

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	<b>7</b> 5.		

SR.NO.	TEST	SPECIFICATION	RESULT
A	Pineapple Flavour		
1.0	Description	Yellow coloured, homogenized jelly, with sweet taste and	Yellow coloured, homogenized jelly, with sweet
		pleasant odour.	taste and pleasant odour.
			Complies
2.0	Identification	The retention time of the major peak in the chromatogram	The rejention time of the major peak in the
		of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation
		due to Tadalafil in the chromatogram of the standard	corresponds to that of the peak due to Tadalafil
		preparation, as obtained in the assay.	in the chromatogram of the standard preparation,
			as obtained in the assay.
			Complies
3.0	Average weight of	$6.2~{ m g}\pm5.0\%$	6.103 g
	filled sachets		
4.0	Average net filled	Not less than the labeled amount (5.0 g).	5.267 g
	weight per sachet		
5.0	Uniformity of weight	Not more than 2 of the individual weight of the contents	Min = 5.0355  g,Max = 5.4338  g
	(Mass)	deviate from the average net filled weight by more than	Avg = 5.2665 g
		7.5% and none deviates by more than 15%.	Complies
6.0	рН	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	Individual Value
		labeled claim.	101.040
			99.110
			99.740
			101.140
			101.260
			99.210
			100.960
			98.810

Remark: A - Release ( Country General Export )							
Comment: The	Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00						
Analysed By	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: I	Printed By: Pravin Kocheta         Printed On: 14.02.2021         9:52:06         Page No.: 1 of 13						
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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	<b>A.</b>	

CD NO	TOPO OT	CDECARACA	Drown
SR.NO.	TEST	SPECIFICATION	RESULT
			101.190
			100.070
			Average- 100.253
			Minimum- 98.810
			Maximum- 101.260
8.0	Assay		
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the	98.310 %
		labeled claim.	
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
В	Orange Flavour		
1.0	Description	Orange coloured, homogenised jelly, with sweet taste and	Orange coloured, homogenised jelly, with sweet
	$\wedge$ $\times$ )	pleasant odour.	taste and pleasant odour.
			Complies
2.0	<b>Identification</b>	The retention time of the major peak in the chromatogram	The retention time of the major peak in the
		of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation

Domark: A 1	Pologo (Country Conord Ermont)				-		
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	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: I	Printed By:         Pravin Kocheta         Printed On: 14.02.2021         9:52:06         Page No.: 2 of 13						
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NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg	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 12/40%3				
SAMPLED BY	Abhijit Korde	SAMPLING DATE \$5.01.202				
SAMPLED QTY.	175 SAH	RELEASED DATE 14.02.2021				
PROCESS ORDER NO.	70005317	PACK SIZE				

SR.NO.	TEST	SPECIFICATION	RESULT
		due to Tadalafil in the chromatogram of the standard	corresponds to that of the peak due to Tadalafil
		preparation, as obtained in the assay.	in the chromatogram of the standard preparation,
			as obtained in the assay.
		· ·	Complies
3.0	Average weight of	$6.2 \text{ g} \pm 5.0\%$	6.087 g
	filled sachets		
4.0	Average net filled	Not less than the labeled amount (5.0 g).	5.25 g
	weight per sachet		
5.0	Uniformity of weight	Not more than 2 of the individual weight of the contents	Min = 5.0998 g,Max = 5.3885 g
	(Mass)	deviate from the average net filled weight by more than	Avg = 5.2545g
		7.5% and none deviates by more than 15%.	Complies
6.0	рН	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	99.700
		labeled claim.	101.730
			98.320
			100.420
			99.880
			101.310
			101.010
			98.760
			101.050
			101.690
			Average- 100.387
			Minimum- 98.320
	AX )		Maximum- 101.730
8.0	Assay	•	•
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the	97.200 %
		labeled claim.	

Remark: A - 1	Remark: A - Release ( Country General Export )						
Comment: The	Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00						
Analysed By	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		
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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	<b>A.</b> (		

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SR.NO.	TEST	SPECIFICATION	RESULT
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than IU 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
С	Strawberry Flavour		
1.0	Description	Light pinkish-red coloured, homogenised jelly, with sweet	Light pinkish-red coloured, homogenised jelly,
		taste and pleasant odour.	with sweet taste and pleasant odour.
			Complies
2.0	Identification	The retention time of the major peak in the chromatogram	The retention time of the major peak in the
		of the sample preparation corresponds to that of the peak	chromatogram of the sample prepration corresponds
		due to Tadalafil in the chromatogram of the standard	to that of the peak due to Tadalafil in the
		preparation, as obtained in the assay.	chromatogram of the standard preparation, as
			obtained in the assay.
			Complies
3.0	Average weight of	6.2 g ± 5.0%	6.118 g
	filled sachets		
4.0	Average net filled	Not less than the labeled amount (5.0 g).	5.280 g
	weight per sachet		

