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-25		
Generic Name :	Sildenafil Citrate Tablets		
Batch No. :	QRAM01	**A. R. No. :**	F2011091606
Mfg. Date :	Sep.2011	**Pack Size :**	1x10TAB
Exp. Date :	Aug.2014	**Pack Type :**	Tablets
Batch Size :	103000 TAB	**Sampled On :**	16/09/2011
Product Code :	AQRAM	**Sample Quantity :**	60.00 TAB
Specification No. :	FPS/AQRAM-00	**Sampled By :**	KHUSHAL SINGH
Ref. STP No. :	AKUMS/STP/030	**Analyzed By :**	OMPRAKASH
Manufactured For :	DELTA ENTERPRISES	**Date of Analysis :**	22/09/11
Manufactured By :	AKUMS	**Release Date :**	22/09/11

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Blue coloured, oval, biconvex & one side scored film coated tablets. 10 Tablets packed in a blister of clear PVC film & printed aluminum foil.	Blue coloured, oval, biconvex & one side scored film coated tablets. 10 Tablets packed in a blister of clear PVC film & printed aluminum foil.
2	Dimensions	As below	As below
	Length	12.6 mm ± 0.2 mm	12.57mm
	Width	9.7 mm ± 0.2 mm	9.58mm
	Thickness	3.8 mm ± 0.3 mm	3.68mm
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 solurion .	Complies
4	Average weight	333.0 mg ± 5%	333.80mg
5	Uniformity of weight	Within ± 5 % of Average weight	-1.1% to +1.9%
6	Disintegration Time	Not more than 30 minutes	Passes(06min15sec)
7	Dissolution .	NLT 70 % (D)	98.68%, 98.68%, 97.14%, 98.81%, 97.78%, 96.76%
8	Related Substances	As below	As below
	N-oxide Impurity	NMT 1.0%	0.01%

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai. India

Q.C. Sign 22/9/11

Prepared By (Sign/Date) 22/09/11

Checked By QC Executive (Sign/Date) 22/09/11

Approved By Head QC (Sign/Date) 22/09/11

DELTA ENTERPRISES

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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

[redacted]me :	DELGRA-50		
[redacted]me :	Sildenafil Citrate Tablets		
[redacted] :	10/UA/2004		
[redacted]	QRAL02	A. R. No. :	F2012020921
Mfg. [redacted]	Jan.2012	Pack Size :	1x10TAB
Exp. [redacted]	Dec.2014	Pack Type :	Tablets
Batch Size :	100000 TAB	Sampled On :	09/02/2012
Product Code :	AQRAL	Sample Quantity :	30.00 TAB
Specification No. :	FPS/AQRAL-00	Sampled By :	SANTOSH
Ref. STP No. :	AKUMS/STP/030	Analyzed By :	Upender
Manufactured For :	DELTA ENTERPRISES	Date of Analysis :	09/02/12
Manufactured By :	AKUMS	Release Date :	11/02/12

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description [redacted]	Blue coloured, oval, biconvex & one side scored film coated tablets. 10 Tablets packed in a blister of clear PVC film & printed aluminum foil.	Blue coloured, oval, biconvex & one side scored film coated tablets. 10 Tablets packed in a blister of clear PVC film & printed aluminum foil.
2	Dimension	As below	As below
	Length	12.6 mm ± 0.2 mm	12.55mm
	Width	9.7 mm ± 0.2 mm	9.64mm
	Thickness	3.8 mm ± 0.3 mm	3.64mm
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	337.0 mg ± 5%	344.20mg
5	Uniformity of weight	Within ± 5 % of Average weight	-2.4% to +2.6%
6	Disintegration Time	Not more than 30 minutes	Passes(04min15sec)
7	Dissolution .	NLT 70 % (D)	92.89%, 92.89%, 94.59%, 95.36%, 97.06%, 93.05%
8	Related Substances	As below	As below
	N-oxide Impurity (RRT 0.54)	NMT 1.0%	Below detection limit
	Single Impurity	NMT 0.8%	0.13%

DELTA ENTERPRISES Mumbai. India Manufacturers & Exporters of Pharmaceuticals

Q.A. APPROVED
SIGN. DATE 11/02/12

Prepared By (Sign / Date) 11/02/12

Checked By QC Executive (Sign / Date) 11/02/12

Approved By (Head QC) (Sign / Date) 11/2/12

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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

Product Name :	Delgra 100 mg Chewable		
Generic Name :	Sildenafil Citrate Chewable Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAP01	**A. R. No. :**	F2012042128
Mfg. Date :	Mar.2012	**Pack Size :**	1x10TAB
Exp. Date :	Feb.2014	**Pack Type :**	Tablets
Batch Size :	51000 TAB	**Sampled On :**	21/04/2012
Product Code :	40008980	**Sample Quantity :**	80.00 TAB
Specification No. :	STS/FP/40008980-00	**Sampled By :**	RAJVEER
Ref. STP No. :	STP/FP/40008980-00	**Analyzed By :**	KESHAV
Manufactured For :	DELTA ENTERPRISES	**Date of Analysis :**	21/04/12
Manufactured By :	AKUMS	**Release Date :**	25/04/12

