



UNI MEDICOLABS

WORKING COPY
Sign & Date: *[Signature]*
10/06/2022

Factory Plot No. 21-22, Pharmacy, Selaqui Dehradun-248011 (Uttarakhand).

Ph.: 0135-2698706, Fax: 0135-2698707

CERTIFICATE OF REVIEW FOR COMPLIANCE TO SPECIFICATION AND CODE OF GMP

MANUFACTURER: Unimedicolabs Dehradun

LICENCING AUTHORITY: FDA

LICENCE NO.: 74/UA/LL/2016

MAH/NDC No.: NA

PRODUCT NAME: Silagra-100

CODE NO.: 32007671

STRENGTH: Sildenafil citrate IP eq. to sildenafil
.. 100mg

PACK SIZE 40X10X4

PACKING BATCH NUMBER: N420275

MANUFACTURING BATCH NUMBER: N420268

MANUFACTURING DATE: JUN-22

EXPIRY DATE: MAY 25

NAME OF API MANUFACTURER: Rakshi + Drugs

BATCH SIZE: 4.50 lac

DISPATCH QUANTITY: 110400X4 Tabs

SAMPLE QUANTITY: a) Stability sample: ~~NA~~ 235X4 Tabs

EXPORT ORDER NO.: Domestic

b) Validation sample: NA

c) Other sample: 181X4 Tabs

YIELD OF BATCH: 98.50 %
(STD. Limit in %: 95.50-100.00 %)

THIS IS TO CERTIFY THAT THE BATCH DOCUMENTS HAVE BEEN REVIEWED BY QUALITY ASSURANCE PERSONNEL AND FOUND TO BE ACCEPTABLE TO PERMIT RELEASE FROM MANUFACTURER.

Document and processes review has assured that:

- No change has occurred in the formulation of the above batch for which registration has been approved (Current BMR/BPR). This includes the quality, grade and test methods of starting material used in this batch.
- The documentation of each step wise process from dispensing of raw material to final dosage form including in process and final product testing to specified limit, has been followed. The results of tests and records so documented have been compared to predetermined and specified limit and that they show no errors, omissions or anomalies.
- No deviations/OOT has occurred from predetermined tolerance for product yield and material reconciliation at each stage of process. Or with deviations/OOT assessed as having no effect on the quality of the finished product. Details of any such deviations are appended.
- Finished dosage form complies with finished product specification requirement in all respects.
- Operations have been carried out in accordance with the requirements of the country code of GMP (Schedule M / WHO GMP / TGA / MCC / USFDA / MHRA / EU GMP) or to the requirements of the equivalent Authority in the country of manufacturer.
- Reserve sample and complete records of testing are maintained and may be made available in case of any untoward medical reaction.
- Applicability of OOS , OOT , Deviation (mark if Yes and X for Not applicable)

Comments, if any: MLT Batch
Signature: *[Signature]*
Name: Sachin Kumar
Head Unit Quality:
Date: 29/06/2022

Remarks: Printed foil, carton, shipper initial
Send proof checked for overprinting
item code, MFL LN No and storage condition
& found satisfactory

Remarks: 200% Inspection as per SOP

Attachment: Certification of analysis for the batch

Printed foil → 02 A.R. Not used in batch
Inner carton → 02 A.R. Not used in batch
Outer carton → 02 A.R. Not used in batch
Page 1 of 1

x Entry Error
[Signature]
29/06/2022



UNI MEDICOLABS, DEHRADUN
QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product Name:	Silagra- 100		
Generic Name:	(Sildenafil Citrate Tablets IP)		
Product Code:	32007671	A. R. No. :	GIFP220232
Batch No.:	N420275	Pack Size/Type:	10x 04 Tablets
Batch Size:	4.5 LAC	Date of Sampling:	11/06/2022
Mfg. Date:	JUN.22	Sample Quantity:	148 Tablets
Exp. Date:	MAY 25	Sampled By:	Ankit
Specification No.:	1035-32021904, Version No:01	Mfg. Lic. No.:	74/UA/LL/2016
STP No.:	1035-32021904, Version No:01	Analysis initiated on:	13/06/2022
Manufacturer:	UNI MEDICOLABS	Release Date:	29/06/2022

