

Gut N0:11,12,14,15,
Chitegaon, Paithan road,
Aurangabad-431 105
Maharashtra - INDIA

**CERTIFICATE OF ANALYSIS
(Finished Product)**

NAME OF THE PRODUCT: SUPER KAMAGRA (Sildenafil 100 mg and Dapoxetine 60 mg Tablets)

MFG. DATE	May-2023	EXP. DATE	Apr-2026
BATCH SIZE	200000.000 BL	BATCH No.	CT05803
SAP LOT QTY.	198138.000 BL	SAMPLED QTY.	88 BL
SAMPLED BY	AAK	SAMPLED ON	May 30, 2023
A.R. NUMBER	CTGN/FP/2023/000378	INSPECTION LOT No.	040000115347
SPECIFICATION No.	FPS/W/22-23/0085/00	PRODUCT CODE	5003345
PACK SIZE	1X4	STP No.	STP/W/22-23/0085/00

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Green coloured, triangular shaped, film coated tablets, plain on both sides.	Light green to green coloured, triangular shaped, film coated tablets, plain on both sides.
2	Identification		
2.1	Sildenafil Citrate IP A. By High performance liquid chromatography	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.
2.2	B. By Thin layer chromatography	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.
2.3	Dapoxetine Hydrochloride IP A.By High performance liquid chromatography	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.

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Country : Deemed Export

ANALYSED BY	Sunil.Aihat(Officer)	CHECKED BY	Sachin.Suryawanshi (Sr. Executive)	APPROVED BY	Chandrakant..Patil (Manager)
DATE	Jun 08, 2023 11:34	DATE	Jun 08, 2023 11:34	DATE	Jun 08, 2023 11:46
Printed by: Sachin.Suryawanshi			Printed on: Jun 08, 2023 11:50		
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2.4	B. By Thin layer chromatography	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.
2.5	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.
2.6	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.
2.7	Titanium Dioxide	An orange-red colour appears/develops.	An orange-red colour appears/develops.
3	Average weight	412.030 mg	410.000 mg $\pm$ 5.0% (389.500 mg to 430.500 mg)
4	Uniformity of weight	Minimum: -2 % Maximum: 1 %	Not more than 2 of the individual weights deviate from the average weight by more

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			than $\pm 5\%$ and none deviates by more than $\pm 10\%$.
5	Disintegration time	4 min 48 sec.	Not more than 15 minutes.
6	Water content	4.0 %	Not more than 6.0%
7	Dissolution		
7.1	Sildenafil Citrate IP equivalent to Sildenafil	Tablet 1:103 % Tablet 2:100 % Tablet 3:103 % Tablet 4:100 % Tablet 5:103 % Tablet 6:100 % Minimum:100 % Maximum:103 % Mean:101 %	Not less than 80% (Q) of the labeled amount released in 15 minutes.
7.2	Dapoxetine Hydrochloride IP equivalent to Dapoxetine	Tablet 1:99 % Tablet 2:99 % Tablet 3:99 % Tablet 4:99 % Tablet 5:99 % Tablet 6:99 % Minimum:99 % Maximum:99 % Mean:99 %	Not less than 70% (Q) of the labeled amount released in 30 minutes.
8	Uniformity of dosage units (by content uniformity) USP < 905>		
8.1	Sildenafil Citrate IP equivalent to Sildenafil	2.8	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

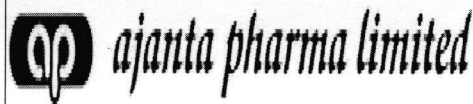
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			$[1+(0.01)(L2)]M$. L1 is 15.0 & L2 is 25.0.
8.2	Dapoxetine Hydrochloride IP equivalent to Dapoxetine	4.9	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 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.
9	Related substances		
9.1	(i) Sildenafil Related Compound A	Not Detected	Not more than 0.3%
9.2	(ii) Sildenafil N-Oxide	Not Detected	Not more than 0.2%
9.3	(iii) Single maximum unknown impurity	Not Detected	Not more than 0.5%
9.4	(iv) Total impurities	0.0 %	Not more than 2.0%
10	Residual solvents		
10.1	Isopropyl Alcohol	Not Detected	Not more than 5000 ppm
10.2	Methylene Chloride	Not Detected	Not more than 600 ppm
11	Assay		
11.1	Sildenafil Citrate IP equivalent to Sildenafil	103.1 %	Not less than 95.0% and not more than 105.0% of the labeled claim.
11.2	Dapoxetine Hydrochloride IP equivalent to Dapoxetine	97.5 %	Not less than 95.0% and not more than 105.0% of the labeled claim.
12	Microbiological purity		
12.1	Total aerobic microbial count	< 10cfu/g	Not more than 10^3 CFU/g
12.2	Total combined yeasts and molds count	< 10cfu/g	Not more than 10^2 CFU/g
12.3	Pathogens : Escherichia coli	Absent	Absent/g

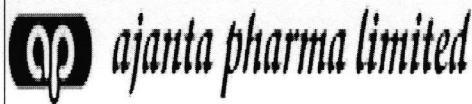
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