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White, diamond shape, biconvex & '100' engraved on one side uncoated chewable tablet. 10 tablets packed in a blister of clear PVC film & printed aluminum foil.	White, diamond shape, biconvex & '100' engraved on one side uncoated chewable tablet. 1 X 10 tablets packed in a blister of clear PVC film & printed aluminum foil.
2	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
3	Dimension	As below	As below
	Length	14.4 mm ± 0.2 mm	14.49mm
	Width	10.4 mm ± 0.2 mm	10.31mm
	Thickness	4.9 mm ± 0.3 mm	4.88mm
4	Average weight	481.0 mg ± 5.0%	481.40mg
5	Uniformity of weight	Within ± 5.0 % of Average weight	-1.5% to +1.6%
6	Hardness	Not less than 3.5 kg/cm²	4.20kg/cm2
7	Friability	Not more than 1.0 % w/w	0.16% w/w
9	**Assay - Each Chewable tablet contains:**	**Release** / **Shelf Life**	**Found/Tab.** **Stated/Tab.**

Q.A APPROVED
SIGN. DATE: 26/04/12

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai India

Prepared By (Sign / Date) 25/04/12

Checked By QC Executive (Sign / Date) 25/04/12

Approved By Head QC (Sign / Date) 25/04/12

Address: Office No.2, 2nd Floor, Kolsawala Building,16, Cawasji Patel Street, Fort, Mumbai-400 001, Maharashtra, India,
Tel & Fax: +91-22-22875727 **Tel. No:** +91-22-66517498 **Website:** deltaenterprises.org **Email:** deltaenterprises@cryptoheaven.co

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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

Product Name :	Delgra 100 mg Chewable		
Generic Name :	Sildenafil Citrate Chewable Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAP02	**A.R. No. :**	F2012120708
Mfg. Date :	Nov. 2012	**Pack Size :**	1X10 TAB
Exp. Date :	Oct. 2014	**Pack Type :**	Blister
Batch Size :	100000 TAB	**Sampled On :**	07/12/12
Product Code :	40008980	**Sample Qty.:**	80 TAB
Specification No. :	STS/FP/40008980-00	**Sampled By :**	ARUN
Ref. STP No. :	STP/FP/40008980-00	**Analyzed By :**	ROBINDRA
Manufactured For :	Delta Enterprises	**Date of Analysis :**	07/12/12
Manufactured By :	Akums Drugs (Plant-1)	**Completion Date :**	11/12/12

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
1	Description	White, diamond shape, biconvex & '100' engraved on one side uncoated chewable tablet. 10 tablets packed in a blister of clear PVC film & printed aluminum foil.		White, diamond shape, biconvex & "100" engraved on one side uncoated chewable tablet. 10 tablets packed in a blister of clear PVC film & printed aluminum foil.
2	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
3	Dimension	As below		As below
3.a	Length	14.4 mm ± 0.2 mm		14.47 mm
3.b	Width	10.4 mm ± 0.2 mm		10.33 mm
3.c	Thickness	4.9 mm ± 0.3 mm		4.79 mm
4	Average weight	481.0 mg ± 5.0%		480.30 mg
5	Uniformity of weight	Within ± 5.0 % of Average weight		-2.4% to +2.2%
6	Hardness	Not less than 3.5 kg/cm²		4.60 kg/cm2
7	Friability	Not more than 1.0 % w/w		0.01 % w/w
8	**Assay - Each Chewable tablet contains:**	**Shelf Life Limit**	**Release Limit**	**Found/Tab. Stated/Tab.**

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

Prepared By (Sign & Date) 11/12/12

Checked By QC Executive (Sign & Date) 11/12/12

Approved By Head QC (Sign & Date) 11/12/12

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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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 CRITERIA	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 solurion .	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

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals
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CERTIFICATE OF ANALYSIS

PRODUCT	:	DELGRA FM TABLETS Sildenafil Citrate Tablets	DATE OF SAMPLING	:	07.04.2012
BATCH NO.	:	T-198001	DATE OF ANALYSIS	:	08.04.2012
BATCH SIZE	:	100000 Tablets	DATE OF RELEASE	:	08.04.2012
MFG DT.	:	04/2012	EXP DT.	:	09/2014

SR. NO.	TEST	RESULTS	SPECIFICATION
1.	Description	A pink colored, diamound shaped,film coated slightlyl biconvex,engraved 100"On both side of tablets.	A pink colored, diamound shaped, film coated slightyl biconvex,engraved 100" on both side of tablets.
2.	Identification	Complies	Must Complies as per HIS
3.	Uniformity of Wt.	530.2 mg	527.87 mg ± 5%
4.	Uniformity of content	complies	Complies Within ± 5%
5.	HEIGHT	14.44 mm	14.40mm ±0.1mm
6.	Thickness	4.92 mm	4.90 mm ±0.2mm
7.	Disintegration time	5'58" mintes in : Water	NMT 30 min
8.	Dissolution	101.94%	NLT 70%
9.	Assay	104.63%	Each film coated tablet contains: SILDENFIL Citrate Eq. to SildenafilTablets 100 MG (LIMIT :90% TO 110%)

Checked By
QC CHEMIST

DELTA ENTERPRISES Mumbai, India Manufacturers & Exporters of Pharmaceuticals

Approved By
QC IN CHARGE

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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CERTIFICATE OF ANALYSIS

Name of product	: Delgra-100		
Generic Name	: Sildenafil Citrate Softgel Capsules		
Manufactured for	: Delta Enterprises	A.R. No.	: FD-0167/02-12
Batch No.	: 0280312 D	Mfg. Date	: Mar. 2012
Batch Size	: 1,00,000 Capsules	Exp. Date	: FEB. 2014
Sample Quantity	: 100 Capsules	Date of Sampling	: 05th Mar. 2012
Reference STP No.	: EP/STP/FP/479/00	Date of Analysis	: 05th Mar. 2012