S.No	TEST	SPECIFICATION			RESULTS
1.	Description	Violet coloured, Oval shaped, biconvex film coated tablets with deep score line on one side and plain on the other side.			Violet coloured, Oval shaped, biconvex film coated tablets with deep score line on one side and plain on the other side.
2.	Average weight	Not less than 0.347 g Not more than 0.383g. (0.365± 5%)			0.360 g
3.	Uniformity of weight	Not more than two of the individual weights deviate from the average weight by more than ± 5.0% of the average weight and none deviate by more than ± 10.0%			Complies (- 1.20 % to + 1.20 %)
4.	Identification (By High Performance Liquid Chromatography)	In the assay, The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution			In the assay, The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution
5.	Dissolution	Stage	No	Acceptance Criteria	
		S ₁	6	Each unit is not less than 70 %(D) +5% which is equivalent to 75% of the labeled claim released in 30 minutes.	

	Prepared	Checked By	Approved By
Signature			
Date	29/06/2022	29/06/2022	29/06/2022
Name	Aadesh Kumar	Gurunam Singh	Naveen Benjwal
Designation	Sr. Executive	Asst. Manager	Dy. Manager
Department	Quality Control	Quality Control	Quality Control



UNI MEDICOLABS, DEHRADUN
QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product Name:	Silagra- 100		
Generic Name:	(Sildenafil Citrate Tablets IP)		
Product Code:	32007671	A. R. No. :	GIFP220232
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Manufacturer:	UNI MEDICOLABS	Release Date:	29/06/2022

S.No	TEST	SPECIFICATION	RESULTS									
		<table border="1"> <tr> <td>S₂</td> <td>6</td> <td>If any unit fails to meet the S₁ acceptance criteria the test must be repeated on an additional 6 units and the following S₂ condition must be met.</td> <td rowspan="3">Not Applicable</td> </tr> <tr> <td colspan="2">S₂ stage-Condition I</td> <td>Average of 12 units(S₁+S₂) is equal to or greater than 70%(D)</td> </tr> <tr> <td colspan="2">S₂ stage-Condition II</td> <td>No unit is less than 55 % (D-15%)</td> </tr> </table>	S ₂	6	If any unit fails to meet the S ₁ acceptance criteria the test must be repeated on an additional 6 units and the following S ₂ condition must be met.	Not Applicable	S ₂ stage-Condition I		Average of 12 units(S ₁ +S ₂) is equal to or greater than 70%(D)	S ₂ stage-Condition II		No unit is less than 55 % (D-15%)
S ₂	6	If any unit fails to meet the S ₁ acceptance criteria the test must be repeated on an additional 6 units and the following S ₂ condition must be met.	Not Applicable									
S ₂ stage-Condition I		Average of 12 units(S ₁ +S ₂) is equal to or greater than 70%(D)										
S ₂ stage-Condition II		No unit is less than 55 % (D-15%)										
		<table border="1"> <tr> <td>S₃</td> <td>12</td> <td>If any unit fails to meet the S₂ acceptance criteria the test must be repeated on an additional 12 units and the following S₃ condition must be met.</td> <td rowspan="2">Not Applicable</td> </tr> <tr> <td colspan="2">S₃ stage-Condition I</td> <td>Average of 24 units(S₁+S₂ + S₃) is equal to or greater than 70%(D)</td> </tr> </table>	S ₃	12	If any unit fails to meet the S ₂ acceptance criteria the test must be repeated on an additional 12 units and the following S ₃ condition must be met.	Not Applicable	S ₃ stage-Condition I		Average of 24 units(S ₁ +S ₂ + S ₃) is equal to or greater than 70%(D)			
S ₃	12	If any unit fails to meet the S ₂ acceptance criteria the test must be repeated on an additional 12 units and the following S ₃ condition must be met.	Not Applicable									
S ₃ stage-Condition I		Average of 24 units(S ₁ +S ₂ + S ₃) is equal to or greater than 70%(D)										
		<table border="1"> <tr> <td>S₃ stage-Condition II</td> <td></td> <td>Not more than 2 units are less than 55% (D-15%)</td> <td rowspan="2">Not Applicable</td> </tr> <tr> <td>S₃ stage-Condition III</td> <td></td> <td>No unit is less than 45% (D-25%)</td> </tr> </table>	S ₃ stage-Condition II		Not more than 2 units are less than 55% (D-15%)	Not Applicable	S ₃ stage-Condition III		No unit is less than 45% (D-25%)			
S ₃ stage-Condition II		Not more than 2 units are less than 55% (D-15%)	Not Applicable									
S ₃ stage-Condition III		No unit is less than 45% (D-25%)										

