

Manufacturers & Exporters of Pharmaceuticals www.deltaenterprises.org

QUALITY CONTROL DEPARTMENT

: JUL-2012

: DEC-2014

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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

Packing : 10x10 TAB

Generic Name : TADALAFIL 40MG TABLETS

Product Code Batch No. : T-134002

Actual Batch Size : 54000 TAB

Packing Batch Size: 54000 TAB

Sample Size : 50 TAB Released Qty Remarks : pass

: TADA24

Exp. Dt.

.Test Packing : 50 TAB Mfg. Lic No. : G/1325 Test As Per : IH

Mfg. Dt.

: 54000 TAB

A.R. No. : F/527-A/12

Rel. Dt. : 03-08-2012

T.R. Slip No. : CBPTP12549 T.R. Slip Dt. : 03-08-2012

: 03-08-2012 Analysis Date

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: Tadelafil 40 mg [Limit :90 % to 110 %]
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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

KRISHNA PANCHAL O.C.IN CHARGE

Approved By