



Manufacturers & Exporters of Pharmaceuticals  
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QUALITY CONTROL DEPARTMENT

Page 1 of 1

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

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : DELGRA 200	A.R. No. : F/841/12
Packing : 10x10 TAB	Rel. Dt. : 01-11-2012
Generic Name : SILDENAFIL CITRATE TABLETS	T.R. Slip No. : CBPTP12834
Product Code : DELG05	T.R. Slip Dt. : 30-10-2012
Batch No. : T-229002	Analysis Date : 01-11-2012
Actual Batch Size : 54000 TAB	
Packing Batch Size : 54000 TAB	
Sample Size : 100 TAB	
Released Qty : 54000 TAB	
Remarks : pass	
Mfg. Dt. : OCT-2012	Location : GORWA01
Exp. Dt. : MAR-2015	Make : CENTURION
Test Packing : FINISH	
Mfg. Lic No. : G/25/1325	
Test As Per : IH	

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A blue coloured, diamond shaped, biconvex, film coated tablets plain on both side.	A blue coloured, diamond shaped, biconvex, film coated tablets plain on both side.
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	531.49 mg	527.870 mg ± 5 %
4	UNIFORMITY OF WEIGHT	U.L: 0.30% L.L: -0.24%	Complies Within ± 5 %
5	THICKNESS	5.02 mm	5.00 mm ± 0.2 mm
6	HEIGHT	14.65 mm	14.60 mm ± 0.1 mm
7	DJSINTEGRATION TIME	12' 20" Sec. in Water Medium at 37°C	NMT 30 Min.
8	ASSAY	102.53 %	Each Film Coated Tablet Contains: Sildenafil Citrate Eq. to Sildenafil 200 mg [Limit :90.00 % to 110.00 %]
9	DISSOLUTION	81.32%	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.

Analysed By  VAISHAV PATEL QC CHEMIST	Approved By  KRISHNA PANCHAL Q.C IN CHARGE
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