Health and Family Welfare Department
Shimla -9, Himachal Pradesh, India

No. MFG / FSC/ FG / 289 Date: 13/07/2014

FREE SALE CERTIFICATE

This is to certify that M/s. FARMA GLOW, Village – Kotla, PO – Barotiwala, Solan, Himachal Pradesh, India hold valid Manufacturing License No. HP/06/109 on form 25 respectively to manufacture for sales drug formulations under the categories of Compressed Tablets, Hard Gelatin Capsules, Liquid Orals, Liquid Injections & Dry Powder Injections with external preparation including the below preparations:

License No. : HP/06/109 **on Form:** 25

Catergory : Compressed Tablets

Pharmacopoeial Name	Brand Name	Composition
Sildenafil Citrate Tablets 100mg	**SUNPOWER 100**	Each film-coated tablet Contains: Sildenafil Citrate Eqv. to Sildenafil 100mg Excipients q. s.

This is further certified that above mentioned drug has been authorized to be marketed in domestic market and for export by M/s. Farma Glow.

This certificated is issued to M/s FARMA GLOW, Village – Kotla, PO – Barotiwala, Solan, Himachal Pradesh, India, on their request for submission to Ministry of Health of Importing Countries for registration and exporting their products.

FARMA GLOW
Village – Kotla, PO - Barotiwala
Solan, Himachal Pradesh India

ATTESTED TO BE TRUE COPY
ASHOK BHARDWAJ
ADVOCATE & NOTARY
DIST. GURGAON (Haryana) India

02/07/14

Licensing Authority
H. P. Shimla - 9

Licensing & Controlling Authority (Drugs) Himachal Pradesh

DELTA
ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

www.deltaenterprises.org

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

(Under Drugs & Cosmetics Act 1940 & Rules made there under)

Product Name :	DELGRA-100		
Generic Name :	Sildenafil Citrate Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAJ04	**A. R. No. :**	F2012042228
Mfg. Date :	Apr.2012	**Pack Size :**	1x10TAB
Exp. Date :	Mar.2015	**Pack Type :**	Tablets
Batch Size :	400000 TAB	**Sampled On :**	22/04/2012
Product Code :	AQRAJ	**Sample Quantity :**	60.00 TAB
Specification No. :	FPS-AQRAJ	**Sampled By :**	RINKY
Ref. STP No. :	AKUMS/STP/030	**Analyzed By :**	KESHAW
Manufactured For :	DELTA ENTERPRISES	**Date of Analysis :**	22/04/12
Manufactured By :	AKUMS	**Release Date :**	02/05/12

S.No.	TEST	ACCEPTANCE CRITFRIA	RESULTS
1	Description	Blue coloured diamond shape, biconvex with engraved 100 on one side and plain on other side & film coated tablets. 1 x 10 Tablets packed in a blister containing clear PVC film & printed aluminum foil.	Blue coloured diamond shape, biconvex with engraved 100 on one side and plain on other side & film coated tablets. 1 x 10 Tablets packed in a blister containing clear PVC film & printed aluminum foil.
2	Dimension	As below	As below
	Length	14.5 mm ± 0.2 mm	14.52mm
	Width	10.40 mm ± 0.2 mm	10.33mm
	Thickness	5.0 mm ± 0.4 mm	4.62mm
3	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution .	Complies
4	Average weight	490.0 mg ± 5%	493.80mg
5	Uniformity of weight	Within ± 5 % of Average weight	-1.8% to +2.9%
6	Disintegration Time	Not more than 30 minutes	Passes(03min37sec)
7	Dissolution .	NLT 70 % (D)	94.91%, 96.15%, 93.37%, 96.3%, 96.69%, 96.77%
8	Related Substances	As below	As below

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

Q.A. APPROVED
SIGN.. DATE 02/05/12

Prepared By (Sign / Date) 02/05/12

Checked By QC Executive (Sign / Date) 02/05/12

Approved By Head QC (Sign / Date) 02/05/12

SUNRISE REMEDIES PVT. LTD.