Sr. No.	Tests	Specifications	Observation
01.	Description	Sky blue coloured oval shape soft gelatin capsule filled with light cream viscous paste.	Sky blue coloured oval shape soft gelatin capsule filled with light cream viscous paste.
02.	Average weight	0.510 g ± 7.5%	0.513 g
03.	Average filled weight	0.350 g ± 7.5%	0.333 g
04.	Uniformity of weight	± 7.5% of actual average weight	- 3.60 to + 4.20%
05.	Loss on drying	Between 6.0% & 13.0%	8.38 %
06.	Disintegration time	Not more than 60 minutes	07 to 08 minutes
07.	Identification		
	Sildenafil Citrate	To Comply	Complies
08.	Assay		
	Sildenafil Citrate Claim: 100.00 mg /capsule	NLT 90.0mg/cap to 110.0mg/cap (NLT 90.0% to 110.0% of labeled amount)	99.18 mg 99.18%

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Remarks: The above sample Complies / Does not comply to the prescribed standards of quality in respect of the above tests as per finished product Specification No. EP/SPC/FP/479/00

Analysed By:	Checked By:	Approved By:
05th Mar. 2012	05th Mar 2012	05th Mar 2012
Signature / Date	Signature / Date	Signature / Date

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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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	: DELPECIA TABLETS			**A.R. No.**	: F/208/12
Packing	: 10x10 TAB				
Generic Name	: FINASTERIDE TABLETS USP 1MG			**Rel. Dt.**	: 15-05-2012
				T.R. Slip No.	: CBPTP12210
Product Code	: DELP01	**Mfg. Dt.**	: MAY-2012	**T.R. Slip Dt.**	: 14-05-2012
Batch No.	: T-04602E12	**Exp. Dt.**	: OCT-2014	**Analysis Date**	: 15-05-2012
Actual Batch Size	: 108000 TAB				
Packing Batch Size	: 108000 TAB	**Test Packing**	: 50 TAB		
Sample Size	: 50 TAB	**Mfg. Lic No.**	: G/1325		
Released Qty	: 108000 TAB	**Test As Per**	: USP		
Remarks : pass				**Location**	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	Brick red coloured, Round shaped, Biconvex, Film Coated tablet.	Brick red coloured, Round shaped, Biconvex, Film Coated tablet.
2	IDENTIFICATION	complies	Must complies as per USP
3	Thickness	3.28 mm	3.20 ± 0.2 mm
4	DIAMETER	6.06 mm	6.00 ± 0.1 mm
5	AVERAGE WEIGHT	108.20 mg	110.160 mg± 7.5 %
6	UNIFORMITY OF WEIGHT	Complies	Complies within ± 7.5 %
7	UNIFORMITY OF CONTENT	Complies	Must complies as per USP
8	DISSOLUTION	88.18%	NLT 80.0%
9	ASSAY	98.09 % Complies by vaibhav certi.No:120515/05631/106	Each Film Coated Tablet Contains : Finasteride USP 1 MG [Limit :95 % to 105 %]

DELTA ENTERPRISES Mumbai, India Manufacturers & Exporters of Pharmaceuticals

Conclusion : The above sample complies as per USP

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.

Analysed By

RISHIKA
QC CHEMIST

Approved By

KRISHNA PANCHAL
QC IN CHARGE

DELTA ENTERPRISES

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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	: FINADEL 5			A.R. No.	: F/223/12
Packing	: 10x10 TAB				
Generic Name	: FINASTERIDE TABLETS USP 5MG			Rel. Dt.	: 16-05-2012
				T.R. Slip No.	: CBPTP12223
Product Code	: FINA02	Mfg. Dt.	: MAY-2012	T.R. Slip Dt.	: 16-05-2012
Batch No.	: T-05802E12	Exp. Dt.	: APR-2015	Analysis Date	: 16-05-2012
Actual Batch Size	: 54000 TAB				
Packing Batch Size	: 54000 TAB	Test Packing	: 50 TAB		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 54000 TAB	Test As Per	: USP		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	Sky blue coloured, Round shaped, slightly Biconvex, Film Coated tablets plain on both sides.	Sky blue coloured, Round shaped, slightly Biconvex, Film Coated tablets plain on both sides.
2	IDENTIFICATION	complies	Must complies as per USP
3	THICKNESS	3.31 mm	3.20 ± 0.2 mm
4	DIAMETER	6.08 mm	6.00 ± 0.1 mm
5	AVERAGE WEIGHT	111.69 mg	113.31 mg± 7.5 %
6	UNIFORMITY OF WEIGHT	Complies	Complies within ± 7.5 %
7	DISSOLUTION	88.67%	NLT 80% (Q)
8	UNIFORMITY OF CONTENT	Complies	Must Complies as per USP
9	ASSAY	98.00 % Complete testing complies by vaibhav certi.No:120511/05123/88	Each Film Coated Tablet Contains : Finasteride USP 5MG [Limit :95 % to 105 %]

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals

Conclusion : The above sample complies as per USP

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.