D					-	
	Release ( Country General Export )					
Comment: The	sample submitted Complies with the p	rescribed Finis	shed product specification FPS/16-1	7/0503 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	
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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	<b>A</b> . (		

SR.NO.	TEST	SPECIFICATION	RESULT
5.0	Uniformity of weight	Not more than 2 of the individual weight of the contents	Min = 5.0733 g,Max = 5.4184 g
	(Mass)	deviate from the average net filled weight by more than	Avg = 5.2800 g
		7.5% and none deviates by more than 15%.	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	102.140
		labeled claim.	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		98.460 %
		labeled claim.	
9.0	Microbiological purity		
9.1	Total bacterial count	Not more than 1000 CFU/g	Less than 10 CFU/g
		le .	Complies
9.2	Total fungal count	Not more than 100 CFU/g	Less than 10 CFU/g
			Complies
9.3	Pathogens	T	
9.3.1	Lcoli	Absent	Absent
			Complies

Domark: A I	Domoniu A Dologo (Country Country Country)						
	Remark: A - Release (Country General Export)  Comment: The sample submitted Complies with the prescribed Finished product specification FPS/16-17/0503 Ver.00						
Comment: The	sample submitted Compiles with the p	rescribed Finis	snea product speci	fication FPS/16-1	7/0503 Ver.00		
	<u> </u>		1				
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: F	Printed By:         Pravin Kocheta         Printed On: 14.02.2021         9:52:06         Page No.: 5 of 13						
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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	<b>A.</b>		

9.3.2 Salmonella Absent  9.3.3 S.aureus Absent  9.3.4 P.aeruginosa Absent  D Mint Flavour  1.0 Description Blue coloured, homogenised jelly, with weet taste and pleasant odour.	<b>3</b> • •
9.3.4 P.aeruginosa Absent  D Mint Flavour  1.0 Description Blue coloured, homogenised jelly, with weet taste	Absent Complies Absent Complies  Blue coloured, homogenised jelly, with sweet taste and pleasant odour. Complies  The retention time of the major peak in the
9.3.4 P.aeruginosa Absent  D Mint Flavour  1.0 Description Blue coloured, homogenised jelly, with weet taste	Absent Complies  Blue coloured, homogenised jelly, with sweet taste and pleasant odour. Complies  The retention time of the major peak in the
D Mint Flavour  1.0 Description Blue coloured, homogenised jelly, with weet taste	Absent Comples  Blue coloured, homogenised jelly, with sweet taste and pleasant odour. Complies The retention time of the major peak in the
D Mint Flavour  1.0 Description Blue coloured, homogenised jelly, with weet taste	Comples  Blue coloured, homogenised jelly, with sweet taste and pleasant odour.  Complies  The retention time of the major peak in the
1.0 Description Blue coloured, homogenised jelly, with weet taste	Blue coloured, homogenised jelly, with sweet taste and pleasant odour.  Complies  The retention time of the major peak in the
1.0 Description Blue coloured, homogenised jelly, with weet taste	and pleasant odour.  Complies  The retention time of the major peak in the
	and pleasant odour.  Complies  The retention time of the major peak in the
and pleasant odour.	Complies  The retention time of the major peak in the
	The retention time of the major peak in the
	<b>~</b> .
2.0 Identification The retention time of the major peak in the chromatogram	
of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation
due to Tadalafil in the chromatogram of the standard	corresponds to that of the peak due to Tadalafil
preparation, as obtained in the assay	in the chromatogram of the standard preparation,
	as obtained in the assay.
	Complies
3.0 Average weight of $6.2 g \pm 5.0\%$	6.125 g
filled sachets	
4.0 Average net filled Not less than the labeled amount (5.0 g).	5.292 g
weight per sachets	
5.0 Uniformity of weight Not more than 2 of the individual weight of the contents	Min = 5.1028 g, Max = 5.4478 g
(Mass) deviate from the average net filled weight by more than	Avg = 5.2916 g
7.5% and none deviates by more than 15%.	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	100.980
labeled claim.	100.830
	99.390
	100.730

D 1 4 7							
	Release ( Country General Export )						
Comment: The	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		
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Chitegaon, Aurangabad-431 105 E info@ajantapharma.com Maharashtra-INDIA W www.ajantapharma.com

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	<b>A.</b> (		

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	99.510 %
		labeled claim.	
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	Ausent	Absent
			Complies
9.3.3	S.aureus	Absent	Absent
			Complies
9.3.4	P.aeruginosa	Absent	Absent
			Complies
E	Mango Flavour	-1	
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	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	
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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	75.		

