JFRL

分析試験成績書

第 19085183001-0201 号
2019年08月27日

依　頼　者　ユナイテッドクリニック

検　体　名　Minoxidil tablet 5mg

一般財団法人
日本食品分析センター
東京都渋谷区元代々木町52番1号

2019年07月22日　当センターに提出された上記検体について分析試験した結果は次のとおりです。

分析試験結果

分　析　試　験　項　目	結　　果	定量下限	注	方　　法
ﾐﾉｷｼｼﾞﾙ	4.8 mg/粒	.....		高速液体ｸﾛﾏﾄｸﾞﾗﾌｨｰ
一粒の重さ	0.124 g	.....		.....

100g当たりの結果から計算した。

以　上

JFRL

分析試験成績書

第 19085183002-0201 号
2019年08月27日

依　頼　者　ユナイテッドクリニック

検　体　名　Minoxidil tablet 10mg

一般財団法人
日本食品分析センター
東京都渋谷区元代々木町52番1号

2019年07月22日　当センターに提出された上記検体について分析試験した結果は次のとおりです。

分析試験結果

分　析　試　験　項　目	結　　果	定量下限	注	方　　法
ﾐﾉｷｼｼﾞﾙ	10 mg/粒	……		高速液体ｸﾛﾏﾄｸﾞﾗﾌｨｰ
一粒の重さ	0.129 g	……		……

100g当たりの結果から計算した。

以　上

JFRL

分析試験成績書

第 19082139001-0101 号
2019年08月16日

依　頼　者　ユナイテッドクリニック

検　体　名　Minoxidil 5

一般財団法人
日本食品分析センター
東京都渋谷区元代々木町52番1号

2019年07月16日 当センターに提出された上記検体について分析試験した結果は次のとおりです。

分析試験結果

分析試験項目	結果	定量下限	注	方法
ﾐﾉｷｼｼﾞﾙ	5.1 g/100g	----		高速液体ｸﾛﾏﾄｸﾞﾗﾌｨｰ

以　上

JFRL

分析試験成績書

第 19082139002-0101 号
2019年08月16日

依 頼 者　ユナイテッドクリニック

検 体 名　Minoxidil 15

一般財団法人
日本食品分析センター
東京都渋谷区元代々木町52番1号

2019年07月16日 当センターに提出された上記検体について分析試験した結果は次のとおりです。

分析試験結果

分析試験項目	結果	定量下限	注	方法
ﾐﾉｷｼｼﾞﾙ	16 g/100g	----		高速液体ｸﾛﾏﾄｸﾞﾗﾌｨｰ

以 上

Test Report

Date : 2018-06-01
No. : HC18051277

Applicant (Code:01311126): Succeed Holdings Ltd
荃灣沙咀道 1-9 號永南貨倉大廈 18 樓

Description of Sample(s) : One submitted sample said to be Orlifast 120mg 2x21 capsules.
Batch / Lot No.: 7E190B
Exp Date : 06/2020
Country of Origin : Philippines

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2018-05-25

Date Tested : 2018-05-30 to 2018-05-31

Investigation Requested : Orlistat

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Orlistat	121.8 mg/capsule

Note : Average filled weight per capsule : 0.2373g

KWOK Nga Yan, Bernice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

******* End of Test Report *******

STC Test Report

Date : 2015-09-08
No. : HC373862

Applicant (Code: SUH017) : Succeed Holdings Ltd
荃灣沙咀道 1-9 號永南貨倉大廈 18 樓

Description of Sample(s) : One submitted sample said to be Tadacip.
Batch / Lot No.: BT4041
Pack Size : 4 tablets/box
Exp Date : Jan 16
Country of Origin : India

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2015-08-28

Date Tested : 2015-09-04

Investigation Requested : Tadalafil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Tadalafil	20.3 mg/tablet

Note: Average weight= 0.3457 g/tablet

TAM Leong Hang, Anthony
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 E-mail : hkstc@hkstc.org Website: www.stc-group.org

SUNRISE REMEDIES PVT. LTD.

Formerly named as : SUNRISE REMEDIES PRIVATE LIMITED
BLOCK NO. 2244,,OPP. SHAH ALLOYS LTD.,TAL.: KALOL,,SANTEJ-382721
REG.OFF.: 104, SAHJANAND COMPLEX,,NR. THALTEJ CROSS ROAD,,S.G.HIGHWAY,,AHMEDABAD-380059
C.I.No. : U24231GJ1996PTC028804

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: TADARISE-20 TABLET			A.R. No.	: FPE180218
Packing	: 10x10 TAB				
Generic Name	: TADALAFIL TABLET 20 MG			Rel. Dt.	: 10-10-2018
				T.R. Slip No.	: PAQA180597
Product Code	: TADA11	Mfg. Dt.	: 30/09/2018	T.R. Slip Dt.	: 09-10-2018
Batch No.	: T22918	Exp. Dt.	: 31/08/2021	Analysis Date	: 10-10-2018
Actual Batch Size	: 250000 TAB	Test Packing	: 60 TAB	Specification No.	: FPSP/TADA11/00
Packing Batch Size	: 250000 TAB	Mfg. Lic No.	: G/1428		
Sample Size	: 60.000 TAB			STP No.	: MOA/TADA11/00
Released Qty	: 250000.000 TAB	Test As Per	: IH		
				Location	: SANTEJ
				Make	: SUNRISE

Sr.	Test	Result	Specification
1	DESCRIPTION	GOLDEN COLOURED FILMCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN	GOLDEN COLOURED FILMCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN
2	WEIGHT OF 20 TABLETS	6.8520 GM	6.8680 GM ± 5 %
3	AVERAGE WEIGHT (TABLETS)	342.6 MG	343.40 mg ± 5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 5%
5	DISINTEGRATION TIME	02 MIN 24 SEC	NOT MORE THAN 30 MINUTE
6	THICKNESS	4.13 MM	BET. 4.0 MM TO 5.0 MM
7	HARDNESS	4.0 KG/CM²	NOT LESS THAN 3.0 KG/CM²
8	IDENTIFICATION	COMPLIES	COMPLY THE TEST
• 9	ASSAY	RESULT LABEL CLAIM 19.45 MG 20.0MG 97.25%	Each film coated tab contains : Tadalafil 20MG [Limit : 18.0 MG TO 22.0 MG] [BET 90.0% TO 110.0%]
10	FRIABILITY	0.027 %	NMT 1.0 %
11	DISSOLUTION	AFTER 10 MIN : 46.57 % AFTER 30 MIN : 85.0 %	NOT LESS THAN 80 %

Conclusion : The above sample complies as per IH
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

ANALYSIS BY
DILIP B VALA
LAB CHEMIST

UNCONTROLLED COPY
Sign
Date 19/06/19

APPROVED BY
MANISH B MODH
MANAGER Q.A & Q.C.

