

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	KAMAGRA JELLY 100 mg (Sildenafil Oral Jelly 100 mg/5 g) (One Week Pack-Volume II)		
PRODUCT CODE	5000247	INSPECTION LOT NO.	4000033218
BATCH NO.	CT0279D	BATCH SIZE	910000 SAH
MFG. DATE	04.2019	EXP. DATE	03.2022
SAMPLED BY	Prashant Rajhans	SAMPLING DATE	28.04.2019
SAMPLED QTY.	175 SAH	RELEASED DATE	18.05.2019
PROCESS ORDER NO.	70002338	PACK SIZE	7'S

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

SR.NO.	TEST	SPECIFICATION	RESULT
A Mint Flavour			
1.0	Description	Blue coloured, homogenised jelly with sweet taste and pleasant odour.	Blue coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time 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 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
3.0	Average weight of filled sachet	7.3 g ± 7.5%	7.098 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.047 g
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0028 g Max. = 5.1465 g Avg. = 5.0472 g Complies
6.0	pH	3.0 to 5.0	4.34
7.0 Assay			
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	101.630 %
B Rose Flavour			
1.0	Description	Light pink to pink coloured, homogenised jelly with sweet taste and pleasant odour.	Light pink coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak	The retention time of the major peak in the chromatogram of the sample preparation

Remark: A - Release

Comment: The sample submitted complies with the prescribed Finished product specification FPS/16-17/0679 VER.00.

Analysed By	Gauri Deshmukh	Checked By	Sachin Suryawanshi	Approved By	Swati Dhoke
Designation	Officer	Designation	Executive	Designation	Asst. Manager
Date	18.05.2019	Date	18.05.2019	Date	18.05.2019
Printed By:	Pravin Kocheta	Printed On:	18.05.2019 14:29:27	Page No.:	1 of 6
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SR.NO.	TEST	SPECIFICATION	RESULT
		due to Sildenafil in the chromatogram of the standard preparation, as obtained in the assay.	corresponds to that of the peak due to Sildenafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachet	7.3 g \pm 7.5%	7.162 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.051 g
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0038 g Max. = 5.0988 g Avg. = 5.0507 g Complies
6.0	pH	3.0 to 5.0	4.14
7.0	Assay		
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	100.990 %
C	Mango Flavour		
1.0	Description	Yellow coloured, homogenised jelly with sweet taste and pleasant odour.	Yellow coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time 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 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
3.0	Average weight of filled sachet	7.3 g \pm 7.5%	7.186 g
4.0	Average net filled	Not less than 5.0 g	5.055 g

Remark: A - Release
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SR.NO.	TEST	SPECIFICATION	RESULT
	weight per sachet		
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0059 g Max. = 5.1170 g Avg. = 5.0549 g Complies
6.0	pH	3.0 to 5.0	4.29
7.0	Assay		
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	100.790 %
D	Lemon Flavour		
1.0	Description	Lemon yellow coloured, homogenised jelly with sweet taste and pleasant odour.	Lemon yellow coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time 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 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
3.0	Average weight of filled sachet	7.3 g ± 7.5%	7.139 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.059 g
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0027 g Max. = 5.1487 g Avg. = 5.0586 g Complies
6.0	pH	3.0 to 5.0	4.21
7.0	Assay		
7.1	Sildenafil Citrate IP	Not less than 90.0% and not more than 110.0% of the	100.840 %

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SR.NO.	TEST	SPECIFICATION	RESULT
	EQV to Sildenafil [a]	labeled claim.	
E	Cherry Flavour		
1.0	Description	Red wine coloured, homogenised jelly with sweet taste and pleasant odour.	Red wine coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time 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 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
3.0	Average weight of filled sachet	7.3 g ± 7.5%	7.108 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.048 g
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0039 g Max. = 5.1009 g Avg. = 5.0475 g Complies
6.0	pH	3.0 to 5.0	4.18
7.0	Assay		
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	101.180 %
F	Chocolate Flavour		
1.0	Description	Chocolate brown coloured, homogenised jelly with sweet taste and pleasant odour.	Chocolate brown coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak	The retention time of the major peak in the chromatogram of the sample preparation

Remark: A - Release

Comment: The sample submitted complies with the prescribed Finished product specification FPS/16-17/0679 VER.00.

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		due to Sildenafil in the chromatogram of the standard preparation, as obtained in the assay.	corresponds to that of the peak due to Sildenafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachet	7.3 g \pm 7.5%	7.117 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.042 g
5.0	Uniformity of weight (Mass)	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%.	Complies
6.0	pH	3.0 to 5.0	4.23
7.0	Assay		
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	100.530 %
G	Watermelon Flavour		
1.0	Description	Red coloured, homogenised jelly with sweet taste and pleasant odour.	Red coloured, homogenised jelly with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time 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 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
3.0	Average weight of filled sachet	7.3 g \pm 7.5%	7.196 g
4.0	Average net filled	Not less than 5.0 g	5.071 g

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SR.NO.	TEST	SPECIFICATION	RESULT
	weight per sachet		
5.0	Uniformity of weight (Mass)	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%.	Min. = 5.0057 g Max. = 5.1773 g Avg. = 5.0709 g Complies
6.0	pH	3.0 to 5.0	4.30
7.0	Assay		
7.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	101.540 %

Section : [a] Abbreviation

Sildenafil Citrate IP EQV to Sildenafil [a]: Sildenafil Citrate IP equivalent to Sildenafil.
 Sildenafil Citrate IP EQV to Sildenafil [a]: Sildenafil Citrate IP equivalent to Sildenafil.
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