Analysed By
RISHIKA
QC CHEMIST

Approved By
KRISHNA PANCHAL
Q.C.INCHARGE

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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

ANALYSED BY
20/10/12

ANIL BAHEL
TESTING INCHARGE
20/10/12

Page 1 of 1

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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	: LOVEVITRA 40			A.R. No.	: F/770/12
Packing	: 10x10 TAB				
Generic Name	: VARDENAFIL TABLETS 40 MG			Rel. Dt.	: 09-10-2012
				T.R. Slip No.	: CBPTP12762
Product Code	: LOVE01	Mfg. Dt.	: SEP-2012	T.R. Slip Dt.	: 09-10-2012
Batch No.	: T-265001	Exp. Dt.	: FEB-2015	Analysis Date	: 09-10-2012
Actual Batch Size	: 25000 TAB				
Packing Batch Size	: 25000 TAB	Test Packing	: FINISH		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 25000 TAB	Test As Per	: IH		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A Yellow colored, Round shaped slighty Biconvex, Bisected on one side and plain on other side, film coated tablet.	A Yellow colored, Round shaped slighty Biconvex, Bisected on one side and plain on other side, film coated tablet.
2	IDENTIFICATION	Complies	Must Complies as per IHS
3	AVERAGE WEIGHT	281.82 mg	283.12 mg ± 5 %
4	UNIFORMITY OF WEIGHT	Complies	Within ± 5 %
5	DIAMETER	9.64 mm	9.60 mm ± 0.2 mm
6	THICKNESS	4.06 mm	4.00 mm ± 0.2 mm
7	DISINTEGRATION TIME	12'34" Min. in : Water Medium at 37°c	NMT 30 Min.
8	ASSAY	101.38 %	Each Film Coated Tablet Contains : Vardenafil Hcl Eq to Vardenafil 40 mg [Limit 90 % to 110 %]

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

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.

Analysed By

QC CHEMIST

Approved By

KRISHNA PANCHAL
Q.C. IN CHARGE

DELTA ENTERPRISES

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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	: TADADEL 2.5 TABLETS			A.R. No.	: F/286/12
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL TABLETS 2.5 MG			Rel. Dt.	: 29-05-2012
				T.R. Slip No.	: CBPTP12287
Product Code	: TADA22	Mfg. Dt.	: MAY-2012	T.R. Slip Dt.	: 29-05-2012
Batch No.	: T-12102E12	Exp. Dt.	: OCT-2014	Analysis Date	: 29-05-2012
Actual Batch Size	: 108000 TAB				
Packing Batch Size	: 108000 TAB	Test Packing	: 50 TAB		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 108000 TAB	Test As Per	: IH		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A Light Yellow coloured, round shaped,biconvex film coated tablet.	A Light Yellow coloured, round shaped,biconvex film coated tablet.
2	IDENTIFICATION	Complies.	Must Complies as per IHS
3	Thickness	3.19 mm	3.20mm ± 0.2 mm
4	DIAMETER	6.08 mm	6.00 mm ± 0.2 mm
5	DISINTEGRATION TIME	5 min 40 Sec in : Water Medium at 37°c	NMT 30 Min
6	AVERAGE WEIGHT (TABLETS)	110.46 mg	107.18mg ± 7.5%
7	UNIFORMITY OF WEIGHT	Complies.	Within ± 7.5%
8	UNIFORMITY OF CONTENT	Complies	Must complies as per IHS
9	ASSAY	94.0 %	Each Film Coated Tablet contains : 1) Tadalafil 2.5 mg [Limit :90 % to 110 %]

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

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.

Analysed By

MVV
QC CHEMIST

Approved By

KRISHNA PANCHAL
Q.C.A. CHARGE

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals
www.deltaenterprises.org

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	: TADADEL 5 TABLETS			A.R. No.	: F/268-A/12
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL 5MG TABLETS			Rel. Dt.	: 25-05-2012
				T.R. Slip No.	: CBPTP12281
Product Code	: TADA23	Mfg. Dt.	: MAY-2012	T.R. Slip Dt.	: 25-05-2012
Batch No.	: T-12202E12	Exp. Dt.	: OCT-2014	Analysis Date	: 25-05-2012
Actual Batch Size	: 108000 TAB				
Packing Batch Size	: 108000 TAB	Test Packing	: FINISH		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 108000 TAB	Test As Per	: IH		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	Description	A Light yellow colored, Round shaped, Biconvex, film Coated tablets.	A Light yellow colored, Round shaped, Biconvex, film Coated tablets.
2	IDENTIFICATION	Complies	Must Complies as per IHS
3	AVERAGE WEIGHT	110.24 mg	107.20 mg ± 7.5 %
4	UNIFORMITY OF WEIGHT	Complies	Complies Within ± 7.5 %
5	Thickness	3.17 mm	3.20 mm ± 02 mm
6	DIAMETER	6.10 mm	6.20 mm ± 0.2 mm
7	DISINTEGRATION TIME	258 Min. in Water Medium at 37°c	NMT 30 Min.
8	UNIFORMITY OF CONTENT	Complies	Must Complies as per IHS
9	ASSAY	99.60 %	Each Film Coated Tablet Contains Tadalafil 5 mg [Limit :90 % to 110 %]

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai. India

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.