FGANLCERT

(1)

STC Test Report

Date : 2015-03-16
No. : HC361308

Applicant (Code: SUH017) : Succeed Holdings Ltd
Workshop I, J, K, L Superluck Ind Ctr Phase II
57 Sha Tsui Rd
Tsuen Wan NT HK

Description of Sample(s) : One submitted sample said to be Sildenafil 100mg Film-coated Tablets.
Batch / Lot No.: 3027971E
Pack Size : 4 tablets/box
Country of Origin : France

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2015-03-12

Date Tested : 2015-03-16

Investigation Requested : Sildenafil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Sildenafil 100mg Film-coated Tablets
Sildenafil	99.0 mg/tablet

Note: Average weight= 0.6290 g/tablet

KWOK Nga Yan, Bernice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

(2)

STC Test Report

Date : 2015-09-08
No. : HC373860

Applicant(Code: SUH017) : Succeed Holdings Ltd
荃灣沙咀道 1-9 號永南貨倉大廈 18 樓

Description of Sample(s) : One submitted sample said to be Xenical 42 Cap.
Batch / Lot No.: M2087M3
Pack Size : 42 capsules
Exp Date : Jan 16
Country of Origin : Italy

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2015-08-28

Date Tested : 2015-09-02

Investigation Requested : Orlistat

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Orlistat	120 mg/capsule

Note : Average weight per capsule : 0.2435g

TAM Leong Hang, Anthony
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 E-mail : hkstc@hkstc.org Website: www.stc-group.org

(3)

STC Test Report

Date : 2015-03-23
No. : HC361381

Applicant (Code: SUH017) : Succeed Holdings Ltd
Workshop I, J, K, L Superluck Ind Ctr Phase II
57 Sha Tsui Rd
Tsuen Wan NT HK

Description of Sample(s) : One submitted sample said to be KAMAGRA-100 Gold.
Batch / Lot No.: AK0034G
Pack Size : 4 tablets/box
Country of Origin : Mumbai

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2015-03-13

Date Tested : 2015-03-23

Investigation Requested : Sildenafil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	KAMAGRA-100 Gold
Sildenafil	100.3 mg/tablet

Note: Average weight= 0.5047 g/tablet

TAM Leong Hang, Anthony
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

(4)

STC Test Report

Date : 2016-08-04
No. : HC393193

Applicant(Code: SUH017) : Succeed Holdings Ltd
荃灣沙咀道 1-9 號永南貨倉大廈 18 樓

Description of Sample(s) : One submitted sample said to be Noxidil Tablets.
Batch / Lot No.: 8136019
Pack Size : 100 tablets/bottle
Country of Origin : Thai

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2016-07-26

Date Tested : 2016-08-03

Investigation Requested : Minoxidil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Minoxidil	5.01 mg/tablet

* Average weight per tablet : 0.12497g

TAM Leong Hang, Anthony
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

STC Test Report

Date : 2016-08-04
No. : HC393194

Applicant(Code: SUH017) : Succeed Holdings Ltd
荃灣沙咀道 1-9 號永南貨倉大廈 18 樓

Description of Sample(s) : One submitted sample said to be Noxidil Forte Tablets.
Batch / Lot No.: 8137025
Pack Size : 100 tablets/bottle
Country of Origin : Thai

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2016-07-26

Date Tested : 2016-08-03

Investigation Requested : Minoxidil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Minoxidil	9.68 mg/tablet

* Average weight per tablet : 0.1288g

TAM Leong Hang, Anthony
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 E-mail : hkstc@hkstc.org Website: www.stc-group.org

(6)

STC Test Report

Date : 2012-08-01
No. : HC305084

Applicant (Code: SUH017) : Succeed Holdings Ltd
7/F Workshop I-L Superluck Ind Centre (Phase II)
57 Sha Tsui Rd
Tsuen Wan NT HK

Description of Sample(s) : One submitted sample said to be Finalo.
Country of Origin : India

Sample(s) Received Condition: In plastic container under ambient temperature

Date Sample(s) Received : 2012-07-20

Date Tested : 2012-07-30

Investigation Requested : Finasteride

Method(s) Used : High Performance Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Finalo
Finasteride	1.00 mg/tablet

Note: Average weight = 0.1546g/tablet

KWOK Nga Yan, Bernice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

STC Test Report

Date : 2018-02-28
No. : HC18020495

Applicant(Code: 01311126)

Description of Sample(s) : One submitted sample said to be LEVITRA 20mg.
Batch / Lot No.: BXHCHE1
Exp : 09/2019
Country of Origin : Germany

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2018-02-15

Date Tested : 2018-02-27

Investigation Requested : Vardenafil

Method(s) Used : High Performance Liquid Chromatography

Test Result(s) :

Test Item(s)	Result
Vardenafil	19.8 mg/tablet

Average weight per tablet : 0.1882g

Kwok Nga Yan, Bernice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

***** End of Test Report *****

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 E-mail : hkstc@hkstc.org Website: www.stc-group.org

(8)

Test Report

Date : 2018-12-11
No. : HC18111232

Applicant (Code:01311126): Succeed Holdings Limited
香港新界青衣青衣航運路36號亞洲物流中心順豐大廈11樓2室