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	The retention time of the major peak in the
		of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation
		due to Tadalafil in the chromatogram of the standard	corresponds to that of the peak due to Tadalafil
		preparation, as obtained in the assay.	in the chromatogram of the standard preparation,
			as obtained in the assay.
			Complies
3.0	Average weight of	$6.2~{ m g}\pm5.0\%$	6.117 g
	filled sachets		
4.0	Average net filled	Not less than the labeled amount (5.0 g).	5.284 g
	weight per sachet		
5.0	Uniformity of weight	Not more than 2 of the individual weight of the contents	Min = 5.1994  g, Max = 5.4535  g
	(Mass)	deviate from the average net filled weight by more than	Avg = 5.2840 g
		7.5% and none deviates by more than 15%.	Complies
6.0	рН	3.5 to 4.5	4.160
7.0	Uniformity of content	Not less than \$5.0% and not more than 115.0% of the	101.330
		labeled claim.	98.790
			101.580
			99.170
			101.040
			101.530
			101.110
			99.920
	$\wedge X$		101.550
			99.550
			Average- 100.557
			Minimum- 98.790

Domaila A. D.L., (Compt. ComplEment)							
	Remark: A - Release ( Country General Export )						
Comment: The	sample submitted Complies with the p	rescribed Finis	shed product specification FPS/16-1	7/0503 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		
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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 <b>RELEASED DATE</b> 14.02.2021				
PROCESS ORDER NO.	70005317	PACK SIZE	<b>A</b>		

SR.NO.	TEST	SPECIFICATION	RESULT
			Maximum- 101.580
8.0	Assay	<u>'</u>	
8.1	Tadalafil	Not less than 90.0% and not more than 110.0% of the	98.370 %
		labeled claim.	
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	Purple coloured, homogenised jelly, with sweet
		pleasant odour.	taste and pleasant odour.
			Complies
2.0	Identification	The retention time of the major peak in the chromatogram	The retention time of the major peak in the
		of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation
	$\wedge$	due to Tadalafil in the chromatogram of the standard	corresponds to that of the peak due to Tadalafil
		preparation, as obtained in the assay.	in the chromatogram of the standard preparation,
			as obtained in the assay.
	,		Complies

Remark: A - Release ( Country General Export )						
Comment: The	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	
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Printed By:	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.: 9 of	f 13	
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Format No. CQA/	Format No. CQA/F/160, Version:01 Reference SOP No. SOP/CQA/089					



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 <b>RELEASED DATE</b> 14.02.2021				
PROCESS ORDER NO.	70005317	PACK SIZE	<b>A.</b>		

SR.NO.	TEST	SPECIFICATION	RESULT
3.0	Average weight of	$6.2 \text{ g} \pm 5.0\%$	6.090 g
	filled sachets		
4.0	Average net filled	Not less than the labeled amount (5.0 g).	5.261 g
	weight per sachet		
5.0	Uniformity of weight	Not more than 2 of the individual weight of the contents	Min - 5.0854g, Max =5.3792 g
	(Mass)	deviate from the average net filled weight by more than	Avg = 5.2608 g
		7.5% and none deviates by more than 15%	Complies
6.0	рН	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	101.510
		labeled claim.	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	97.850
		labeled claim.	
	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

Domanlu A I	Remark: A - Release ( Country General Export )						
	· • • • • • • • • • • • • • • • • • • •			O			
Comment: The	sample submitted Complies with the p	rescribed Finis	shed product speci	tication FPS/16-1	7/0503 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: F	Pravin Kocheta	Printed On:	14.02.2021	9:52:06	Page No.: 10 (	of 13	
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SAMPLED BY	Abhijit Korde	SAMPLING DATE	25.01.2021		
SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021		
PROCESS ORDER NO.	70005317	PACK SIZE	<b>A</b>		

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

Remark: A - Release (Country General Export)						
Comment: The	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: I	Pravin Kocheta	Printed On :	14.02.2021 9:52:06	Page No.: 11 (	of 13	
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SAMPLED QTY.	175 SAH	RELEASED DATE	14.02.2021		
PROCESS ORDER NO.	70005317	PACK SIZE	<b>A</b>		

SR.NO.	TEST	SPECIFICATION	RESULT
7.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the	101.850
		labeled claim.	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	98.510 %
		labeled claim.	
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
		1	Complies
9.3.2	Salmonella	Absent	Absent
			Complies
9.3.3	S. aureus	Absent	Absent
	'		Complies
		· · · · · · · · · · · · · · · · · · ·	l .

Domanic A. Dologo (Country Conord Ernout)							
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	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		
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Format No. CQA/F	Format No. CQA/F/160, Version:01 Reference SOP No. SOP/CQA/089						

NAME OF THE SAMPLE	APCALIS SX ORAL JELLY 20 mg (Ta	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	A .	

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