Analysed By
QC CHEMIST

Approved By
KRISHNA PANCHAL
Q.C. IN CHARGE

DELTA ENTERPRISES

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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	: TADADEL 10 TABLETS			**A.R. No.**	: F/174/12
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL TABLETS 10MG			**Rel. Dt.**	: 10-05-2012
				T.R. Slip No.	: CBPTP12168
Product Code	: TADA30	**Mfg. Dt.**	: APR-2012	**T.R. Slip Dt.**	: 09-05-2012
Batch No.	: T-15301D12	**Exp. Dt.**	: SEP-2014	**Analysis Date**	: 10-05-2012
Actual Batch Size	: 108000 TAB				
Packing Batch Size	: 108000 TAB	**Test Packing**	: 50 TAB		
Sample Size	: 50 TAB	**Mfg. Lic No.**	: G/1325		
Released Qty	: 108000 TAB	**Test As Per**	: IH		
Remarks : PASS				**Location**	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A Yellow coloured, ovalshaped, Biconvex , Film Coated tablet	A Yellow coloured, oval shaped, Biconvex , Film Coated tablet
2	IDENTIFICATION	Complies	Must Complies as per IHS
3	AVERAGE WEIGHT	305.05 mg	309.00 mg ± 5 %
4	UNIFORMITY OF WEIGHT	Complies	Complies Within ± 5 %
5	HEIGHT	12.53 mm	12.50 mm ± 0.2 mm
6	THICKNESS	4.28 mm	4.30 mm ± 0.2 mm
7	DISINTEGRATION TIME	6 Min. 25 Sec. in : Water Medium at 37°c	NMT 30 Min.
8	UNIFORMITY OF CONTENT	complies	complies
9	ASSAY	101.2%	Each Film Coated Tablet Contains: Tadalafil 20 mg [Limit :90 % to 110 %]

DELTA ENTERPRISES Mumbai. India Manufacturers & Exporters of Pharmaceuticals

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.

Analysed By	Approved By
QC CHEMIST	KRISHNA PANCHAL Q/C IN CHARGE

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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

Product Name :	TADADEL 20 mg Chewable		
Generic Name :	Tadalafil Chewable Tablets		
Mfg. Lic. No. :	10/UA/2004		
Batch No. :	QRAO01	**A. R. No. :**	F2011102121
Mfg. Date :	Oct.2011	**Pack Size :**	1x10TAB
Exp. Date :	Sep.2014	**Pack Type :**	Tablets
Batch Size :	103000 TAB	**Sampled On :**	21/10/2011
Product Code :	AQRAO	**Sample Quantity :**	80.00 tab
Specification No. :	FPS/AQRAO-00	**Sampled By :**	QA
Ref. STP No. :	AKUMS/STP/1456-00	**Analyzed By :**	Rajeshwar
Manufactured For :	DELTA ENTERPRISES	**Date of Analysis :**	28/10/11
Manufactured By :	AKUMS	**Release Date :**	28/10/11

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS	
1	Description	White colour, Oval shaped, biconvex& one side scored uncoated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.		White colour, Oval shaped, biconvex& one side scored uncoated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.	
2	Identification	Positive for Tadalafil		Complies	
3	Dimensions	As below		As below	
	Length	12.5 mm ± 0.2 mm		12.46mm	
	Width	9.6 mm ± 0.2 mm		9.46mm	
	Thickness	3.7 mm ± 0.3 mm		4.00mm	
4	Average weight	349.0 mg ± 5.0%		348.80mg	
5	Uniformity of weight	Within ± 5.0% of Average Weight		-1.7% to +1.8%	
6	Hardness	NLT 3.0 kg/cm2		3.30kg/cm2	
7	Friability	NMT 1.0 % w/w		0.27% w/w	
8	Uniformity of content	85% to 115% of average value		93.97% to 103.9%	
9	**Assay - Each uncoated chewable tablet contains.**	**Release**	**Shelf Life**	**Found/Tab.**	**Stated/Tab.**

DELTA ENTERPRISES Mumbai, India Manufacturers & Exporters of Pharmaceuticals

Q.A. APPROVED SIGN. DATE 28/10/11

Prepared By (Sign / Date) 28/10/11

Checked By QC Executive (Sign / Date) 28/10/11

Approved By Head QC (Sign / Date) 28/10/11

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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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.... **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

Address: Office No.2, 2nd Floor, Kolsawala Building,16, Cawasji Patel Street, Fort, Mumbai-400 001, Maharashtra, India,
Tel & Fax: +91-22-22875727 **Tel. No:** +91-22-66517498 **Website:** deltaenterprises.org **Email:** deltaenterprises@cryptoheaven.com

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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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	: TADADEL 40 TABLETS			A.R. No.	: F/527-A/12
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL 40MG TABLETS			Rel. Dt.	: 03-08-2012
				T.R. Slip No.	: CBPTP12549
Product Code	: TADA24	Mfg. Dt.	: JUL-2012	T.R. Slip Dt.	: 03-08-2012
Batch No.	: T-134002	Exp. Dt.	: DEC-2014	Analysis Date	: 03-08-2012
Actual Batch Size	: 54000 TAB				
Packing Batch Size	: 54000 TAB	Test Packing	: 50 TAB		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 54000 TAB	Test As Per	: IH		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A light yellow coloured, oval shaped, biconvex ,plain on both side, film coated tablet.	A light yellow coloured, oval shaped, biconvex ,plain on both side, film coated tablet.
2	IDENTIFICATION	Complies	Must Complies as per IHS.
3	AVERAGE WEIGHT	311.6mg	312.90 mg ± 5 %
4	UNIFORMITY OF WEIGHT	Complies	Complies within ± 5 %
5	HEIGHT	12.59 mm	12.60 mm ± 0.1 mm
6	THICKNESS	4.47 mm	4.50 mm ± 0.2 mm
7	DISINTEGRATION TIME	3 Min. 50 Sec. In : Water Medium at 37°c	NMT 30 Min.
8	ASSAY	103.8 %	Each Film Coated Tablet Contains: Tadalafil 40 mg [Limit :90 % to 110 %]

DELTA ENTERPRISES Mumbai. India Manufacturers & Exporters of Pharmaceuticals

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.