Description of Sample(s) : One submitted sample said to be Regrowth Labs M5 60ml.
Batch / Lot No.: W6810302A
Exp Date : 2020/11
Country of Origin : USA

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2018-11-30

Date Tested : 2018-12-04

Investigation Requested : Minoxidil

Method(s) Used : Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Result
Minoxidil	5.21% w/v

Density : 0.9893 g/ml

Alice

CHOW Hoi Yi, Alice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

******* End of Test Report *******

(9)

Test Report

Date : 2019-01-24
No. : HC19010730

Applicant(Code:01311126) : Succeed Holdings Limited
香港新界青衣青衣航運路 36 號亞洲物流中心順豐大廈 11 樓 2 室

Description of Sample(s) : One submitted sample said to be Regrowth Labs M15 60ml.
Batch / Lot No.: W6812173A
Exp : 12/2020
Country of Origin : USA

Sample(s) Received Condition(s): In intact original package under ambient temperature

Date Sample(s) Received : 2019-01-15

Date Tested : 2019-01-23

Investigation Requested : Minoxidil

Method(s) Used : Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Result
Minoxidil	16.84% (w/v)

Density: 1.0558g/ml

Alice

CHOW Hoi Yi, Alice
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

******* End of Test Report *******

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 E-mail hksto@stc.group Website: www.stc.group

PAREX PHARMACEUTICALS PVT.LTD

D-145, Industrial Area Phase-7.S.A.S.Nagar (Mohali)-160055 INDIA

CERTIFICATE OF ANALYSIS

Sample : Sildigra 100 tablet Mfd by : M/s Parex Pharmaceuticals Pvt.Ltd Received from –do-				Report no. 19-20/19 Ref.no.19 Recd. On. 16/04/19
Batch no.	D/M	D/E	Batch size	Sample qty.
S-57	04/2019	03/2022	1,82,000 tablets	100 tablets
RESULT OF ANALYSIS				
Reference of protocol applied : FG-12				

Chemical test

1. Description – Blue coloured diamond shaped coated tablet in blister pack.
2. Avg. weight - 485mg
3. Hardness – 4.9kg/cm^2
4. Friability - 0.21 %
5. Assay – Each coated tablet contains:

	Result	claim	%age
Sildenafil citrate	99.91mg	100mg	99.91%

Eq.to Sildenafil

REPORT: The sample received complies/ ~~does not comply~~ with the prescribed standards of quality as per IP/BP/USP.

Date: 16/04/2019

Authorised signatory

PAREX PHARMACEUTICALS PVT.LTD

D-145, Industrial Area Phase-7.S.A.S.Nagar (Mohali)-160055 INDIA

CERTIFICATE OF ANALYSIS

Sample : Sildigra 100 Tablet Mfd by : M/s Parex Pharmaceuticals Pvt.Ltd Received from –do-			Report no. 19-20/28 Ref.no.28 Recd. On. 24/04/19	
Batch no.	D/M	D/E	Batch size	Sample qty.
S-58	04/2019	03/2022	47,000 Tablets	100 tablets
RESULT OF ANALYSIS				
Reference of protocol applied : FG-12				

Chemical test

1. Description – Blue coloured diamond shaped film coated tablet in blister pack.
2. Avg. weight - 488mg
3. Hardness – 5kg/cm^2
4. Friability - 0.20%
5. Assay – Each film coated tablet contains:

	Result	claim	%age
Sildenafil citrate	99.9mg	100mg	99.9%

Eq.to Sildenafil

REPORT: The sample received complies/ ~~does not comply~~ with the prescribed standards of quality as per IP/BP/USP.

Date: 24/04/2019

Authorised signatory

PAREX PHARMACEUTICALS PVT.LTD

D-145, Industrial Area Phase-7.S.A.S.Nagar (Mohali)-160055 INDIA

CERTIFICATE OF ANALYSIS

Sample : Sildigra 50 Tablet Mfd by : M/s Parex Pharmaceuticals Pvt.Ltd Received from –do-			Report no. 19-20/04 Ref.no.04 Tested. On. 03/04/19	
Batch no.	D/M	D/E	Batch size	Sample qty.
ST-34	04/2019	03/2022	95,000 Tablets	100 tablets
RESULT OF ANALYSIS				
Reference of protocol applied : FG-11				

Chemical test

1. Description – Blue colored diamond shaped film coated tablet in blister pack.
2. Avg. weight - 501mg
3. Hardness – 5.5kg/cm^2
4. Assay – Each film coated tablet contains:

	Result	claim	%age
Sildenafil citrate	49.68mg	50mg	99.37%

Eq.to Sildenafil

REPORT: The sample received complies/ ~~does not comply~~ with the prescribed standards of quality as per IP/BP/USP.

Date: 03/04/2019

Authorised signatory

Subject to Mumbai Court Jurisdiction only

ESTD : 1985

PARALAB PRIVATE LTD.

F.D.A. Mumbai-Maharashtra Approved Public Testing Lab

ANALYTICAL TESTING OF PHARMACEUTICALS, FOODS, AYURVEDIC, PESTICIDE, COSMETICS, CHEMICALS, WATER, EFFLUENT.

202, 203 Triumph House Near Express Zone Tower, Off. Western Express Highway, Goregaon (East), Mumbai-400 063. INDIA.

PARALAB Lab. Tel.: 022-6525 7704 / 2873 0805 / 2874 2719 Mob.: 09819783494, 09321212149 E-mail : paralab_2005@yahoo.com, info@paralab.in, Web : www.Paralab.in

Our Valid FDA Approval. No.: TL-35

THE DRUGS AND COSMETICS ACT, 1940 AND THE RULES THERE UNDER (C.O.A.)

