

## CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	SUPER TADALIS SX (Tadalafil 20 mg and Dapoxetine 60 mg Tablets)		
PRODUCT CODE	5000550	INSPECTION LOT NO.	40000102325
BATCH NO.	CT11132	BATCH SIZE	25000 BL
MFG. DATE	10.2022	EXP. DATE	09.2024
SAMPLED BY	Abhijit Korde	SAMPLING DATE	07.11.2022
SAMPLED QTY.	30 BL	RELEASED DATE	23.11.2022
PROCESS ORDER NO.	10080607	PACK SIZE	1X4's

**Note : [a] for Abbreviations. Detail provided in Abbreviation section.**

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	<b>Description</b>	Buff yellow to dark yellow coloured, triangular shaped, film coated tablets, plain on both sides.	Buff yellow coloured, triangular shaped, film coated tablets, plain on both sides. Complies
2.0	<b>Identification</b>		
2.1	<b>Tadalafil</b>	The retention time of one of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil in the chromatogram of the standard preparation, as obtained in the assay.	The retention time of one of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
2.2	<b>Dapoxetine</b>	The retention time of one of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Dapoxetine in the chromatogram of the standard preparation, as obtained in the assay.	The retention time of one of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Dapoxetine in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	<b>Average weight</b>	400.0 mg $\pm$ 5.0% (380.000 mg to 420.000 mg)	396.520 mg
4.0	<b>Uniformity of weight</b>	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 5% and none deviates by more than $\pm$ 10%.	Min. = 391.1 mg Max. = 404.2 mg Avg. = 397.1 mg Complies
5.0	<b>Disintegration time</b>	Not more than 30 minutes.	03 min. 58 sec. Complies
6.0	<b>Dissolution</b>		
6.1	<b>Tadalafil</b>	Not less than 70% of the labeled amount released in 45 minutes.	Individual Value 101.300 100.500 99.800

**Remark: A - Release (Country: India/West Asia)**

**Comment:** The sample submitted Complies with the prescribed Finished product specification FPS/W/20-21/0131 Ver.00

<b>Analysed By</b>	Vandana Ahire	<b>Checked By</b>	Sachin Suryawanshi	<b>Approved By</b>	Chandrakant Patil
<b>Designation</b>	Asst. Executive	<b>Designation</b>	Sr. Executive	<b>Designation</b>	Manager
<b>Date</b>	23.11.2022	<b>Date</b>	23.11.2022	<b>Date</b>	23.11.2022
<b>Printed By :</b>	Prashant Rajhans	<b>Printed On :</b>	23.11.2022 14:10:35	<b>Page No.:</b>	1 of 3

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SR.NO.	TEST	SPECIFICATION	RESULT
			100.800 102.300 101.400 Average- 101.017 Minimum- 99.800 Maximum- 102.300
6.2	Dapoxetine HCl equi to Dapoxetine	Not less than 70% of the labeled amount released in 45 minutes.	86.910 86.910 86.370 89.000 87.710 87.450 Average- 87.392 Minimum- 86.370 Maximum- 89.000
7.0	Uniformity of dosage units		Complies
7.1	Tadalafil (By CU)	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 units & calculate the acceptance value. The acceptance value of the 30 dosage units is less than or equal to L1 and no individual content of any dosage unit is less than $[1-(0.01)(L2)]M$ nor more than $[1+(0.01)(L2)]M$ . L1 is 15.0 & L2 is 25.0.	AV = 1.5 Complies
7.2	Dapoxetine HCl equi to Dapoxetine(By CU)	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 units & calculate the acceptance value. The acceptance value of the 30 dosage	AV = 1.3 Complies

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Designation	Asst. Executive	Designation	Sr. Executive	Designation	Manager
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Printed By : Prashant Rajhans		Printed On : 23.11.2022 14:10:35		Page No.: 2 of 3	
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SR.NO.	TEST	SPECIFICATION	RESULT
		units is less than or equal to L1 and no individual content of any dosage unit is less than [1-(0.01)(L2)]M nor more than [1+(0.01)(L2)]M. L1 is 15.0 & L2 is 25.0.	
<b>8.0</b>	<b>Related substances</b>		
<b>8.1</b>	<b>Single maximum unknown impurity</b>	Not more than 1.0%	0.02 %
<b>8.2</b>	<b>Total impurities [a]</b>	Not more than 2.0%	0.03 %
<b>9.0</b>	<b>Assay</b>		
<b>9.1</b>	<b>Tadalafil</b>	Not less than 90.0% and not more than 110.0% of the labeled claim.	99.650 %
<b>9.2</b>	<b>Dapoxetine HCl equi to Dapoxetine</b>	Not less than 90.0% and not more than 110.0% of the labeled claim.	100.370 %

**Section : [a] Abbreviation**

Total impurities [a]: Total impurities (Sum of all specified and unspecified impurities).

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