

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.	40000034075
BATCH NO.	CT0609D	BATCH SIZE	100000 BL
MFG. DATE	04.2019	EXP. DATE	03.2022
SAMPLED BY	Pravin Kocheta	SAMPLING DATE	15.05.2019
SAMPLED QTY.	120 BL	RELEASED DATE	03.06.2019
PROCESS ORDER NO.	10022199	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%	593.910 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. = 589.9 mg Max. = 600.0 mg Avg. = 595.6 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.09 %
5.2	Total impurities [a]	Not more than 2.0%	0.16 %
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.	103.00 %
b	Pineapple Flavour		
1.0	Description	Light yellow to yellow coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap' logo on	Yellow coloured, diamond shaped, uncoated, chewable tablets, engraved with 'ap'

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

Analysed By	Vandana Ahire	Checked By	Sachin Suryawanshi	Approved By	Swati Dhoke	
Designation	Sr. Officer	Designation	Executive	Designation	Asst. Manager	
Date	03.06.2019	Date	03.06.2019	Date	03.06.2019	
Printed By:	Pravin Kocheta	Printed On:	03.06.2019 9:27:06	Page No.:	1 of 4	
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		one side and 'KGR 100' on the other side and with slight mottled appearance.	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%	597.310 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. = 589.6 mg Max. = 602.6 mg Avg. = 595.8 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.08 %
5.2	Total impurities [a]	Not more than 2.0%	0.16 %
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.	102.90 %
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. Complies
2.0	Identification		
2.1	Sildenafil	The retention time of the major peak in the chromatogram	The retention time of the major peak in the

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		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.	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%	595.570 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. = 569.9 mg Max. = 609.6 mg Avg. = 593.5 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.09 %
5.2	Total impurities [a]	Not more than 2.0%	0.16 %
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.	102.60 %
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
3.0	Average weight	600.6 mg \pm 5.0%	592.340 mg

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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. = 582.8 mg Max. = 603.4 mg Avg. = 592.9 mg Complies
5.0	Related substances		
5.1	Individual impurity	Not more than 1.0%	0.09 %
5.2	Total impurities [a]	Not more than 2.0%	0.16 %
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.	101.20 %

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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