FORM [39 See Rule 150-E (f)]

ANALYSIS REPORT NUMBER (C.O.A.): D0809/007/19

Report of Test or Analysis By Approved Institution

ANALYSIS REPORT DATE: 20/08/2019

1. Party's Name & Address (From Whom Sample is Received)	Name of the Manufacturer / Supplier from whom R. M. is received by the party name or address of / can Licensee (As Applicable)	Valid F.D.A. Mfg. / RPG Lic. No.
SEVENTH SKY 124,GR.FLOOR, GODOWN. CAMA DOWN DYANAND SARASWATI CHOWK MINT ROAD FORT	NS	PB/DRUGS/T 562-OSP

2. Reference number and date of the letter from the manufacturer / party under which the sample is received (submitted sample is drawn by the party, and not drawn nor in the presence of Paralab.)	3. Date of receipt of the sample submitted at PARALAB	4. Quantity of the sample received
NIL DT 05/08/2019	09/08/2019	5X10 TABLETS

5. Name of drugs / Cosmetics / Raw Material / Finished Product Purporting obtained in the submitted sample of technical name of raw Material / Finished Product Formulation: SILDIGRA 50 MG

6. Details of Raw Materials / Final product (in bulk) final product (in finished pack) as obtained from the Manufacturer (AS UNDER)

(A) Original Manufacturer's name (in case of Raw Material)	(B) Batch No./Lot No of the submitted sample	Batch size as represented by the submitted sample	(D) Date of Mfg. of the submitted sample	(E) Date of expiry / use before of the submitted sample
NA	ST-35	NS	06/2019	05/2022

ANALYSIS REQUIRED BY THE PARTY: IDENTIFICATION, AVERAGE WEIGHT, ASSAY

Result of test or Analysis with protocols of test or Analysis applied: IP Under Sildenafil Citrate Tablets

1 Description : Blue coloured tetragonal biconvex film coated tablet with 50mg mark on one side of each tablet

2 Average weight of a tablet : 0.4999gm

3 Identification Test for sildenafil citrate : Test complies

4 Composition

	EA	LA	%LA
Each film coated tablet contains Sildenafil citrate eq to Sildenafil	50.37mg	50mg	100.74% (Limit 90% to 110%)

The sample complies w.r.t above noted test

2008 sm

OPINION : In the opinion of the undersigned, the sample referred to above IS OF STANDARD QUALITY as defined in the Act and the Rules thereunder for the reason given below.

The sample complies with prescribed standard IP Under Sildenafil Citrate

Subject to terms & Conditions Mentioned Overleaf

(Signature of the person in-charge of testing)

PARALAB (P) LTD. MUMBAI-63

CHEMICAL (Wet Chemistry) LAL (Bacterial Endotoxin) R.I. DETECTOR MICRO STERILITY FTIR HPLC AAS Stability And Environmental Studies G.C.

Subject to Mumbai Court Jurisdiction only

ESTD : 1985

PARALAB PRIVATE LTD.

F.D.A. Mumbai-Maharashtra Approved Public Testing Lab

ANALYTICAL TESTING OF PHARMACEUTICALS, FOODS, AYURVEDIC, PESTICIDE, COSMETICS, CHEMICALS, WATER, EFFLUENT,

292, 293 Triumph House Near Express Zone Tower, Off. Western Express Highway, Goregaon (East), Mumbai-400 063. INDIA.
Lab. Tel.: 022-6525 7704 / 2873 0805 / 2874 2719 Mob.: 09819783494, 09321212149 E-mail : paralab_2005@yahoo.com, info@paralab.in, Web : www.Paralab.in

PARALAB

Our Valid FDA Approval. No.: TL-35

THE DRUGS AND COSMETICS ACT. 1940 AND THE RULES THERE UNDER (C.O.A.)

FORM [39 See Rule 150-E (f)]

ANALYSIS REPORT NUMBER (C.O.A.) D0809/006/19

Report of Test or Analysis By Approved Institution

ANALYSIS REPORT DATE 20/08/2019

1. Party's Name & Address (From Whom Sample is Received)	Name of the Manufacturer / Supplier from whom R. M. is received by the party name or address of Loan Licensee (As Applicable)	Valid F.D.A. Mfg. / RPG Lic. No.
SEVENTH SKY 124,GR.FLOOR, GODOWN. CAMA DOWN DYANAND SARASWATI CHOWK MINT ROAD FORT	NS	PB/DRUGS/T 562-OSP

2. Reference number and date of the letter from the manufacturer / party under which the sample is received (submitted sample is drawn by the party, and not drawn nor in the presence of Paralab.)	3. Date of receipt of the sample submitted at PARALAB	4. Quantity of the sample received
NIL DT 05/08/2019	09/08/2019	5X10 TABLETS

5. Name of drugs / Cosmetics / Raw Material / Finished Product Purporting obtained in the submitted sample of technical name of raw Material / Finished Product Formulation. SILDIGRA 100 MG

6. Details of Raw Materials / Final product (in bulk) final product (in finished pack) as obtained from the Manufacturer (AS UNDER)

(A) Original Manufacturer's name (in case of Raw Material)	(B) Batch No./Lot No of the submitted sample	Batch size as represented by the submitted sample	(D) Date of Mfg. of the submitted sample	(E) Date of expiry / use before of the submitted sample
NA	S-63	NS	06/2019	05/2022

ANALYSIS REQUIRED BY THE PARTY: IDENTIFICATION, AVERAGE WEIGHT, ASSAY

Result of test or Analysis with protocols of test or Analysis applied: IP Under Sildenafil Citrate Tablets

1 Description : Blue coloured tetragonal biconvex film coated tablet with 100mg mark on one side of each tablet

2 Average weight of a tablet : 0.5032gm

3 Identification Test for sildenafil citrate : Test complies

4 Composition

	EA	LA	%LA
Each film coated tablet contains Sildenafil citrate eq to Sildenafil	96.70mg	100mg (Limit 90% to 110%)	96.70%

The sample complies w.r.t above noted test
2008 sm

OPINION : In the opinion of the undersigned, the sample referred to above IS OF STANDARD QUALITY as defined in the Act and the Rules thereunder for the reason given below.

