

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.	40000052732
BATCH NO.	CT0310F	BATCH SIZE	100000 BL
MFG. DATE	06.2020	EXP. DATE	05.2023
SAMPLED BY	Pravin Kocheta	SAMPLING DATE	17.06.2020
SAMPLED QTY.	120 BL	RELEASED DATE	27.06.2020
PROCESS ORDER NO.	10038255	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.	Light 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%	597.800 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 = 595.6 mg, Max = 601.7 mg Avg = 597.99 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.	99.60 %
b	Pineapple Flavour		
1.0	Description	Light yellow to yellow coloured, diamond shaped,	Light yellow to yellow coloured, diamond shaped,

Remark: A - Release (Domestic- Deemed Export)

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

Analysed By	Vandana Ahire	Checked By	Swati Dhoke	Approved By	Sudhir Deshpande
Designation	Sr. Officer	Designation	Asst. Manager	Designation	Deputy Manager
Date	27.06.2020	Date	27.06.2020	Date	27.06.2020
Printed By :	Pravin Kocheta	Printed On :	27.06.2020 13:50:29	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.	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%	597.520 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 = 594.7 mg, Max = 599.2 mg Avg = 597.29 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.33 %
5.2	Total impurities [a]	Not more than 2.0%	0.33 %
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.	99.20 %
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. Complies
2.0	Identification		

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SR.NO.	TEST	SPECIFICATION	RESULT
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%	597.980 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 = 595.3 mg, Max = 602.1 mg Avg = 598.15 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.25 %
5.2	Total impurities [a]	Not more than 2.0%	0.25 %
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.	97.70 %
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 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

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SR.NO.	TEST	SPECIFICATION	RESULT
3.0	Average weight	600.6 mg \pm 5.0%	598.910 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 = 596.4 mg, Max = 603.9 mg Avg = 599.98 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.10 %
5.2	Total impurities [a]	Not more than 2.0%	0.10 %
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.	97.80 %

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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