



Manufacturers & Exporters of Pharmaceuticals
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QUALITY CONTROL DEPARTMENT

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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 TABLETS	A.R. No.	: F/998/12
Packing	: 10x10 TAB	Rel. Dt.	: 22-12-2012
Generic Name	: TADALAFIL TABLETS 60MG	T.R. Slip No.	: CBPTP13038
Product Code	: TADA20	T.R. Slip Dt.	: 21-12-2012
Batch No.	: T-071002	Analysis Date	: 22-12-2012
Actual Batch Size	: 54000 TAB		
Packing Batch Size	: 54000 TAB	Location	: GORWA01
Sample Size	: 50 TAB	Make	: CENTURION.
Released Qty	: 54000 TAB		
Remarks	: pass		
Mfg. Dt.	: DEC-2012		
Exp. Dt.	: MAY-2015		
Test Packing	: FINISH		
Mfg. Lic No.	: G/1325		
Test As Per	: IH		

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A yellow coloured, oval shaped, Biconvex Film Coated tablet.	A yellow coloured, oval shaped, Biconvex Film Coated tablet.
2	IDENTIFICATION BY HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3	AVERAGE WEIGHT OF 20 TABLETS	330.2mg	329.60 mg \pm 5 %
4	UNIFORMITY OF WEIGHT	L.L = -2.99% U.L = +1.69%	Complies Within \pm 5 %
5	HEIGHT	12.55 mm	12.60 mm \pm 0.1 mm
6	THICKNESS	4.35 mm	4.30 mm \pm 0.2 mm
7	DISINTEGRATION TIME	8 Min. 34 Sec. in : Water Medium at 37°C	NMT 30 Min.
8	ASSAY	98.6 %	Each Film Coated Tablet Contains: Tadalafil 60 mg [Limit : 90 % to 110 %]



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