The sample complies with prescribed standard IP Under Sildenafil Citrate

Subject to terms & Conditions Mentioned Overleaf

(Signature of the person in charge of testing)

PARALAB (P) LTD. MUMBAI

CHEMICAL (Wet Chemistry) LAL (Bacterial Endotoxin) R.I. DETECTOR MICRO STERILITY FTIR HPLC AAS Stability And Environmental Studies G.C.

Subject to Mumbai Court Jurisdiction only

ESTD : 1985

PARALAB PRIVATE LTD.

F.D.A. Mumbai-Maharashtra Approved Public Testing Lab

ANALYTICAL TESTING OF PHARMACEUTICALS, FOODS, AYURVEDIC, PESTICIDE, COSMETICS, CHEMICALS, WATER, EFFLUENT,

202, 203 Triumph House Near Express Zone Tower, Off. Western Express Highway, Goregaon (East), Mumbai-400 063. INDIA.

PARALAB Lab. Tel.: 022-6525 7704 / 2873 0505 / 2874 2719 Mob.: 09819783494, 09321212149 E-mail : paralab_2005@yahoo.com, info@paralab.in, Web : www.Paralab.in

Our Valid FDA Approval. No.: TL-35

THE DRUGS AND COSMETICS ACT. 1940 AND THE RULES THERE UNDER (C.O.A.)

FORM [39 See Rule 150-E (f)]

ANALYSIS REPORT NUMBER (C.O.A.): D0809/010/19

Report of Test or Analysis By Approved Institution

ANALYSIS REPORT DATE: 20/08/2019

1. Party's Name & Address (From Whom Sample is Received)	Name of the Manufacturer / Supplier from whom R. M. is received by the party name or address of Loan Licensee (As Applicable)	Valid F.D.A. Mfg. / RPG Lic. No.
SEVENTH SKY 124,GR.FLOOR, GODOWN. CAMA DOWN DYANAND SARASWATI CHOWK MINT ROAD FORT	SUNRISE	GUJ/DRUG/2 5/1428

2. Reference number and date of the letter from the manufacturer / party under which the sample is received (submitted sample is drawn by the party, and not drawn nor in the presence of Paralab.)	3. Date of receipt of the sample submitted at PARALAB	4. Quantity of the sample received
NIL DT 05/08/2019	09/08/2019	5X10 TABLETS

5. Name of drugs / Cosmetics / Raw Material / Finished Product Purporting obtained in the submitted sample of technical name of raw Material / Finished Product Formulation: TADARISE 20 MG

6. Details of Raw Materials / Final product (in bulk) final product (in finished pack) as obtained from the Manufacturer (AS UNDER)

(A) Original Manufacturer's name (in case of Raw Material)	(B) Batch No./Lot No of the submitted sample	Batch size as represented by the submitted sample	(D) Date of Mfg. of the submitted sample	(E) Date of expiry / use before of the submitted sample
NA	T21818	NS	08/2018	07/2021

ANALYSIS REQUIRED BY THE PARTY: IDENTIFICATION, AVERAGE WEIGHT, ASSAY

Result of test or Analysis with protocols of test or Analysis applied: IP Under Tadalafil Tablets

1 Description : Yellowish brown coloured oval shape film coated tablets

2 Average weight of a tablet : 0.3532gm

3 Identification Test for Tadalafil : Test complies

4 Composition

	EA	LA	%LA
Each film coated tablet contains Tadalafil	19.03mg	20mg	95.17% (Limit 90% to 110%)

The sample complies w.r.t above noted test

2008 sm

OPINION : In the opinion of the undersigned, the sample referred to above IS OF STANDARD QUALITY as defined in the Act and the Rules thereunder for the reason given below.

The sample complies with prescribed standard

IP Under Tadalafil Tablets

CHEMICAL (Wet Chemistry) LAL (Bacterial Endotoxin) R.I. DETECTOR MICRO STERILITY FTIR HPLC AAS Stability And Environmental Studies G.C.

Subject to Mumbai Court Jurisdiction only

ESTD : 1985

PARALAB PRIVATE LTD.

F.D.A. Mumbai-Maharashtra Approved Public Testing Lab

ANALYTICAL TESTING OF PHARMACEUTICALS, FOODS, AYURVEDIC, PESTICIDE, COSMETICS, CHEMICALS, WATER, EFFLUENT,

202, 203 Triumph House Near Express Zone Tower, Off. Western Express Highway, Goregaon (East), Mumbai-400 063. INDIA.

PARALAB Lab. Tel.: 022-6525 7704 / 2873 0805 / 2874 2719 Mob : 09819783494, 09321212149 E-mail : paralab_2005@yahoo.com, info@paralab.in, Web : www.Paralab.in

Our Valid FDA Approval. No.: TL-35

THE DRUGS AND COSMETICS ACT. 1940 AND THE RULES THERE UNDER (C.O.A.)

FORM [39 See Rule 150-E (f)]

ANALYSIS REPORT NUMBER (C.O.A.) D0809/009/19

Report of Test or Analysis By Approved Institution

ANALYSIS REPORT DATE 20/08/2019

1. Party's Name & Address (From Whom Sample is Received)	Name of the Manufacturer / Supplier from whom R. M. is received by the party name or address of Loan Licensee (As Applicable)	Valid F.D.A. Mfg. / RPG Lic. No.
SEVENTH SKY 124,GR.FLOOR, GODOWN. CAMA DOWN DYANAND SARASWATI CHOWK MINT ROAD FORT	SUNRISE	GUJ/DRUG/2 5/1428

2. Reference number and date of the letter from the manufacturer / party under which the sample is received (submitted sample is drawn by the party, and not drawn nor in the presence of Paralab.)	3. Date of receipt of the sample submitted at PARALAB	4. Quantity of the sample received
NIL DT 05/08/2019	09/08/2019	5X10 TABLETS

5. Name of drugs / Cosmetics / Raw Material / Finished Product Purporting obtained in the submitted sample of technical name of raw Material / Finished Product Formulation. **TADARISE 10 MG**

6. Details of Raw Materials / Final product (in bulk) final product (in finished pack) as obtained from the Manufacturer (AS UNDER)