	Prepared	Checked By	Approved By
Signature			
Date	29/06/2022	29/06/2022	29/06/2022
Name	Aadesh Kumar	Gurunam Singh	Naveen Benjwal
Designation	Sr. Executive	Asst. Manager	Dy. Manager
Department	Quality Control	Quality Control	Quality Control



UNI MEDICOLABS, DEHRADUN
QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product Name:	Silagra- 100		
Generic Name:	(Sildenafil Citrate Tablets IP)		
Product Code:	32007671	A. R. No. :	GIFP220232
Batch No.:	N420275	Pack Size/Type:	10x 04 Tablets
Batch Size:	4.5 LAC	Date of Sampling:	11/06/2022
Mfg. Date:	JUN.22	Sample Quantity:	148 Tablets
Exp. Date:	MAY 25	Sampled By:	Ankit
Specification No.:	1035-32021904, Version No:01	Mfg. Lic. No.:	74/UA/LL/2016
STP No.:	1035-32021904, Version No:01	Analysis initiated on:	13/06/2022
Manufacturer:	UNI MEDICOLABS	Release Date:	29/06/2022

S.No	TEST	SPECIFICATION	RESULTS
6.	Related Substances (By High Performance Liquid Chromatography)		
	Single maximum unknown impurity	Not more than 0.80%	BDL
	N-Oxide impurity	Not more than 1.0%	NOT DETECTED
	Total impurities	Not more than 2.0%	BDL
7.	Assay : (By HPLC) Content of Sildenafil Citrate (C ₂₈ H ₃₈ N ₆ O ₁₁ S) is equivalent to Sildenafil in mg per tablet	Not less than 90.0 mg and Not more than 110.0 mg per tablet (Not less than 90.0% and Not more than 110.0% of the labeled claim)	98.8 mg 98.8 %
8.	Microbial enumeration tests		
	(i) Total Aerobic microbial count	Not more than 10 ³ cfu per gm	<10 Cfu per gm
	(ii) Total combined yeast and moulds	Not more than 10 ² cfu per gm	<10 Cfu per gm
	Test for specified microorganism Escherichia coli	Should be absent per g	Absent/g

Remarks: Product complies / ~~does not comply~~ with the prescribed standard of quality with respect to above tests as per specification no. 1035-32021904, 1035-32021904-01 version no.01.

RELEASED BY QA
Signature: Aashu
Date: 29/06/2022

	Prepared	Checked By	Approved By
Signature			
Date	29/06/2022	29/06/2022	29/06/2022
Name	Aadesh Kumar	Gurnam Singh	Naveen Benjwal
Designation	Sr. Executive	Asst. Manager	Dy. Manager
Department	Quality Control	Quality Control	Quality Control

Each film-coated tablet contains Sildenafil Citrate IP equivalent to Sildenafil 100 mg

Colours: Titanium Dioxide IP, Lake Indigo Carmine, Lake Erythrosine & Lake Ponceau 4R

® Registered Trademark
Mfd. by Cipla LTD.
Cipla Plot No. 21-22, Pharmacy, Selagui, Dehradun - 248 014, Uttarakhand.

