

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	4000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
A	Pineapple Flavour		
1.0	Description	Yellow coloured, homogenized jelly, with sweet taste and pleasant odour.	Yellow coloured, homogenized jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.103 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.267 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.0355 g, Max = 5.4338 g Avg = 5.2665 g Complies
6.0	pH	3.5 to 4.5	3.92
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	Individual Value 101.040 99.110 99.740 101.140 101.260 99.210 100.960 98.810

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	1 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
			101.190 100.070 (Average- 100.253 Minimum- 98.840 Maximum- 101.260
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	98.340 %
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	20 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureus	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
B	Orange Flavour		
1.0	Description	Orange coloured, homogenised jelly, with sweet taste and pleasant odour.	Orange coloured, homogenised jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak	The retention time of the major peak in the chromatogram of the sample preparation

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	2 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	4000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
		due to Tadalafil in the chromatogram of the standard preparation, as obtained in the assay.	corresponds to that of the peak due to Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.087 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.255 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.0998 g, Max = 5.3885 g Avg = 5.2545g Complies
6.0	pH	3.5 to 4.5	4.10
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	99.700 101.730 98.320 100.420 99.880 101.310 101.010 98.760 101.050 101.690 Average- 100.387 Minimum- 98.320 Maximum- 101.730
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	97.200 %

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021

Printed By : Pravin Kocheta **Printed On :** 14.02.2021 9:52:06 **Page No.:** 3 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureus	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
C	Strawberry Flavour		
1.0	Description	Light pinkish-red coloured, homogenised jelly, with sweet taste and pleasant odour.	Light pinkish-red coloured, homogenised jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.118 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.280 g

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	4 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.0733 g, Max = 5.4184 g Avg = 5.2800 g Complies
6.0	pH	3.0 to 5.0	4.08
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	102.140 101.430 99.560 97.920 102.150 102.500 99.550 101.380 99.030 99.100 Average- 100.476 Minimum- 97.920 Maximum- 102.500
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	98.460 %
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	5 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureus	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
D	Mint Flavour		
1.0	Description	Blue coloured, homogenised jelly, with sweet taste and pleasant odour.	Blue coloured, homogenised jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.125 g
4.0	Average net filled weight per sachets	Not less than the labeled amount (5.0 g).	5.292 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.1028 g, Max = 5.4478 g Avg = 5.2916 g Complies
6.0	pH	3.5 to 4.5	4.06
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	100.980 100.830 99.390 100.730

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	6 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
			100.000 100.700 100.180 98.300 101.100 100.750 Average- 100.296 Minimum- 98.300 Maximum- 101.100
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	99.510 %
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	10 CFU /g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureus	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
E	Mango Flavour		
1.0	Description	Orange coloured, homogenised jelly, with sweet taste and	Orange coloured, homogenised jelly, with sweet

Remark: A - Release (Country General Export)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00					
Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	7 of 13
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	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
		pleasant odour.	taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.117 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.284 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.1994 g, Max = 5.4535 g Avg = 5.2840 g Complies
6.0	pH	3.5 to 4.5	4.160
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	101.330 98.790 101.580 99.170 101.040 101.530 101.110 99.920 101.550 99.550 Average- 100.557 Minimum- 98.790

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	8 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
			Maximum- 101.580
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	98.370 %
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureu	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
F	Black currant Flavour		
1.0	Description	Purple coloured, homogenised jelly, with sweet taste and pleasant odour.	Purple coloured, homogenised jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	9 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.090 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.261 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.0854g, Max =5.3792 g Avg = 5.2608 g Complies
6.0	pH	3.0 to 5.0	4.000
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	101.510 100.460 99.770 99.140 97.600 101.740 100.200 100.310 98.220 99.720 Average- 99.867 Minimum- 97.600 Maximum- 101.740
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	97.850
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g

Remark: A - Release (Country General Export)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00					
Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By : Pravin Kocheta		Printed On : 14.02.2021 9:52:06		Page No.: 10 of 13	
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	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	4000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
			Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	S.aureus	Absent	Absent Complies
9.3.4	P.aeruginosa	Absent	Absent Complies
F	Chocolate Flavour		
1.0	Description	Chocolate brown coloured, homogenised jelly, with sweet taste and pleasant odour.	Chocolate brown coloured, homogenised jelly, with sweet taste and pleasant odour. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Tadalafil 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 Tadalafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight of filled sachets	6.2 g ± 5.0%	6.118 g
4.0	Average net filled weight per sachet	Not less than the labeled amount (5.0 g).	5.286 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15%.	Min = 5.1285 g, Max = 5.4329 g Avg = 5.2856 g Complies
6.0	pH	3.0 to 5.0	4.100

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	11 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	101.850 101.710 103.100 100.430 102.020 101.620 101.870 99.540 101.530 101.870 Average- 101.554 Minimum- 99.540 Maximum- 103.100
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	98.510 %
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g Complies
9.3	Pathogens		
9.3.1	E.coli	Absent	Absent Complies
9.3.2	Salmonella	Absent	Absent Complies
9.3.3	St aureus	Absent	Absent Complies

Remark: A - Release (Country General Export)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00

Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By :	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.:	12 of 13

Note : This document has been generated electronically and is valid without signature

Copy No. 1

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Tadalafil Oral Jelly 20 mg/5 g) (One week pack- Volume I)		
PRODUCT CODE	5000863	INSPECTION LOT NO.	40000064632
BATCH NO.	CT0401A	BATCH SIZE	280000 SAH
MFG. DATE	01.2021	EXP. DATE	12.2023
SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021
PROCESS ORDER NO.	70005317	PACK SIZE	175

SR.NO.	TEST	SPECIFICATION	RESULT
9.3.4	P.aeruginosa	Absent	Absent Complies

TENGUDDOU.NE

Remark: A - Release (Country General Export)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00					
Analysed By	Gauri Deshmukh	Checked By	Vandana Ahire	Approved By	Sachin Suryawanshi
Designation	Officer	Designation	Sr. Officer	Designation	Executive
Date	13.02.2021	Date	13.02.2021	Date	13.02.2021
Printed By : Pravin Kocheta		Printed On : 14.02.2021 9:52:06		Page No.: 13 of 13	
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