BLOCK NO. 2244,OPP. SHAH ALLOYS LTD,TAL : KALOL,SANTEJ-382721

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: MALEGRA PRO 100 TABLET			**A.R. No.**	: **FPE120051**
Packing	: 10x10 TAB				
Generic Name	: SILDENAFIL CITRATE SUBLINGUAL TABLET			**Rel. Dt.**	: 21-08-2012
				T.R. Slip No.	: PAQA120284
Product Code	: MALE06	**Mfg. Dt.**	: AUG-2012	**T.R. Slip Dt.**	: 20-08-2012
Batch No.	: E-559	**Exp. Dt.**	: JUL-2015	**Analysis Date**	: 20-08-2012
Actual Batch Size	: 105000 TAB			**Specification No.**	: FPSETMALIH006
Packing Batch Size	: 105000 TAB	**Test Packing**	: 60 TAB	**Specification Dt.**	: 01-03-2010
Sample Size	: 60 TAB	**Mfg. Lic No.**	: G/1428	**SOP No.**	: S1FPSETMALIH006
Released Qty	: 105000 TAB	**Test As Per**	: IH	**Location**	: SANTEJ
				Make	: SUNRISE

Sr. No.	Test	Result	Specification
1	DESCRIPTION	LIGHT PINK COLOURED CIRCULAR UNCOATED SLIGHTLY BICONVEX TABLET.	LIGHT PINK COLOURED CIRCULAR UNCOATED SLIGHTLY BICONVEX TABLET. (SUBLINGUL)
2	WEIGHT OF 20 TABLETS	10.0517 GM	9.8000 GM ± 5 %
3	AVERAGE WEIGHT (TABLETS)	502.585 mg	490.0 mg ± 5 %
4	THICKNESS	5.4 MM	BET. 4.5 MM TO 5.5 MM
5	ASSAY	result 96.18 MG 96.18 % lable claim 100.0 MG	Each uncoated tab contains : SILDENAFIL CITRATE EQ. TO SILDENAFIL 100mg [Limit : 90.0 MG TO 110.0 MG] (90.0 % to 110.0 %)

Conclusion : The above sample complies as per IH

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

ANALYSIS BY

BHUMIKA G. RATHOD
MANGER Q A & Q.C.

SUNRISE REMEDIES PVT. LTD. SANTEJ

APPROVED BY

BHUMIKA G. RATHOD
MANGER Q A & Q.C.

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The Drugs & Cosmetics Act 1940 and the Rules thereunder

CERTIFICATE OF ANALYSIS

REPORT NO	: GSPF-0988/12-13		
SAMPLE	: LOVEVITRA - 20 TABLET		
GENERIC NAME	: VARDENAFIL		
BATCH NO	: 12SGJT007	RECIEVED ON	: 19/10/2012
BATCH SIZE	: 100000 TABLET	STAGE	: FINISH
SAMPLE SIZE	: 60.00 TABLET	MFG. DATE	: Oct, 2012
		EXP. DATE	: Sep, 2014

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Yellow coloured, round, biconvex, film coated tablets.	Yellow coloured, round, biconvex, film coated tablets.
IDENTIFICATION	Positive for Vardenafil Hydrochloride.	It should be positive for Vardenafil Hydrochloride.
AVERAGE WEIGHT	135.72 mg	128.25-141.75 mg
UNIFORMITY OF WEIGHT	133.5-139.8 mg	±5 %
DISINTEGRATION TIME	1 -2 minutes	NMT 30 minutes

ASSAY

Each Film coated tablets on an average weight contains:

Ingredients	Obtained	Claim	Limit
VARDENAFIL HYDROCHLORIDE EQ TO VARDENAFIL	20.32 mg	20 mg	18-22 mg

REPORT : In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made there under

REMARKS : Complies

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

20/10/2012
DATE OF COMPLETION
Page 1 of 1

ANALYSED BY
20/10/12

ANIL BAHEL
TESTING INCHARGE
20/10/12

Address: Office No.2, 2nd Floor, Kolsawala Building,16, Cawasji Patel Street, Fort, Mumbai-400 001, Maharashtra, India,
& Fax: +91-22-22875727 Tel. No: +91-22-66517496 Website: deltaenterprises.org Email: deltaenterprises@cryptoheaven.com

SUNRISE REMEDIES PVT. LTD.

