

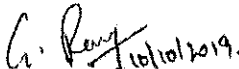
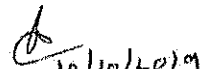
CERTIFICATE OF ANALYSIS

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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	Not Detected
7.	Related substances by HPLC (%)		
	TDL-III content	Not more than 0.10	Not Detected
	Unspecified impurity	Not more than 0.10	BDL
	Total impurities	Not more than 0.3	BDL
8.	Loss on drying Under vacuum at 105°C for 3hours (% , w/w)	Not more than 0.5	0.26
9.	Sulphated ash (% , w/w)	Not more than 0.1	0.04
10.	Assay by HPLC (On dried substance) (% , w/w)	Not less than 97.5 and Not more than 102.0	99.8
11.	Residual solvents by GC (ppm)		
	Method-I		
	Methanol	Not more than 3000	Not Detected
	Acetone	Not more than 5000	278
	Isopropyl alcohol	Not more than 5000	Not Detected
	Methylene chloride	Not more than 600	Not Detected
	Method-II		
	Triethylamine	Not more than 320	Not Detected

Conclusion: - The product confirms to the **Ph.Eur.** Specifications.

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

