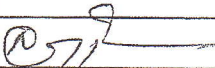


**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

Product	Tadalafil Ph.Eur.		
Batch No.	1504000722	A.R. No.	40000059335
Mfg. Date	JUN-2015	Retest Date	MAY-2018
Batch Size	44.60 Kg.	Date of Analysis	10/06/2015

Sr. No.	TESTS	RESULTS	SPECIFICATIONS
01	Appearance	White powder	White or almost white powder
02	Solubility	Complies	Practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride
03	Identification By A Infrared Absorption Spectrometry B HPLC	Complies Complies	Absorption spectrum of the test sample should be concordant with the absorption spectrum of Tadalafil Reference standard/Working standard The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a) in the test of impurities - A, B and C (By HPLC)
04	Impurities-A, B and C (By HPLC) Impurity A Any individual unspecified impurity	Not detected Not detected	Not more than 0.15 % w/w Not more than 0.10 % w/w
05	Related substances (By HPLC) Any individual unspecified impurity Total impurities	Below Disregard Limit Below Disregard Limit	Not more than 0.10 % w/w Not more than 0.30 % w/w
06	Loss on drying	0.22 % w/w	Maximum 0.50 % w/w

COA Date:		Prepared By	Checked By	Approved By
10/06/2015	Sign.	D.G. Thacker		BGG
	Date	10/06/2015	10/06/2015	10/06/2015
	Name	Dharini Thacker	Rajesh Gujjar	Bhavin Gandhi
	Designation	Executive-QC	Asst. Manager-QC	Asst. Manager-QC

Page : 1 of 2

**ALEMBIC PHARMACEUTICALS LIMITED
API UNIT-III, KARAKHADI**

CIN L24230GJ2010PLC061123

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550 • FAX : (0265) 2284729

Website : www.alembic-india.com • E-mail : alembic@alembic.co.in

FACTORY : SURVEY NO. 842,843, VILL. KARAKHADI, TAL. PADRA, DIST. VADODARA-391 450 • TEL.:02662-300700, 300701 • FAX : 02662-300732
E-mail : karakhadi.api@alembic.co.in

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product	Tadalafil Ph.Eur.		
Batch No.	1504000722	A.R. No.	40000059335
Mfg. Date	JUN-2015	Retest Date	MAY-2018
Batch Size	44.60 Kg.	Date of Analysis	10/06/2015

Sr. No.	TESTS	RESULTS	SPECIFICATIONS
07	Sulphated Ash	0.05 % w/w	Maximum 0.10 % w/w
08	Assay (by HPLC)	99.9 % w/w	97.5 % w/w to 102.0 % w/w (dried substance)
09	Heavy Metals	Less than 10 ppm	Not more than 10 ppm
10	Residual Solvents (By GC) Methanol Methylene chloride 2-Propanol	BQL (LOQ 41.8 ppm) 41 ppm 385 ppm	Not more than 3000 ppm Not more than 600 ppm Not more than 5000 ppm
11	Particle Size by Malvern D (10) D (50) D (90)	2.9 µm 12.9 µm 52.0 µm	Not more than 10 µm Not more than 35 µm Between 50 µm and 65 µm

Remarks: Batch complies with respect to customer specification.

BQL: Below Quantification Limit, LOQ: Limit of Quantification.

Disregard Limit: 0.05 % w/w

Storage Condition : Store in tightly closed container at 20-25°C.

COA Date:		Prepared By	Checked By	Approved By
10/06/2015	Sign.	D.G. Thacker		B885
	Date	10/06/2015	10/06/2015	10/06/2015
	Name	Dharini Thacker	Rajesh Gujjar	Bhavin Gandhi
	Designation	Executive-QC	Asst. Manager-QC	Asst. Manager-QC

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