BLOCK NO. 2244,OPP. SHAH ALLOYS LTD,TAL : KALOL,SANTEJ-382721

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: FEMALEGRA-100 TABLET			A.R. No.	: FPE130162
Packing	: 10x4 TAB				
Generic Name	: SILDENAFIL TABLET 100MG			Rel. Dt.	: 18-11-2013
				T.R. Slip No.	: PAQA130504
Product Code	: FEMA01	Mfg. Dt.	: 07/11/2013	T.R. Slip Dt.	: 18-11-2013
Batch No.	: E-823	Exp. Dt.	: 31/10/2016	Analysis Date	: 18-11-2013
Actual Batch Size	: 50000 TAB	Test Packing	: 60 TAB	Specification No.	: FPSETFEMIH001
Packing Batch Size	: 50000 TAB	Mfg. Lic No.	: G/1428	Specification Dt	: 01-03-2010
Sample Size	: 60 TAB	Test As Per	: IH	STP No.	: S1FPSETFEMIH001
Released Qty	: 50000 TAB			Location	: SANTEJ
				Make	: SUNRISE

Sr. No.	Test	Result	Specification
1	DESCRIPTION	PINK COLOURED CRISTAL SHAPED SLIGHTLY BICONVAX FILM COATED TABLET	PINK COLOURED CRISTAL SHAPED SLIGHTLY BICONVAX FILM COATED TABLET
2	WEIGHT OF 20 TABLETS	10.0490 GM	10.0000 GM ± 5 %
3	AVERAGE WEIGHT (TABLETS)	502.45 mg	500.0 mg ± 5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 5%
5	DISINTEGRATION TIME	0 MIN 55 SEC	NOT MORE THAN 30 MINUTE.
6	THICKNESS	5.18 MM	BET. 4.5 MM TO 5.5 MM
7	HARDNESS	6.5 KG/CM²	NOT LESS THAN 3.0 KG/CM²
8	IDENTIFICATION	COMPLIES	COMPLIES AS PER IHS
9	ASSAY	LABLE CLAIM RESULT 100.0 mg 94.35 mg 94.35 %	EACH FILM COATED TAB CONTAINS : SILDENAFIL CITRATE EQ. TO SILDENAFIL [Limit : 90.0 MG TO 110.0 MG] [BET 90.0% TO 110.0%]
10	DISSOLUTION	mini: 96.23 % maxi: 105.76 %	nlt 70.0 %

Conclusion : The above sample complies as per IH

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

ANALYSIS BY

BINA THANKI
LAB CHEMIST

SUNRISE REMEDIES PVT. LTD. SANTEJ

APPROVED BY

BHUMIKA G. RATHOD
MANGER Q A & Q.C.

FGANLCERTQA

SUNRISE REMEDIES PVT. LTD.

BLOCK NO. 2244,OPP. SHAH ALLOYS LTD,TAL : KALOL,SANTEJ-382721

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: AVANA-50 TABLET			**A.R. No.**	: FPE120053
Packing	: 4 TAB				
Generic Name	: AVANAFIL TABLET 50MG			**Rel. Dt.**	: 21-08-2012
				T.R. Slip No.	: PAQA120287
Product Code	: AVAN01	**Mfg. Dt.**	: AUG-2012	**T.R. Slip Dt.**	: 21-08-2012
Batch No.	: E-560	**Exp. Dt.**	: JUL-2014	**Analysis Date**	: 21-08-2012
Actual Batch Size	: 15000 TAB	**Test Packing**	: 60 TAB	**Specification No.**	: FPEAVANAIH001
Packing Batch Size	: 15000 TAB	**Mfg. Lic No.**	: G/1428		
Sample Size	: 60 TAB	**Test As Per**	: IH	**SOP No.**	: STFPEAVANAIH001
Released Qty	: 15000 TAB			**Location**	: SANTEJ
				Make	: SUNRISE