Analysed By

PRA
QC CHEMIST

Approved By

KRISHNA PANCHAL
Q.C IN CHARGE

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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	: TADADEL FM			A.R. No.	: F/469/12
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL 20MG TABLETS			Rel. Dt.	: 14-07-2012
				T.R. Slip No.	: CBPTP12480
Product Code	: TADA36	Mfg. Dt.	: JUN-2012	T.R. Slip Dt.	: 14-07-2012
Batch No.	: T-198001	Exp. Dt.	: NOV-2014	Analysis Date	: 14-07-2012
Actual Batch Size	: 54000 TAB				
Packing Batch Size	: 54000 TAB	Test Packing	: 50 TAB		
Sample Size	: 50 TAB	Mfg. Lic No.	: G/1325		
Released Qty	: 54000 TAB	Test As Per	: IN HOUSE		
Remarks : pass				Location	: GORWA01
				Make	: CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A Pink coloured, drop shaped,biconvex, engraved "20" on one side & "T" on other side,film coated tablet.	A Pink coloured, drop shaped,biconvex, engraved "20" on one side & "T" on other side,film coated tablet.
2	IDENTIFICATION	Complies	Must Complies as per IHS
3	THICKNESS	3.86 mm	4.00 mm ± 0.2 mm
4	HEIGHT	12.57mm	12.50 mm ± 0.2 mm
5	DISINTEGRATION TIME	4'34" Minutes in Water : Medium at 37°c	NMT 30 MIN
6	AVERAGE WEIGHT (TABLETS)	305.1mg	312.90 mg ± 5 %
7	UNIFORMITY OF WEIGHT	Complies	Complies within ± 5 %
8	ASSAY	103.6%	Each Film Coated Tablet contains : Tadalafil 20 MG [LIMIT : 90% TO 110%]

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai. India

Conclusion : The above sample complies as per IN HOUSE

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.

Analysed By

JSP
QC CHEMIST

Approved By

KRISHNA PANCHAL
Q.C IN-CHARGE

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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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.**

DELTA ENTERPRISES Manufacturers & Exporters of Pharmaceuticals Mumbai, India

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,
Tel & Fax: +91-22-22875727 **Tel. No:** +91-22-66517498 **Website:** deltaenterprises.org **Email:** deltaenterprises@cryptoheaven.

DELTA ENTERPRISES

Manufacturers & Exporters of Pharmaceuticals

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CERTIFICATE OF ANALYSIS

Name of product	: Tadadel-20		
Generic Name	: Tadalafil Softgel Capsules		
Manufactured for	: Delta Enterprises	A.R. No.	: FD-0166/02-12
Batch No.	: 0290312 D	Mfg. Date	: Mar. 2012
Batch Size	: 1,00,000 Capsules	Exp. Date	: FEB. 2014
Sample Quantity	: 100 Capsules	Date of Sampling	: 05th Mar. 2012
Reference STP No.	: EP/STP/FP/478/00	Date of Analysis	: 05th Mar. 2012

Sr. No.	Tests	Specifications	Observation
01.	Description	Yellow coloured oval shaped soft gelatin capsule filled with yellow coloured medicament.	Yellow coloured oval shaped soft gelatin capsule filled with yellow coloured medicament.
02.	Average weight	0.400 g ± 10.0%	0.403 g
03.	Average filled weight	0.230 g ± 10.0%	0.243 g
04.	Uniformity of weight	±10.0% of actual average weight	- 4.93 to + 4.93%
05.	Loss on drying	Between 6.0% & 13.0%	8.38 %
06.	Disintegration time	Not more than 60 minutes	07 to 08 minutes
07.	Identification		
	Tadalafil	To Comply	Complies
08.	Assay		
	Tadalafil Claim: 20.0 mg/Capsule	18.0 mg/cap to 22.0 mg/cap (90.0% to 110.0% of labeled amount)	19.68 mg/cap 98.40%

DELTA ENTERPRISES Mumbai, India Manufacturers & Exporters of Pharmaceuticals

Remarks: The above sample Complies / ~~Does not~~ comply to the prescribed standards of quality in respect of the above tests as per finished product Specification No. EP/SPC/FP/478/00

Analysed By:	Checked By:	Approved By:
05th Mar. 2012	05th mar-2012	05th Mar. 2012
Signature / Date	Signature / Date	Signature / Date

ESTD : 1985

PARALAB (P) LTD.

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ANALYTICAL TESTING OF PHARMACEUTICALS, COSMETICS, FOODS, AYURVEDIC, PESTICIDES, VARIOUS CHEMICALS AND EFFLUENT.

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Lab. Tel.: 022-6525 7704 / 2873 0804 Telefax : 022-2874 2719 H. O. Tel.: 022-2208 3494 / 3453 Mob.: 9819783494 Email : paralab_2005@yahoo.com • Web.: www.paralab.in

Form-39

(Rule 150(f) of Drugs and Cosmetics Act - 1945)

Report of test Analysis by F.D.A. Approved Institution

Certificate of Analysis

ORIGINAL COPY

ANALYSIS REPORT NUMBER	ANALYSIS REPORT DATE
2010/034/01	23/01/2010

1. Party's Name & Address (From Whom Sample is Received)	Name of the manufacturer/supplier from whom R.M. is received by the party.	F.D.A. Mfg. / RPC Lic. No.
DELTA ENTERPRISES SH9, MEZZANINE FLOOR, RAMJI NANJI PLOT 25 ST, MARY'S RD, NEAR MAZGAON COURT MUMBAI-400 010	NS	MH/DRU GS/KD-19