(A) Original Manufacturer's name (in case of Raw Material)	(B) Batch No./Lot No of the submitted sample	Batch size as represented by the submitted sample	(D) Date of Mfg. of the submitted sample	(E) Date of expiry / use before of the submitted sample
NA	T11417	NS	04/2017	03/2020

ANALYSIS REQUIRED BY THE PARTY: IDENTIFICATION, AVERAGE WEIGHT, ASSAY

Result of test or Analysis with protocols of test or Analysis applied: IP Under Tadalafil Tablets

1 Description	: Yellowish brown coloured oval shape film coated tablets		
2 Average weight of a tablet	: 0.3525gm		
3 Identification Test for Tadalafil	: Test complies		
4 Composition	EA	LA	%LA
Each film coated tablet contains Tadalafil	10.92mg	10mg	109.22% (Limit 90% to 110%)

The sample complies w.r.t above noted test

2008 sm

OPINION : In the opinion of the undersigned, the sample referred to above IS OF STANDARD QUALITY as defined in the Act and the Rules thereunder for the reason given below.

The sample complies with prescribed standard IP Under Tadalafil Tablets

Subject to terms & Conditions Mentioned Overleaf

(Signature of the person-in-charge of Testing)

PARALAB (P) LTD. MUMBAI-63

CHEMICAL (Wet Chemistry) LAL (Bacterial Endotoxin) R.I. DETECTOR MICRO STERILITY FTIR HPLC AAS Stability And Environmental Studies G.C.

Test Report

Date : 2019-10-02
No. : HC19090711

Applicant(Code: 01311126) : Succeed Holdings Limited
香港新界青衣青衣航運路 36 號亞洲物流中心順豐大廈 11 樓 2 室

Description of Sample(s) : One submitted sample said to be UC Minoxidil 5mg (FTL).
Batch / Lot No.: 9SG04A
Exp Date : 2021/8/31
Country of Origin : Philippines

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2019-09-20

Date Tested : 2019-09-27 to 2019-09-29

Investigation Requested : Minoxidil

Method(s) Used : Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Result
Minoxidil	5.34 mg/tablet

Average weight per tablet : 127.0mg

CHUNG On Ping, Karen
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

******* End of Test Report *******

Note: When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

Test Report

Date : 2019-10-02
No. : HC19090710

Applicant(Code: 01311126) : Succeed Holdings Limited
香港新界青衣青衣航運路 36 號亞洲物流中心順豐大廈 11 樓 2 室

Description of Sample(s) : One submitted sample said to be UC Minoxidil 2.5mg (FTL).
Batch / Lot No.: 9SG07A
Exp Date : 2021/8/31
Country of Origin : Philippines

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2019-09-20

Date Tested : 2019-09-27 to 2019-09-29

Investigation Requested : Minoxidil

Method(s) Used : Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Result
Minoxidil	2.54 mg/tablet

Average weight per tablet : 123.5mg

CHUNG On Ping, Karen
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

******* End of Test Report *******

Note: When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

Test Report

Date : 2019-09-03
No. : HC19080951

Applicant(Code: 01311126) : Succeed Holdings Limited
香港新界青衣青衣航運路 36 號亞洲物流中心順豐大廈 11 樓 2 室

Description of Sample(s) : One submitted sample said to be UC Finasteride 1mg.
Batch / Lot No.: 9SG01A
Exp Date : 2021/7/31
Country of Origin : Philippines

Sample(s) Received Condition: In intact original package under ambient temperature

Date Sample(s) Received : 2019-08-23

Date Tested : 2019-08-30 to 2019-09-03

Investigation Requested : Finasteride

Method(s) Used : Liquid Chromatography – Diode Array Detector

Test Result(s) :

Test Item(s)	Result
Finasteride	1.04 mg/tablet

Average weight per tablet : 151.0 mg

CHUNG On Ping, Karen
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

THE HONG KONG STANDARDS AND TESTING CENTRE LTD.

******* End of Test Report *******

Note: When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

VAIBHAV ANALYTICAL SERVICES

Page No : 1 of 1

303,3rd Floor, Sahjanand Shopping Centre, Near Police Commissioner Office, Shahibaug, AHMEDABAD-380004. Phone : 25624555, 25624330, 25621354, 25624646 Email: vaibhavlab@hotmail.com

LICENCE NO. GTL/17
(FORM-39)
CERTIFICATE OF ANALYSIS

(The Drugs & Cosmetics Act, 1940 & The Rules thereunder)
(Sample Drawn & Submitted by the Party)

Party Ref# : ----	**Dt.:** 18/12/2019	**Certificate No. :**	191219/29586/05
Sample Name: UC-AVANAFIL-200 TABLETS(AVANAFIL TABLET)		**Date of Receipt:**	19/12/2019
Mfg. By : CENTURION REMEDIES PVT.LTD.		**Sample Qty.** :	20 TABLETS
Supplied By : CENTURION REMEDIES PVT.LTD.		**Mfg. Lic. No.** :	
Batch No. : TU-070001	**D/M :** 11/2019 **D/E:** 10/2022	**Batch Size** :	50230 TABLETS

TEST DATA

Reference to protocols of Tests : AS PER IN HOUSE SPECIFICATION

DESCRIPTION : PINK COLOURED,OBLONG SHAPED,BICONVEX,FILM COATED TABLETS

WEIGHT OF 20 TABLETS : 6.194 GM

AVERAGE WEIGHT OF TABLET : 0.3097 GM

ASSAY : EACH FILM COATED TABLET CONTAINS

	Label Claim	Result	% Label Claim
AVANAFIL	: 200.0 MG.	197.73 MG.	98.87 %
		[LIMIT : 90.0 % - 110.0 %]	

--**-- END OF REPORT --- ** --

Report : In the opinion of the undersigned, the sample referred to above IS OF / ~~IS NOT OF~~ standard quality as defined in the act and the rules thereunder.