Sr. No.	Test	Result	Specification
1	DESCRIPTION	MARRON COLOURED TRIANGULAR SHAPED FILMCOATED BICONVEX TABLET WITH ONE SIDE PLAIN AND OTHER SIDE EMBOSSED SRPL.	MARRON COLOURED TRIANGULAR SHAPED FILMCOATED BICONVEX TABLET WITH ONE SIDE PLAIN AND OTHER SIDE EMBOSSED SRPL.
2	WEIGHT OF 20 TABLETS	10.2896 GM	10.2400 GM ± 5 %
3	AVERAGE WEIGHT (TABLETS)	514.48 mg	512.0 mg ± 5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 5%
5	DISINTEGRATION TIME	2 MIN 42 SEC	NOT MORE THAN 30 MINUTE.
6	THICKNESS	5.3 MM	BET. 4.5 MM TO 5.5 MM
7	HARDNESS	4.0 KG/CM²	NOT LESS THAN 3.0 KG/CM²
8	IDENTIFICATION	COMPLIES	COMPLIES AS PER IHS
9	ASSAY	result lable claim 52.10 mg 50.0 mg 104.20 %	Each film coated tab contains : Avanafil 50 mg [Limit : 45.0 MG TO 55.0 MG] [BET 90.0% TO 110.0%]

Conclusion : The above sample complies as per IH

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

ANALYSIS BY

BHUMIKA G. RATHOD
MANGER Q.A & Q.C.

APPROVED BY

BHUMIKA G. RATHOD
MANGER Q.A & Q.C.

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

(Under Drugs & Cosmetics Act 1940 & Rules made there under)

Product Name :	TADADEL 20 mg		
Generic Name :	Tadalafil Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAN04	**A. R. No. :**	F2012042201
Mfg. Date :	Apr.2012	**Pack Size :**	1x10TAB
Exp. Date :	Mar.2015	**Pack Type :**	Tablets
Batch Size :	400000 TAB	**Sampled On :**	22/04/2012
Product Code :	40009113	**Sample Quantity :**	60.00 TAB
Specification No. :	STS/FP/40009113-00	**Sampled By :**	RAJVEER
Ref. STP No. :	STP/FP/40009113-00	**Analyzed By :**	AVDHESH
Manufactured For :	DELTA ENTERPRISES	**Date of Analysis :**	27/04/12
Manufactured By :	AKUMS	**Release Date :**	30/04/12

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
1	Description	Yellow coloured, Drop shaped & T 20 embossed on upper side of each film coated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.		Yellow coloured, Drop shaped & T 20 embossed on upper side of each film coated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.
2	Identification	Positive for Tadalafil		Complies
3	Dimension	As below		As below
	Length	12.1 mm ± 0.2 mm		12.27mm
	Width	7.5 mm ± 0.3 mm		7.62mm
	Thickness	4.3 mm ± 0.4 mm		4.15mm
4	Average weight	308.0 mg ± 5.0%		312.95mg
5	Uniformity of weight	Within ± 5.0% of Average Weight		-1.9% to +1.9%
6	Disintegration Time	Not more than 30 Minutes		Passes(04min36sec)
7	Uniformity of Content	85% to 115% of average value		94.48% to 103.1%
8	Colour Identification	Positive for Yellow Oxide of Iron & Titanium Dioxide BP		Complies
9	**Assay - Each film coated tablet contains.**	**Release**	**Shelf Life**	**Found/Tab. Stated/Tab.**

