sangeetha QA
(QC.Officer)	(QC.Sr.Executive)	(QA Manager)