ajanta pharma limited

Gut No. 11/12/14/15,
Paithan Road, Chitegaon,
Aurangabad - 431 105
Maharashtra - INDIA

T +91 2431 6650 00
F +91 2431 6650 13
E info@ajantapharma.com
W www.ajantapharma.com

CERTIFICATE OF ANALYSIS -FINISHED PRODUCT

NAME OF THE SAMPLE	SUPER KAMAGRA (Sildenafil 100 mg and Dapoxetine 60 mg Tablets)		
PRODUCT CODE	5000864	INSPECTION LOT NO.	40000091318
BATCH NO.	CT03632	BATCH SIZE	100000 BL
MFG. DATE	04.2022	EXP. DATE	03.2025
SAMPLED BY	Abhijit Korde	SAMPLING DATE	07.05.2022
SAMPLED QTY.	75 BL	RELEASED DATE	22.05.2022
PROCESS ORDER NO.	10071118	PACK SIZE	1X4'S

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

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	Description	Light green to green coloured, triangular shaped, film coated tablets, plain on both sides.	Green coloured, triangular shaped, film coated tablets, plain on both sides. Complies
2.0	Identification		
2.1	Sildenafil Citrate USP		
2.1.1	By HPLC [a]	The retention time of one of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Sildenafil 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 Sildenafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
2.1.2	By TLC	One of the purple spot on white background under UV light at 254 nm, in the chromatogram obtained with test solution is similar in position, size and intensity to that of the purple spot in the chromatogram obtained with Sildenafil Citrate standard solution.	One of the purple spot on white background under UV light at 254 nm, in the chromatogram obtained with test solution is similar in position, size and intensity to that of the purple spot in the chromatogram obtained with Sildenafil Citrate standard solution. Complies
2.2	Dapoxetine Hydrochloride		
2.2.1	By HPLC [a]	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

Remark: A - Release (Country: Iraq)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/W/18-19/0270 Ver. 02

Analysed By	Vandana Ahire	**Checked By**	Sachin Suryawanshi	**Approved By**	Vinod Umrikar
Designation	Asst. Executive	**Designation**	Sr. Executive	**Designation**	Asst. Manager
Date	22.05.2022	**Date**	22.05.2022	**Date**	22.05.2022
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SR.NO.	TEST	SPECIFICATION	RESULT
2.2.2	By TLC	One of the purple spot on white background under UV light at 254 nm, in the chromatogram obtained with test solution is similar in position, size and intensity to that of the purple spot in the chromatogram obtained with Dapoxetine Hydrochloride standard solution.	One of the purple spot on white background under UV light at 254 nm, in the chromatogram obtained with test solution is similar in position, size and intensity to that of the purple spot in the chromatogram obtained with Dapoxetine Hydrochloride standard solution. Complies
2.3	Brilliant Blue FCF	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Brilliant Blue in the chromatogram of the standard preparation.	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Brilliant Blue in the chromatogram of the standard preparation. Complies
2.4	Quinoline Yellow	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Quinoline Yellow in the chromatogram of the standard preparation.	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Quinoline Yellow in the chromatogram of the standard preparation. Complies
2.5	Titanium Dioxide	An orange-red colour appears/develops.	An orange-red colour appears. Complies
3.0	Average weight	410.000 mg ± 5.0% (389.500 mg to 430.500 mg)	410.9700 mg
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than ± 5% and none deviates by more than ± 10%.	Min. = 410.8 mg Max. = 418.2 mg Avg. = 414.9 mg Complies
5.0	Disintegration time	Not more than 15 minutes	03 min. 16 sec. Complies

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SAMPLED QTY.	75 BL	RELEASED DATE	22.05.2022
PROCESS ORDER NO.	10071118	PACK SIZE	1X4'S

SR.NO.	TEST	SPECIFICATION	RESULT
6.0	Water content	Not more than 6.0%	2.06 %
7.0	Dissolution		
7.1	Sildenafil Citrate USP EQV to Sildenafil	Not less than 80%*(Q) of the labeled amount released in 15 minutes.	Individual Value 100.900 97.200 99.000 99.100 100.000 104.200 Average- 100.067 Minimum- 97.200 Maximum- 104.200
7.2	Dapoxetine HCl equi to Dapoxetine	Not less than 70%*(Q) of the labeled amount released in 30 minutes.	99.200 99.600 99.600 98.100 101.800 95.600 Average- 98.983 Minimum- 95.600 Maximum- 101.800
8.0	Uniformity of dosage units (by CU)		
8.1	Sildenafil Citrate USP EQV to Sildenafil	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	AV = 9.82 Complies

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SR.NO.	TEST	SPECIFICATION	RESULT
		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.	
8.2	Dapoxetine HCl EQV to Dapoxetine [a]	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 = 11.14 Complies
9.0	Related substances		
9.1	Sildenafil related compound A	Not more than 0.3%	BLOQ 0.0210 %
9.2	Sildenafil N-Oxide	Not more than 0.2%	Not Detected 0.0000 %
9.3	Single maximum unknown impurity	Not more than 0.5%	BLOQ 0.0300 %
9.4	Total impurities [a]	Not more than 2.0%	BLOQ 0.0300 %
10.0	Residual solvents		
10.1	Isopropyl alcohol	Not more than 5000 ppm	1002.000 ppm
10.2	Methylene chloride	Not more than 600 ppm	Not Detected 0.000 ppm
11.0	Assay		
11.1	Sildenafil Citrate USP EQV to Sildenafil	Not less than 95.0% and not more than 105.0% of the labeled claim.	101.30 %
11.2	Dapoxetine HCl EQV to	Not less than 95.0% and not more than 105.0% of the	100.60 %

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SR.NO.	TEST	SPECIFICATION	RESULT
	Dapoxetine [a]	labeled claim.	
12.0	Microbiological purity		
12.1	Total aerobic microbial count	Not more than 10^3 CFU/g	Less than 10 CFU/g Complies
12.2	Total combined yeasts and molds count	Not more than 10^2 CFU/g	Less than 10 CFU/g Complies
12.3	Pathogens		
12.3.1	E.coli	Absent	Absent Complies

Section : [a] Abbreviation

By HPLC [a]: By High performance liquid chromatography.
By HPLC [a]: By High performance liquid chromatography.
Dapoxetine HCl EQV to Dapoxetine [a]: Dapoxetine Hydrochloride equivalent to Dapoxetine.
Total impurities [a]: Total impurities (Sum of all specified and unspecified impurities).
Dapoxetine HCl EQV to Dapoxetine [a]: Dapoxetine Hydrochloride equivalent to Dapoxetine.

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