Warning: To be sold by retail on the prescription of a Urologist/Psychiatrist/Endocrinologist/Dermatologist/Venereologist only.
M.L. 74/UALL/2018 21076666

SCHEDULE H PRESCRIPTION DRUGS
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Rx Sildenafil Citrate Tablets IP

Silagra-100

फायरफ़्लैम १००

Each film-coated tablet contains Sildenafil Citrate IP equivalent to Sildenafil 100 mg

Colours: Titanium Dioxide IP, Lake Indigo Carmine, Lake Erythrosine & Lake Ponceau 4R

Dosage: As directed by the Physician
Store below 30°C. Protect from moisture.
Keep away from children

SCHEDULE H PRESCRIPTION DRUGS - CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner

Warning: To be sold by retail on the prescription of a Urologist/Psychiatrist/Endocrinologist/Dermatologist/Venereologist only.

**B.NO. N420275
MFD. JUN. 2015
EXP. MAY 2016
M.R.P. RS. 159.50
4 TABS. (INCL. OF ALL TAXES)**

SILAGRA-100 SILAGRA-100 SILAGRA-100

M.R.P. Rs. for 4 tablets (Incl. of All Taxes)

RS.159.50

B.NO.N420275

MFD.JUN.22

EXP.MAY 25

WORKING COPY
Sign & Date
(QA Officer) 29/06/2022

Cipla
Vikhroli

Location: Uni Medical Labs Dehradun

Suhagra-100 **PACK STOCK INSPECTION CHECKLIST (Blister/Strip/Containers)** Tablets/ Hard gelatin/ Soft gelatin Capsules
 Previous Product Name: Suhagra-100 * Previous Batch No: NU102778N410265 Line No: (111)
 Product Name: Suhagra-100 Batch No: N420275 Mfg. Date: JUN 22 Exp. Date: MAY 25
 EXPORT/LOCAL: Local Date of Inspection: from 21/06/2022 to 23/06/2022

Sr. No	Defects	Shipper No.									
		01	02	03	45	08	125	175	234	275	276
1	Shipper Top/Bottom taping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
2	Shipper Overprinting/Labeling	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
3	Shipper Fill Value	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4	4x10x4
4	Packer Name	Kaanti	Kaanti	Kaanti	Kaanti	Kaanti	Kaanti	Kajal	Kajal	Kajal	Kajal
5	Bundling/Pouch Quality	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
6	Outer Carton overprinting/container label	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
7	Inner carton/ container label Overprinting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
8	Cracked tablets/Half tablet	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
9	Deformed capsules/Capsules without lid	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
10	Blister & Strip Overprinting/Smudging/Embossing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
11	Missing units/Extra Units in Blister or Strip	Nil	Nil	Nil	Nil	Nil	Nil	Nil	NA	Nil	Nil
12	Missing leaflet/Enclosures	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
13	Broken Tablet/Capsule	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
14	Black Spot/ Black Particle and Extraneous matter in pocket/Powder in pocket	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Chipping/Picking	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Brittle/Dented/Telescopic capsules	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
17	Blister/Strip wrinkles/ improper knurling	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Sealing Defects	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
19	Other defects	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
20	Total Defects	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
21	Shipper weight of each shipper after inspection	3.395	3.395	3.405	3.395	3.410	3.4105	3.415	3.395	3.410	3.410
22	Total Replaced Units	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
23	Done By	Mishra	Mishra	Mishra	Mishra	Mishra	Mishra	Mishra	Mishra	Mishra	Mishra
24	Checked By										

Cipla
 Controlled Copy
 Sign: [Signature]
 Date: 05.06.2022

(For export mention the export order no.)
 Total Shippers Packed in Batch: 276 Certified By: [Signature] 29/06/2022 (Packing Officer) Rechecked By: [Signature] 29/06/2022 (QA Officer) * Entry Entry Mishra 21/06/2022
 Total Shipper Checked in Batch: 10
 Action Plan for Defects: NA
 Corrective and Preventive Action: NA
 [For details CAPA attach separate sheet with Pack Stock Inspection Checklist as Annexure]
 Decision for further pack stock inspection: No Further Pack Stock Required
 Approved By: [Signature] 29/06/2022 (Unit Quality Assurance Head)
 (CQA-313/F/12)

266

wt 3.400kg

SILAGRA 100 TABS.

B.No.N420275

EXP.MAY 25

QTY. 40 x 10 x 4

Cipla

CIPLA LTD.

CIPLA HOUSE, PBP, LOWER PAREL, MUMBAI 400 013

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