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Shilpa Therapeutics Pvt. Ltd.

(Formerly known as NU Therapeutics Pvt. Ltd.)

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CIN No. : U24239TG2004PTC043005

Certificate of Analysis

Product Name: Tastytia (Tadalafil orally disintegrating strips 20 mg)

Batch No.: TD20D00217

Received on: 29.05.2017

Batch Size: 1,50,000 strips

Date of analysis: 29.05.2017

Mfg. Date : 04/ 2017

Release Date: 30.05.2017

Expiry Date: 03/ 2020

AR No.: QC/AR/FP/119/17

Sample quantity: 120 strips

Reference STP No (IH): STPL/QC/FP/008

S.No.	Tests	Specification	Result
1.	Description	Pink colored strips	Pink colored strips
2.	Identification by HPLC	Retention time of major peak of sample shall comply with standard	Retention time of major peak of sample complies with the standard
3.	Strip Average Weight & Weight Variation	78 mg \pm 10%	79.7mg (-3.5% to 2.4%)
4.	Moisture content(%w/w)	NMT 10.0%	2.4%
5.	Disintegration time	NMT 30 seconds	8 seconds
6.	Dissolution	NLT 40% of the labeled amount of Tadalafil is dissolved in 10 minutes and NLT 80% of the labeled amount of Tadalafil is dissolved in 30 minutes	100.6% in 10 minutes 102.0% in 30 minutes
7.	Impurities i) Individual unknown impurity ii) Total impurities	NMT 0.2% NMT 0.3%	0.05% 0.05%
8.	Assay Each orally disintegrating strip contains Tadalafil	NLT 90 % and NMT 110% of the labeled amount of Tadalafil	101.9% (20.38mg)

Remarks: The product complies with the above specifications.

Analysed by:

Approved by:

Verified by:

Date : 30.05.2017

Date : 30.05.2017

Date : 30.05.2017