

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

CERTIFICATE OF ANALYSIS
(Finished Product)

NAME OF THE PRODUCT: SUPER KAMAGRA ORAL JELLY (Sildenafil 100 mg and Dapoxetine 60 mg Oral Jelly) (Orange flavour)

MFG. DATE	Jun-2024	EXP. DATE	May-2026
BATCH SIZE	100000.000 SAH	BATCH No.	CT07854
SAP LOT QTY.	98812.000 SAH	SAMPLED QTY.	154 SAH
SAMPLED BY	AAK	SAMPLED ON	Jun 20, 2024
A.R. NUMBER	CTGN/FP/2024/000439	INSPECTION LOT No.	040000138748
SPECIFICATION No.	FPS/W/20-21/0042/03	PRODUCT CODE	5004566
PACK SIZE	7 x 5	STP No.	STP/W/20-21/0042/03

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Orange coloured , homogenised jelly with sweet taste and pleasant odour Complies	Orange coloured, homogenised jelly with sweet taste and pleasant odour
2	Identification		
2.1	Sildenafil Citrate IP 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. Complies	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	By Thin layer chromatography	One of the principal spot in the chromatogram obtained with sample solution is similar in position, colour and size to that of the principal spot in the chromatogram obtained with Sildenafil Citrate standard solution. Complies	One of the principal spot in the chromatogram obtained with sample solution is similar in position, colour and size to that of the principal spot in the chromatogram obtained with Sildenafil Citrate standard solution.
2.3	Dapoxetine Hydrochloride IP 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	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	Akshaykumar.Jagtap (Officer)	CHECKED BY	Sulbha.Kingaonkar (Executive)	APPROVED BY	Chandrakant..Patil (Sr. Manager)
DATE	Jun 28, 2024 17:02	DATE	Jun 28, 2024 17:08	DATE	Jun 28, 2024 17:23

Printed by: Sulbha.Kingaonkar

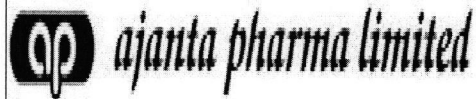
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		standard preparation, as obtained in the assay. Complies	
2.4	By Thin layer chromatography	One of the principal spot in the chromatogram obtained with sample solution is similar in position, colour and size to that of the principal spot in the chromatogram obtained with Dapoxetine Hydrochloride standard solution. Complies.	One of the principal spot in the chromatogram obtained with sample solution is similar in position, colour and size to that of the principal spot in the chromatogram obtained with Dapoxetine Hydrochloride standard solution.
2.5	Sunset Yellow FCF	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Sunset Yellow in the chromatogram of the standard preparation. Complies	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Sunset Yellow in the chromatogram of the standard preparation.
3	Average weight of filled sachets	7.23 g	7.20 g $\pm$ 7.5% (6.66 g to 7.74 g)
4	Average net filled weight per sachet	5.2 g	Not less than 5.0 g
5	Uniformity of weight (Mass)	Maximum: 2.3 %	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.
6	pH	4.2	3.0 to 5.0
7	Uniformity of dosage units (by content uniformity)		

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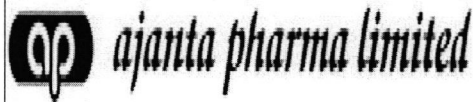
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7.1	Sildenafil Citrate IP equivalent to Sildenafil	3.0	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 units & calculate the acceptance value. The acceptance 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.
7.2	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.
8	Dissolution		
8.1	Sildenafil Citrate IP equivalent to Sildenafil	Sample-1:100 % Sample-2:99 % Sample-3:101 % Sample-4:102 % Sample-5:102 % Sample-6:103 % Minimum:99 % Maximum:103 % Mean:101 %	Not less than 80% *(Q) of the labeled amount released in 20 minutes.
8.2	Dapoxetine Hydrochloride IP equivalent to Dapoxetine	Sample-1:103 % Sample-2:101 % Sample-3:104 %	Not less than 80% *(Q) of the labeled amount released in 20 minutes.

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		Sample-4:105 % Sample-5:104 % Sample-6:106 % Minimum:101 % Maximum:106 % Mean:104 %	
9	Related substances		
9.1	(i) Sildenafil Related Compound A	0.0 %	Not more than 0.3%
9.2	(ii) Sildenafil N-Oxide	0.0 %	Not more than 0.2%
9.3	(iii) Single maximum unknown impurity	0.14 %	Not more than 0.5%
9.4	(iv) Total impurities	0.24 %	Not more than 2.0%
10	Assay		
10.1	Sildenafil Citrate IP equivalent to Sildenafil	103.5	Not less than 90.0% and not more than 110.0% of the labeled claim.
10.2	Dapoxetine Hydrochloride equivalent to Dapoxetine	105.7	Not less than 90.0% and not more than 110.0% of the labeled claim.

Test Plan Remarks: -

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