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

Q.A. APPROVED
SIGN.....h DATE: 30/04/12

Prepared By (Sign / Date) 30/04/12	**Checked By** QC Executive (Sign / Date) 30/04/12	**Approved By** Head QC (Sign / Date) 30/04/12

Министерство здравоохранения и социального развития
Российской Федерации

**Федеральное государственное учреждение
«Научно – исследовательский институт урологии»
Министерства здравоохранения и социального развития
Российской Федерации**
(ФГУ «НИИ урологии» Минздравсоцразвития России)
3-я Парковая ул. 51, г. Москва, 105425 тел/факс (499) 367-75-87/165-09-11

ЭКСПЕРТНОЕ ЗАКЛЮЧЕНИЕ

В Федеральном Государственном Учреждении «НИИ урологии» Минздравсоцразвития РФ проведено:

«Слепое сравнительное рандомизированное плацебоконтролируемое клиническое исследование по изучению эффективности и безопасности препарата ВИАГРА MALEGRA У пациентов с эректильной дисфункцией».

По результатам данного исследования препарат зарекомендовал себя эффективным и безопасным средством для лечения эректильной дисфункции различной этиологии и степени выраженности.

Первый заместитель директора по научной работе А.В. Сивков

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

(Under Drugs & Cosmetics Act 1940 & Rules made there under)

Product Name :	TADADEL PROFESSIONAL		
Generic Name :	Tadalafil Sublingual Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAQ01	**A.R. No. :**	F2012091512
Mfg. Date :	Sep. 2012	**Pack Size :**	1X10 TAB
Exp. Date :	Feb. 2015	**Pack Type :**	Blister
Batch Size :	100000 TAB	**Sampled On :**	15/09/12
Product Code :	40010933	**Sample Qty.:**	130 TAB
Specification No. :	STS/FP/40010933-00	**Sampled By :**	RAJVEER
Ref. STP No. :	STP/FP/40010933-00	**Analyzed By :**	DHANESH
Manufactured For :	Delta Enterprises	**Date of Analysis :**	15/09/12
Manufactured By :	Akums Drugs (Plant-1)	**Completion Date :**	24/09/12

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
1	Description	Yellow colour, drop shape, one side engraved with T 20 uncoated sublingual tablets.10 tablets packed in a blister of clear PVDC film & printed aluminium foil.		Yellow colour, drop shape, one side engraved with T 20 uncoated sublingual tablets.10 tablets packed in a blister of clear PVDC film & printed aluminium foil.
2	Identification	Positive for Tadalafil		Complies
3	Dimension	As below		As below
3.a	Length	12.3 mm ± 0.2 mm		12.27 mm
3.b	Width	7.5 mm ± 0.2 mm		7.52 mm
3.c	Thickness	4.7 mm ± 0.3 mm		4.64 mm
4	Average weight	320.0 mg ± 5.0%		322.50 mg
5	Uniformity of weight	Within ± 5.0% of Average Weight		-1.4% to +2.6%
6	Disintegration Time	Not more than 15 Minutes		Passes(01min48sec)
7	Hardness	Not less than 3.0 kg/cm2		3.00 kg/cm2
8	Friability	Not more than 1.0% w/w		0.18 % w/w
9	Uniformity of Content	85% to 115% of average value		97.39% to 102.38%
10	Colour Identification	Positive for Quinoline Yellow WS		Complies
11	**Assay - Each uncoated sublingual tablet contains:**	**Shelf Life Limit**	**Release Limit**	**Found/Tab. Stated/Tab.**

Prepared By (Sign & Date) 24/09/12

Checked By QC Executive (Sign & Date) 24/09/12

Approved By Head QC (Sign & Date) 24/09/12

Address: Office No.2, 2nd Floor, Kolsawala Building,16, Cawasji Patel Street, Fort, Mumbai-400 001, Maharashtra, India.
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