



Manufacturers & Exporters of Pharmaceuticals

www.deltaenterprises.org

**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

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

<b>Product Name :</b>	TADADEL 20 mg		
<b>Generic Name :</b>	Tadalafil Tablets		
<b>Mfg. Lic. No. :</b>	10/UA/2004		
<b>Batch No. :</b>	QRAN04	<b>A. R. No. :</b>	F2012042201
<b>Mfg. Date :</b>	Apr.2012	<b>Pack Size :</b>	1x10TAB
<b>Exp. Date :</b>	Mar.2015	<b>Pack Type :</b>	Tablets
<b>Batch Size :</b>	400000 TAB	<b>Sampled On :</b>	22/04/2012
<b>Product Code :</b>	40009113	<b>Sample Quantity :</b>	60.00 TAB
<b>Specification No. :</b>	STS/FP/40009113-00	<b>Sampled By :</b>	RAJVEER
<b>Ref. STP No. :</b>	STP/FP/40009113-00	<b>Analyzed By :</b>	AVDHESH
<b>Manufactured For :</b>	DELTA ENTERPRISES	<b>Date of Analysis :</b>	27/04/12
<b>Manufactured By :</b>	AKUMS	<b>Release Date :</b>	30/04/12

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Yellow coloured, Drop shaped & T 20 embossed on upper side of each film coated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.	Yellow coloured, Drop shaped & T 20 embossed on upper side of each film coated tablet. 10 tablets packed in a blister of clear PVC film & printed aluminium foil.
2	Identification	Positive for Tadalafil	Complies
3	Dimension	As below	As below
	Length	12.1 mm ± 0.2 mm	12.27mm
	Width	7.5 mm ± 0.3 mm	7.62mm
	Thickness	4.3 mm ± 0.4 mm	4.15mm
4	Average weight	308.0 mg ± 5.0%	312.95mg
5	Uniformity of weight	Within ± 5.0% of Average Weight	-1.9% to +1.9%
6	Disintegration Time	Not more than 30 Minutes	Passes(04min36sec)
7	Uniformity of Content	85% to 115% of average value	94.48% to 103.1%
8	Colour Identification	Positive for Yellow Oxide of Iron & Titanium Dioxide BP	Complies
9	Assay - Each film coated tablet contains.	Release	Found/Tab.
		Shelf Life	Stated/Tab.



**Q.A. APPROVED**  
**SIGN..... DATE: 30/05/12**

Prepared By  
(Sign / Date) *[Signature]*  
30/04/12

Checked By  
QC Executive  
(Sign / Date) *[Signature]*  
30/04/12

Approved By  
Head QC  
(Sign / Date) *[Signature]*  
30/04/12