ajanta pharma limited

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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.**	40000087506
BATCH NO.	CT01182	**BATCH SIZE**	14285 BOT
MFG. DATE	03.2022	**EXP. DATE**	02.2024
SAMPLED BY	Abhijit Korde	**SAMPLING DATE**	06.03.2022
SAMPLED QTY.	18 BOT	**RELEASED DATE**	15.03.2022
PROCESS ORDER NO.	10068804	**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, blat, 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 ± 5.0% (3420.0 mg to 3780.0 mg)	3550.000 mg
4.0	**Uniformity of weight**	Not more than 2 of the individual weights deviate from the average weight by more than ± 5% and none deviates by more than ± 10%.	Min. = 3529.6 mg Max. = 3607.2 mg Avg. = 3571.8 mg Complies
5.0	**Diameter**	23.0 mm to 23.3 mm	23.110 mm
6.0	**Hardness**	Not less than 1.0 kg/cm²	3.500 kg/cm²
7.0	**Disintegration time**	Not more than 5 minutes.	02 min. 11 sec. Complies
8.0	**Loss on drying**	Not more than 5.0%	2.117 %
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 = 7.52 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	Vandana Ahire	**Checked By**	Sachin Suryawanshi	**Approved By**	Sudhir Deshpande
Designation	Asst. Executive	**Designation**	Sr. Executive	**Designation**	Manager
Date	14.03.2022	**Date**	14.03.2022	**Date**	15.03.2022

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Corporate Identity Number - L24230MH1979PLC022059

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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%	0.10 %
10.2	**Total impurities [a]**	Not more than 2.0%	0.18 %
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.	100.640 %
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

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Designation	Asst. Executive	**Designation**	Sr. Executive	**Designation**	Manager
Date	14.03.2022	**Date**	14.03.2022	**Date**	15.03.2022

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Section : [a] Abbreviation

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

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