2. Reference Number and Date of the letter from the Manufacturer / Party under which the sample was forwarded. (Submitted Sample Drawn by the party, And not drawn by **Paralab.**)	3. Date of receipt of the sample	Quantity of the sample received
NIL DT 04/01/2010	04/01/2010	NS

4. Name of Drugs/Cosmetics/Raw Material/Finished Product purporating to be obtained in the submitted sample or technical name of raw Material / Finished Product Formulation. TAB.TADALAFIL 20MG

5. Details of Raw Material/Final product (in bulk) final product (in finished pack) as received from the Manufacturer. (AS UNDER)

A Original Manufacturer's name (in case of Raw Material)	B Batch No./Lot No. of the sample	C Batch size as represented by the sample	D Date of Mfg. of the sample	E Date of expiry / Use befo of the sample
AURA CHEM	TD-496	NS	NS	NS

ANALYSIS REQUIRED BY THE PARTY: COMPLETE

Result of test Analysis with protocol of test or Analysis applied As per facilities available with us. As per specification

1. Description	: Yellow coloured elongated oval shaped biconvex film Coated tablets embossed with mark E20 on one Side of each tablet.			
2. Average weight of tablet	: 0.3560gm			
3. Identification	: Test passes by HPLC			
4. Uniformity of weight	: Test passes	(Limit ± 5%)		
5. Disintegration time	: 12 min	(Limit NMT 30min)		
6. Assay		Ea	La	%La
Each film coated tablet Contains Tadalafil (by HPLC)	:	19.02mg	20 mg	95.1%
		(Limit 90% to 110%)		

Rv

OUR FDA (MAHARASHTRA APPROVAL NO. : TL/35 RENEWED AND VALID UPTO DATE.

1

OPINION: In the Opinion of the undersigned, the sample refered to be above is of STANDARD Quality as defined in the Act and the rules made thereunder for the reason given below.
The Sample complies with prescribed standard As per specification

PARALAB (P) LTD. MUMBAI-63

(Signature of the Person in -charg

1. The opinion on the above noted unsealed sample received only to the test carried out and applied at our end. 2. The legal liabilities are limited up to the analytical charges only. 3. The results listed refers only to the sample submitted to us and tested as per the facilities available with us Endorsement of the product each neither inferred nor implied. 4. You are advised to retain the courier sample/represented sample at your end till its expiry for the product submitted by you for Analysis purpose for any further references. 5. Containts of the report is for your guidence only this report is not to be reproduce wholly or in the part. It cannot be used as an evidence in any court of law and should not be used in adversiting media without our specific permission in writing. 6. Not negotiable. 7. Incase you notice any discrepancies in the above report, please draw our attention for doing the needful. 8. The balance remained quantity of the above tested sample will be destroyed after 30 days from the date of testing unless otherwise specially instructed in writing. 9. Any Alteration on the face of this report will render this report invalid and in no way our lab will be responsible for the same. 10. Identity and particulars of the unsealed samples are as supplied by the party 13. All report issued in form 39/41 will be subject to the condition that you HOLD VALID licences issued by FDA. 13. The Tested sample of standard quality

D.R. JOHN'S LAB (P) LTD.

Mfg.Licence No. : 113/UA/2007/25&118/UA/SC/P/2007&BB/261

QUALITY CONTROL DEPARTMENT

(FINISH)

Sample : SILDIGRA CAPS
Mfg. & Supplied By : D.R. JOHN'S LAB (P) LTD.
Batch No. : SSRA-006
Batch Size : 200000 CAPS
Mfg.Dt.: Sep.,2009
Sample Qty.: 50CAPS (290MG/CAP)
Report No.: FS-185A091
Ref. No. : SR-0351
Rcpt.Date : 06-09-2009
Expiry Dt.: Aug.,2011

CERTIFICATE OF ANALYSIS

Description : Blue colour soft gelatin capsule containing offwhite colour paste

Avg weight : 0.4015gm

Avg. weight of empty : 0.1202gm

Avg. Fill : 0.2813gm

DISINTEGRATION : 14mins (lt. NMT-60 min)

Assay

Each soft geletin capsule contains

Ingredients	Claim	Obtained	Limit
Sildenafil Citrate	100mg	100.8mg	NLT-90mg

Report : In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the act and the Rules made there under.I.H.

Date: 06-09-2009 Analysed By:

*** End of Report ***

Testing Incharge:

ESTD : 1985

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ANALYTICAL TESTING OF PHARMACEUTICALS, COSMETICS, FOODS, AYURVEDIC, PESTICIDES, VARIOUS CHEMICALS AND EFFLUENT.

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Lab. Tel.: 022-2873 0804 Telefax : 022-2874 2719 H. O. Tel.: 022-2208 3494 / 3453 Mob.: 9819783494 Email : paralab_2005@yahoo.com

Form-39

(Rule 150(f) of Drugs and Cosmetics Act - 1945)

Report of test Analysis by F.D.A. Approved Institution

Certificate of Analysis

ORIGINAL COPY

ANALYSIS REPORT NUMBER	ANALYSIS REPORT DATE
2010/032/01	06/01/2010

1. Party's Name & Address (From Whom Sample is Received)	Name of the manufacturer/supplier from whom R.M. is received by the party.	F.D.A. Mfg. / RPG Lic. No.
DELTA ENTERPRISES SH9, MEZZANINE FLOOR, RAMJI NANJI PLOT 25 ST, MARY'S RD, NEAR MAZGAON COURT MUMBAI-400 010	NS	10/UA/2004

