



Manufacturers & Exporters of Pharmaceuticals
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**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

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

Name :	DELGRA-50		
Generic Name :	Sildenafil Citrate Tablets		
Reg. No. :	10/UA/2004		
Formulation :	QRAL02	A. R. No. :	F2012020921
Mfg. Date :	Jan.2012	Pack Size :	1x10TAB
Exp. Date :	Dec.2014	Pack Type :	Tablets
Batch Size :	100000 TAB	Sampled On :	09/02/2012
Product Code :	AQRAL	Sample Quantity :	80.00 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	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%



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

Prepared By (Sign / Date) *[Signature]* 11/02/12

Checked By (Sign / Date) *[Signature]* 11/02/12
QC Executive

Approved By (Sign / Date) *[Signature]* 11/02/12
Head QC