



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/cm ²	3.30kg/cm ²
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.



Q.A. APPROVED
SIGN. *[Signature]* DATE: 28/10/11

Prepared By
(Sign / Date)
[Signature]
28/10/11

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

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