

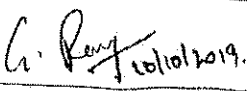
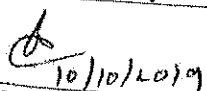
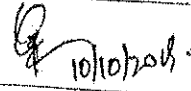
CERTIFICATE OF ANALYSIS

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Name of the Product : Tadalafil Ph. Eur. (Product No.: 0110201901)	Date of Analysis : 28/08/2019
Batch No : TDL/0819019	A.R. No. : FP/19/0109
Dispatch Quantity : 5.0 Kgs	Mfg. Quantity : 56.20 Kg
Mfg. Date : August, 2019	Expiry Date : July, 2024

S. No.	Test parameter	Specification	Results
6.	Impurities A, B and C by HPLC (%)		
	Impurity A	Not more than 0.15	0.01
	Unspecified impurity	Not more than 0.10	
7.	Related substances by HPLC (%)		Not Detected
	TDL-III content	Not more than 0.10	Not Detected
	Unspecified impurity	Not more than 0.10	
	Total impurities	Not more than 0.3	BDL
8.	Loss on drying Under vacuum at 105°C for 3 hours (% w/w)	Not more than 0.5	BDL
9.	Sulphated ash (% w/w)	Not more than 0.1	0.26
10.	Assay by HPLC (On dried substance) (% w/w)	Not less than 97.5 and Not more than 102.0	0.04
11.	Residual solvents by GC (ppm)		99.8
	Method-I		
	Methanol	Not more than 3000	Not Detected
	Acetone	Not more than 5000	
	Isopropyl alcohol	Not more than 5000	278
	Methylene chloride	Not more than 600	Not Detected
	Method-II		Not Detected
	Triethylamine	Not more than 320	Not Detected

Conclusion: - The product conforms the Ph.Eur. Specifications.

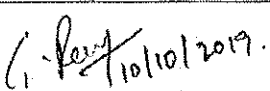
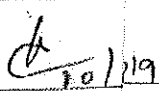
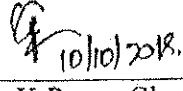
Sign & Date	Prepared by	Reviewed by	Approved by
	 G. Rama Krishna Tr.Chemist - QA	 K. Bhaskara Rao Sr. Manager - QC	 K. Pavan Chand Asst. Manager - QA

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Dispatch Quantity : 5.0 Kgs	Mfg. Quantity : 56.20 Kg
Mfg. Date : August 2019	Expiry Date : July, 2024

S. No.	Test parameter	Specification	Result
1.	Appearance	White or almost white powder.	White powder
2.	Solubility	Practically insoluble in water, Freely soluble in dimethyl -sulfoxide, and Slightly soluble in Methylene chloride.	Practically insoluble in water, Freely soluble in dimethyl -sulfoxide, and Slightly soluble in Methylene chloride.
3.	Identification by IR	The infrared absorption spectrum of the potassium bromide dispersion of the sample preparation should be exhibit maxima only at the same wave numbers as that of a similar preparation of Tadalafil working standard/Reference standard.	The infrared absorption spectrum of the potassium bromide dispersion of the sample preparation is exhibit maxima only at the same wave numbers as that of a similar preparation of Tadalafil working standard
4.	Identification by HPLC	The principal peak in the chromatogram obtained with the test solution should be similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).	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).
5.	Specific optical rotation $[\alpha]^{20}_D$ (dried substance)	+ 78.0 to + 84.0	+82.0

	Prepared by	Reviewed	Approved by
Sign & Date	 10/10/2019.	 10/10/19	 10/10/2019.
Name	G. Rama Krishna	K. Bhaskar	K. Pavan Chand
Designation	Tr.Chemist – QA	Sr.ManagQC	Asst.Manager – QA