

CERTIFICATE OF ANALYSIS -FINISHED PRODUCT

NAME OF THE SAMPLE	KAMAGRA EFFERVESCENT TABLETS 100 mg(Sildenafil Effervescent Tablets 100 mg)(Orange Flavour)		
PRODUCT CODE	5001071	INSPECTION LOT NO.	40000092012
BATCH NO.	CT04802	BATCH SIZE	14285 BOT
MFG. DATE	05.2022	EXP. DATE	04.2024
SAMPLED BY	Abhijit Korde	SAMPLING DATE	18.05.2022
SAMPLED QTY.	18 BOT	RELEASED DATE	06.06.2022
PROCESS ORDER NO.	10072738	PACK SIZE	1X7'S

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

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	Description	Light orange to orange coloured, circular, flat, beveled edged, uncoated tablets with 'ap' 'KGR' logo embossed on one side & breakline on other side with orange mottled surface.	Light orange coloured, circular, flat, beveled edged, uncoated tablets with 'ap' 'KGR' logo embossed on one side & breakline on other side with orange mottled surface. 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
2.2	Citrate	White precipitate soluble in 6M acetic acid is produced.	White precipitate soluble in 6M acetic acid is produced. Complies
3.0	Average weight	3600.0 mg $\pm$ 5.0% (3420.0 mg to 3780.0 mg)	3568.000 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 = 3435.0 mg,Max = 3627.3 mg Avg = 3531.46 mg Complies
5.0	Diameter	23.0 mm to 23.3 mm	23.150 mm
6.0	Hardness	Not less than 1.0 kg/cm ²	10.000 kg/cm ²
7.0	Disintegration time	Not more than 5 minutes.	01 min 20 sec Complies
8.0	Loss on drying	Not more than 5.0%	2.090 %
9.0	Uniformity of content	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 dosage units & calculate the	AV = 4.65 Complies

Remark: A - Release (General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/W/18-19/0352 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sudhir Deshpande
Designation	Sr. Officer	Designation	Asst. Executive	Designation	Manager
Date	06.06.2022	Date	06.06.2022	Date	06.06.2022
Printed By :	Prashant Rajhans	Printed On :	06.06.2022 15:17:44	Page No.:	1 of 3
Note : This document has been generated electronically and is valid without signature					Copy No. 1
Format No. CQA/F/160,Version:01					Reference SOP No. SOP/CQA/089

CERTIFICATE OF ANALYSIS -FINISHED PRODUCT

NAME OF THE SAMPLE	KAMAGRA EFFERVESCENT TABLETS 100 mg(Sildenafil Effervescent Tablets 100 mg)(Orange Flavour)		
PRODUCT CODE	5001071	INSPECTION LOT NO.	40000092012
BATCH NO.	CT04802	BATCH SIZE	14285 BOT
MFG. DATE	05.2022	EXP. DATE	04.2024
SAMPLED BY	Abhijit Korde	SAMPLING DATE	18.05.2022
SAMPLED QTY.	18 BOT	RELEASED DATE	06.06.2022
PROCESS ORDER NO.	10072738	PACK SIZE	1X7'S

SR.NO.	TEST	SPECIFICATION	RESULT
		acceptance value. The acceptance value of the 30 dosage units is less than or equal to L1 and no individual content of any dosage unit is less than (1-L2*0.01)M or more than (1+ L2*0.01)M. L1 is 15.0 & L2 is 25	
10.0	Related substances		
10.1	Single maximum impurity	Not more than 1.0%	0.06 %
10.2	Total impurities [a]	Not more than 2.0%	0.16 %
11.0	Assay		
11.1	Sildenafil Citrate EQV to Sildenafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	100.530 %
12.0	Microbiological purity		
12.1	Total Aerobic Microbial count	Not more than 10 ³ CFU/g	Less than 10 CFU/g Complies
12.2	Total Combined Molds and Yeasts count	Not more than 10 ² CFU/g	Less than 10 CFU/g Complies
12.3	Pathogens		
12.3.1	Bile-Tolerant Gram-Negative Bacteria	Absent	Absent Complies
12.3.2	E.coli	Absent	Absent Complies
12.3.3	Salmonella	Absent	Absent Complies
12.3.4	S.aureus	Absent	Absent Complies
12.3.5	P.aeruginosa	Absent	Absent Complies
12.3.6	Candida albicans	Absent	Absent Complies

Remark: A - Release (General Export)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/W/18-19/0352 Ver.00					
Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sudhir Deshpande
Designation	Sr. Officer	Designation	Asst. Executive	Designation	Manager
Date	06.06.2022	Date	06.06.2022	Date	06.06.2022
Printed By : Prashant Rajhans		Printed On : 06.06.2022 15:17:44		Page No.: 2 of 3	
Note : This document has been generated electronically and is valid without signature					Copy No. 1
Format No. CQA/F/160,Version:01					Reference SOP No. SOP/CQA/089

CERTIFICATE OF ANALYSIS -FINISHED PRODUCT

NAME OF THE SAMPLE	KAMAGRA EFFERVESCENT TABLETS 100 mg(Sildenafil Effervescent Tablets 100 mg)(Orange Flavour)		
PRODUCT CODE	5001071	INSPECTION LOT NO.	40000092012
BATCH NO.	CT04802	BATCH SIZE	14285 BOT
MFG. DATE	05.2022	EXP. DATE	04.2024
SAMPLED BY	Abhijit Korde	SAMPLING DATE	18.05.2022
SAMPLED QTY.	18 BOT	RELEASED DATE	06.06.2022
PROCESS ORDER NO.	10072738	PACK SIZE	1X7'S

Section : [a] Abbreviation

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

Remark: A - Release (General Export)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/W/18-19/0352 Ver.00					
Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sudhir Deshpande
Designation	Sr. Officer	Designation	Asst. Executive	Designation	Manager
Date	06.06.2022	Date	06.06.2022	Date	06.06.2022
Printed By : Prashant Rajhans		Printed On : 06.06.2022 15:17:44		Page No.: 3 of 3	
Note : This document has been generated electronically and is valid without signature					Copy No. 1
Format No. CQA/F/160,Version:01					Reference SOP No. SOP/CQA/089