



RAKSHIT PHARMACEUTICALS LIMITED
Plot No 68/A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India-
531021

CERTIFICATE OF ANALYSIS

Product Name	TADALAFIL Ph.Eur		
Batch Number	TF/09/19/002	A. R. No.	AR/FP/TF/19/0002
Mfg. Date	SEP - 2019	Retest / Expiry Date	AUG-2024
Dispatch Qty.	5.00 Kg	Ref STP No.	STP/FP/TF/001/00
Customer Name	G-RISH PHARMA.		
CEP No.	RO-CEP2016-317-Rev00		

S. No.	Test	Specification	Result
1.	Description	White or almost white powder	White powder
2.	Solubility	Freely soluble in dimethyl sulfoxide, Slightly soluble in dichloromethane and practically insoluble in water.	Complies
3.	Identification		
	A) By IR	The IR absorption spectrum of sample should conform to the spectrum of standard	Complies
	B) By HPLC	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	Complies
4.	Loss on drying (%w/w)	Not more than 0.5	0.36
5.	Sulphated ash (%w/w)	Not more than 0.10	0.06
6.	Impurities A,B and C by HPLC (%)		
	Impurity A ^a	Not more than 0.15	Not detected
	Unspecified Impurity(for each impurity)	Not more than 0.10	Not detected
7.	Related substances by HPLC (%)		
	Unspecified Impurity(for each impurity)	Not more than 0.10	Not detected
	Total impurities	Not more than 0.3	Not detected
8.	Assay by HPLC (on dried basis)(%w/w)	Not less than 97.5 and Not more than 102.0	99.7
9.	Residual Solvents by HSGC		
	Methanol	Not more than 3000 ppm	Not detected
	2-Propanol	Not more than 5000 ppm	Not detected
	Dimethyl Formamide	Not more than 880 ppm	Not detected
	Dichloromethane	Not more than 600 ppm	Not detected

REMARKS: The product conforms as per above specifications.

Storage condition: Preserve in well closed containers, store at room temperature.

	Prepared By	Reviewed By	Approved By
Department	Quality Assurance	Quality Assurance	Quality Assurance
Sign & Date	V. S. 25/08/2020	25/08/2020	25/08/2020