

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	KAMAGRA CHEWABLE TABLETS 100 mg (Sildenafil Chewable Tablets 100 mg)		
PRODUCT CODE	5000562	INSPECTION LOT NO.	40000087571
BATCH NO.	CT01042	BATCH SIZE	100000 BL
MFG. DATE	02.2022	EXP. DATE	01.2025
SAMPLED BY	Abhijit Korde	SAMPLING DATE	07.03.2022
SAMPLED QTY.	134 BL	RELEASED DATE	16.04.2022
PROCESS ORDER NO.	70006744	PACK SIZE	1X4'S

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

SR.NO.	TEST	SPECIFICATION	RESULT
a	Orange Flavour		
1.0	Description	Light orange to orange coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance.	Orange coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance. Complies
2.0	Identification		
2.1	Sildenafil	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	600.6 mg \pm 5.0%	593.620 mg
4.0	Uniformity of weight	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. = 591.4 mg Max. = 608.5 mg Avg. = 596.8 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	Not Detected 0.00 %
5.2	Total impurities [a]	Not more than 2.0%	Not Detected 0.00 %
6.0	Assay		
6.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of the labeled claim.	101.00 %
b	Pineapple Flavour		
1.0	Description	Light yellow to yellow coloured, diamond shaped,	Yellow coloured, diamond shaped, uncoated,

Remark: A - Release (Domestic)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0343 Version: 01.

Analysed By	Bhaskar Garad	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Sr Officer	Designation	Asst. Executive	Designation	Sr. Executive
Date	16.04.2022	Date	16.04.2022	Date	16.04.2022
Printed By:	Prashant Rajhans	Printed On:	16.04.2022 12:52:02	Page No.:	1 of 4

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SR.NO.	TEST	SPECIFICATION	RESULT
		uncoated, chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance.	chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance. Complies
2.0	Identification		
2.1	Sildenafil	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	600.6 mg \pm 5.0%	595.130 mg
4.0	Uniformity of weight	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. = 583.9 mg Max. = 606.1 mg Avg. = 595.6 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	Not Detected 0.00 %
5.2	Total impurities [a]	Not more than 2.0%	Not Detected 0.00 %
6.0	Assay		
6.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of labeled claim.	100.40 %
c	Strawberry Flavour		
1.0	Description	Light pink to pink coloured, diamond shaped, uncoated chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance.	Light pink coloured, diamond shaped, uncoated chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side and with slight mottled appearance.

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SR.NO.	TEST	SPECIFICATION	RESULT
			Complies
2.0	Identification		
2.1	Sildenafil	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	600.6 mg \pm 5.0%	594.980 mg
4.0	Uniformity of weight	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. = 591.1 mg Max. = 609.6 mg Avg. = 596.4 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	Not Detected 0.00 %
5.2	Total impurities [a]	Not more than 2.0%	Not Detected 0.00 %
6.0	Assay		
6.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of labeled claim.	99.70 %
d	Banana Flavour		
1.0	Description	Pale yellow to yellow coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side.	Pale yellow coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap' logo on one side and 'KGR 100' on the other side. Complies
2.0	Identification		
2.1	Sildenafil	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

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Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0343 Version: 01.

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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	600.6 mg \pm 5.0%	599.625 mg
4.0	Uniformity of weight	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. = 587.5 mg Max. = 621.7 mg Avg. = 601.8 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	Not Detected 0.00 %
5.2	Total impurities [a]	Not more than 2.0%	Not Detected 0.00 %
6.0	Assay		
6.1	Sildenafil Citrate IP EQV to Sildenafil [a]	Not less than 90.0% and not more than 110.0% of labeled claim.	100.10 %

Section : [a] Abbreviation

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

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

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

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

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

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

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

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

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