2. Reference Number and Date of the letter from the Manufacturer / Party under which the sample was forwarded. (Submitted Sample Drawn by the party, And not drawn by **Paralab.**)	3. Date of receipt of the sample	Quantity of the sample received
NIL DT 04/01/2010	04/01/2010	NS

4. Name of Drugs/Cosmetics/Raw Material/Finished Product purporating to be obtained in the submitted sample or technical name of raw Material / Finished Product Formulation. TAB.SILDENAFIL 100MG

5. Details of Raw Material/Final product (in bulk) final product (in finished pack) as received from the Manufacturer. (AS UNDER)

A Original Manufacturer's name (in case of Raw Material)	B Batch No./Lot No. of the sample	C Batch size as represented by the sample	D Date of Mfg. of the sample	E Date of expiry / Use before of the sample
AKUMS DRUGS	QRAA02	NS	NS	NS

ANALYSIS REQUIRED BY THE PARTY: COMPLETE

Result of test Analysis with protocol of test or Analysis applied
As per facilities available with us.

As per specification

1. Description : Blue coloured tetragonal biconvex film coated Tablets with a break line on one side of each tablets
2. Average weight of tablet : 0.4815 gm
3. Identification : Test passes by HPLC
4. Uniformity of weight : Test passes (Limit ± 5%)
5. Disintegration time : 13min (Limit NMT 30min)
6. Assay

Each film coated tablet	:	Ea	La	%La
Contains				
Sildenafil citrate	:	96.17mg	100 mg	96.17%
Equivalent to sildenafil (by HPLC)			(Limit 90% to 110%)	

As per partys specific instruction we have carried out the above noted tests.

OUR FDA (MAHARASHTRA APPROVAL NO. : TL/35 RENEWED AND VALID UPTO DATE.

OPINION: In the Opinion of the undersigned, the sample refered to be above is of STANDARD Quality as defined in the Act and the rules made thereunder for the reason given below.
The Sample complies with prescribed standard As per specification

PARALAB (P) LTD. MUMBAI-63

(Signature of the Person-in -charge of testi

ESTD : 1985

PARALAB (P) LTD.

ISO 9001:2000 CERTIFIED

ANALYTICAL TESTING OF PHARMACEUTICALS, COSMETICS, FOODS, AYURVEDIC, PESTICIDES, VARIOUS CHEMICALS AND EFFLUENT.
202, 203 & 307, Triumph House, Near Patel Aluminium, Off Western Express Highway, Goregaon (East), Mumbai - 400 063. INDIA
Lab. Tel.: 022-2873 0804 Telefax : 022-2874 2719 H. O. Tel.: 022-2208 3494 / 3453 Mob.: 9819783494 Email : paralab_2005@yahoo.com

Form-39
(Rule 150(f) of Drugs and Cosmetics Act - 1945)
Report of test Analysis by F.D.A. Approved Institution

Certificate of Analysis

ORIGINAL COPY

ANALYSIS REPORT NUMBER	ANALYSIS REPORT DATE
2010/031/01	06/01/2010

1. Party's Name & Address (From Whom Sample is Received)	Name of the manufacturer/supplier from whom R.M. is received by the party.	F.D.A. Mfg. / RPG Lic. No.
DELTA ENTERPRISES SH9, MEZZANINE FLOOR, RAMJI NANJI PLOT 25 ST, MARY'S RD, NEAR MAZGAON COURT MUMBAI-400 010	NS	10/UA/2004

2. Reference Number and Date of the letter from the Manufacturer / Party under which the sample was forwarded. (Submitted Sample Drawn by the party, And not drawn by **Paralab.**)	3. Date of receipt of the sample	Quantity of the sample received
NIL DT 04/01/2010	04/01/2010	NS

4. Name of Drugs/Cosmetics/Raw Material/Finished Product purporating to be obtained in the submitted sample or technical name of raw Material / Finished Product Formulation. TAB. SILDENAFIL 50MG

5. Details of Raw Material/Final product (in bulk) final product (in finished pack) as received from the Manufacturer. (AS UNDER)

A Original Manufacturer's name (in case of Raw Material)	B Batch No./Lot No. of the sample	C Batch size as represented by the sample	D Date of Mfg. of the sample	E Date of expiry / Use before of the sample
AKUMS DRUGS	QRAC01	NS	NS	NS

ANALYSIS REQUIRED BY THE PARTY: COMPLETE

Result of test Analysis with protocol of test or Analysis applied As per facilities available with us.

As per specification

1. Description : Blue coloured tetragonal biconvex film coated tablets with a break line on one side of each tablets
2. Average weight of a tablet : 0.3310 gm
3. Identification : Test passes by HPLC
4. Uniformity of weight : Test passes (Limit ± 5%)
5. Disintegration time : 14min (Limit NMT 30min)
6. Assay : EA LA % LA

Each film coated tablet contains

Sildenafil citrate	: 47.47mg	50 mg	94.94%
Equivalent to sildenafil (by HPLC)		(Limit 90% to 110%)	

As per partys specific instruction we have carried out the above noted tests

OUR FDA (MAHARASHTRA APPROVAL NO. : TL/35 RENEWED AND VALID UPTO DATE.

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OPINION: In the Opinion of the undersigned, the sample refered to be above is of STANDARD Quality as defined in the Act and the rules made thereunder for the reason given below.
The Sample complies with prescribed standard As per specification

(Signature of the Person-in-charge of te