Analyst : S.D Date : 20/12/2019

Signature of the Person Incharge of Testing

Note:

1. The results refer only to the tested sample & applicable parameters. Endorsement of product is neither inferred nor implied.
2. Total liability of our institute is limited to the invoiced amount of this report.
3. This report is not to be reproduce wholly or in part and cannot be used as an evidence in the court of law, and should not be used in any advertising media without our special permission in writing.
4. Sample drawn & submitted by the party for analysis unless otherwise stated.
5. The report does not infer stability of the product. Subject to Ahmedabad Jurisdiction.
6. The samples would be destroyed after one month from the date of report.

VAIBHAV
ANALYTICAL
SERVICES

...anand Shopping Centre, Near Police Commissioner Office, Shahibaug, AHMEDABAD-380004. Phone : 25624555, 25624330, 25621354, 25624646 Email: vaibhavlab@hotmail.com

LICENCE NO. GTL/17
(FORM-39)
CERTIFICATE OF ANALYSIS

(The Drugs & Cosmetics Act, 1940 & The Rules thereunder)
(Sample Drawn & Submitted by the Party)

Party Ref#	: ---	**Certificate No.**	: 191219/29586/05
Sample Name:	UC-AVANAFIL-200 TABLETS(AVANAFIL TABLET)	**Date of Receipt:**	19/12/2019
Mfg. By	: CENTURION REMEDIES PVT.LTD.	**Sample Qty.**	: 20 TABLETS
Supplied By	: CENTURION REMEDIES PVT.LTD.	**Mfg. Lic. No.**	:
Batch No.	: TU-070001 **D/M :** 11/2019 **D/E:** 10/2022	**Batch Size**	: 50230 TABLETS

Dt.: 18/12/2019

TEST DATA

Reference to protocols of Tests : AS PER IN HOUSE SPECIFICATION

DESCRIPTION : PINK COLOURED,OBLONG SHAPED,BICONVEX,FILM COATED TABLETS

WEIGHT OF 20 TABLETS : 6.194 GM

AVERAGE WEIGHT OF TABLET : 0.3097 GM

ASSAY : EACH FILM COATED TABLET CONTAINS

	Label Claim	Result	% Label Claim
AVANAFIL	: 200.0 MG.	197.73 MG.	98.87 %
		[LIMIT : 90.0 % - 110.0 %]	

---**--- END OF REPORT --- ** ---

Report : In the opinion of the undersigned, the sample referred to above IS OF / ~~IS NOT OF~~ standard quality as defined in the act and the rules thereunder.

Signature of the Person Incharge of Testing

Analyst : S.D Date : 20/12/2019

Note:

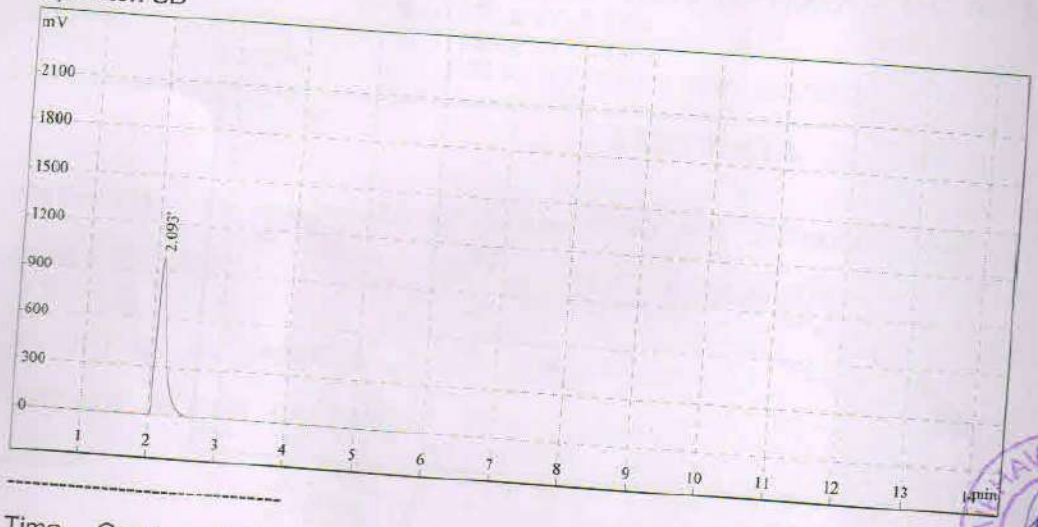
1. The results refer only to the tested sample & applicable parameters. Endorsement of product is neither inferred nor implied.
2. Total liability of our institute is limited to the invoiced amount of this report.
3. This report is not to be reproduce wholly or in part and cannot be used as an evidence in the court of law, and should not be used in any advertising media without our special permission in writing.
4. Sample drawn & submitted by the party for analysis unless otherwise stated.
5. The report does not infer stability of the product. Subject to Ahmedabad Jurisdiction.
6. The samples would be destroyed after one month from the date of report.

D: AVANAFIL
BATCH NO:
TEST: ASSAY
INJ.VOL: 20 ul

Printing time: Fri Dec 20 16:36:29 2019

Injection time: Fri Dec 20 16:19:52 2019

operator: SD



Time	Conc.	Area
2.093	100.00	9586261
	100	9586261

VAISHNAV ANALYTICAL SERVICES

VAIBHAV ANALYTICAL SERVICES

303,3rd Floor, Sahjanand Shopping Centre, Near Police Commissioner Office, Shahibaug, **AHMEDABAD-380004.** Phone : 25624555, 25624330, 25621354, 25624646 Email: vaibhavlab@hotmail.com

LICENCE NO. GTL/17
(FORM-39)
CERTIFICATE OF ANALYSIS
(The Drugs & Cosmetics Act, 1940 & The Rules thereunder)
(Sample Drawn & Submitted by the Party)

Party Ref# : ---	**Dt.:** 08/01/2020	**Certificate No. :**	200109/31795/ 23
Sample Name:	UC UDENAFIL TABLETS 200 MG	**Date of Receipt:**	09/01/2020
Mfg. By :	CENTURION REMEDIES PVT.LTD.	**Sample Qty.** :	20 TABLET(BULK)
Supplied By :	CENTURION REMEDIES PVT.LTD.	**Mfg. Lic. No.** :	
Batch No. :	TV-080001(COA.) **D/M:** 11/2019 **D/E:** 10/2022	**Batch Size** :	50610 TABLETS

