

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.	40000094803
BATCH NO.	CT06442	BATCH SIZE	100000 BL
MFG. DATE	06.2022	EXP. DATE	05.2025
SAMPLED BY	Chandrakant Mehetre	SAMPLING DATE	03.07.2022
SAMPLED QTY.	200 BL	RELEASED DATE	14.07.2022
PROCESS ORDER NO.	70007093	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%	594.075 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. = 585.1 mg Max. = 600.6 mg Avg. = 594.39 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.	102.10 %
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	Sushma Aher	Checked By	Sachin Suryawanshi	Approved By	Vinod Umrikar
Designation	Officer	Designation	Sr. Executive	Designation	Asst. Manager
Date	14.07.2022	Date	14.07.2022	Date	14.07.2022
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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%	595.270 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. = 585.4 mg Max. = 602.8 mg Avg. = 594.97 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.	99.30 %
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.	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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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
			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%	595.505 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. = 586.9 mg Max. = 606.9 mg Avg. = 595.55 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.34 %
5.2	Total impurities [a]	Not more than 2.0%	0.34 %
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.	101.80 %
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 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,

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SR.NO.	TEST	SPECIFICATION	RESULT
			as obtained in the assay. Complies
3.0	Average weight	600.6 mg $\pm$ 5.0%	597.795 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. = 586.6 mg Max. = 606.0 mg Avg. = 595.06 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.	100.30 %

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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