TEST DATA

Reference to protocols of Tests : AS PER IN HOUSE SPECIFICATION

DESCRIPTION : LIGHT YELLOW COLOURED,CAPSULE SHAPED,BICONVEX,FILM COATED TABLETS

IDENTIFICATION : COMPLIES

WEIGHT OF 20 TABLETS : 6.270 GM

AVERAGE WEIGHT OF TABLET : 0.3135 GM

DISSOLUTION : (1) 93.03 %(2) 95.07 %(3) 94.66 %(4) 86.09 %
(5) 93.84 %(6) 92.07 % MEAN VALUE = 92.46 %
[LIMIT : NLT 70.0 % (D)]

ASSAY : EACH FILM COATED TABLET CONTAINS

	Label Claim	Result	% Label Claim
UDENAFIL	: 200.0 MG.	192.60 MG.	96.30 %

[LIMIT : 90.0 % - 110.0 %]

--**-- END OF REPORT --- ** ---

Report : In the opinion of the undersigned, the sample referred to above IS OF / IS NOT OF standard quality as defined in the act and the rules thereunder.

Analyst : H.S. Date : 11/01/2020

Signature of the Person Incharge of Testing

Note:
1. The results refer only to the tested sample & applicable parameters. Endorsement of product is neither inferred nor implied.
2. Total liability of our institute is limited to the invoiced amount of this report.
3. This report is not to be reproduce wholly or in part and cannot be used as an evidence in the court of law, and should not be used in any advertising media without our special permission in writing.
4. Sample drawn & submitted by the party for analysis unless otherwise stated.
5. The report does not infer stability of the product. Subject to Ahmedabad Jurisdiction.
6. The samples would be destroyed after one month from the date of report.

CENTURION REMEDIES PVT. LTD.

G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016
REG.OFF.: G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016
Phone : 2282061,2281074.3290522 Fax : 2280436 C.I.No. : U24231GJ2003PTC42254
Email :-cen_lab@rediff.com

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: UC AVANAFIL - 200	**A.R. No.**	: F/1557/1920
Packing	: 10x10 TAB		
Generic Name	: AVANAFIL TABLETS 200 MG	**Rel. Dt.**	: 17-12-2019
		T.R. Slip No.	: CPT191452
Product Code	: TU-07FORTU	**Mfg. Dt.**	: NOV-2019
Batch No.	: TU-070001	**Exp. Dt.**	: OCT-2022
Actual Batch Size	: 50230 TAB (502 CAR)	**Test Packing**	: 50 TAB
Packing Batch Size	: 50230 TAB	**Mfg. Lic No.**	: G/25/1325
Sample Size	: 50.000 TAB		:
Released Qty	: 50230.000 TAB (502 CAR)	**Test As Per**	: IH
Remarks	: PASS		
		T.R. Slip Dt.	: 17-12-2019
		Analysis Date	: 17-12-2019
		Specification No.	: CRFS/TU-07/1920
		STP No.	: STP/TU-07/IHS
		Location	: GORWA01
		Make	: CENTURION

Sr.	Test	Result	Specification
1	DESCRIPTION	A light red coloured,oval shaped, biconvex,film coated tablet,plain on both sides.	A light red coloured,oval shaped, biconvex,film coated tablet,plain on both sides.
2	AVERAGE WEIGHT OF TABLETS	311.3 mg	314.15 mg ± 3.0% of avg. weigh
3	UNIFORMITY OF WEIGHT	H.L.: +2.38% L.L.: -1.35%	Within ± 5.0% of avg.weight
4	THICKNESS	4.56 mm	4.50 mm ± 0.2 mm
5	HEIGHT	12.63 mm	12.60 mm ± 0.2 mm
6	DISINTEGRATION TIME	07 Minutes 27 Secound . in Water medium at 37°c	NMT 30 Minutes
7	DISSOLUTION	94.77%	NLT 70.0%
8	ASSAY BY HPLC	99.61%	Each Film Coated Tablet Contains: Avanafil 200 mg [Limit :90.00 % to 110.00 %]

Conclusion : The above sample complies as per IH
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
SAGAR QC CHEMIST	ASMITA Q.C IN CHARGE	PUSHPENDRA QA HEAD

CENTURION REMEDIES PVT. LTD.

G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016
REG.OFF.: G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016
Phone : 2282061,2281074.3290522 Fax : 2280436 C.I.No. : U24231GJ2003PTC42254
Email : cen_lab@rediff.com

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: UC UDENAFIL - 200		
Packing	: 10x10 TAB		
Generic Name	: UDENAFIL TABLETS 200 MG		
Product Code	: TU-08 FORT	**Mfg. Dt.**	: 11/2019
Batch No.	: TU-080001	**Exp. Dt.**	: 10/2022
Actual Batch Size	: 50610 TAB (506 CAR)	**Test Packing**	: 50 TAB
Packing Batch Size	: 50610 TAB	**Mfg. Lic No.**	: G/25/1325
Sample Size	: 50.000 TAB		
Released Qty	: 50610.000 TAB (506 CAR)	**Test As Per**	: IH
Remarks	: pass		

A.R. No.	: F/1707/1920
Rel. Dt.	: 13-01-2020
T.R. Slip No.	: CPT191578
T.R. Slip Dt.	: 07-01-2020
Analysis Date	: 07-01-2020
Specification No.	: CRFS/TU-08 FORT/1920
STP No.	: STP/TU-08 FORT/AS PER IHS
Location	: GORWA01
Make	: CENTURION

Sr.	Test	Result	Specification
1	DESCRIPTION	A yellow coloured, oval shaped, biconvex, film coated tablet, plain on both sides.	A yellow coloured, oval shaped, biconvex, film coated tablet, plain on both sides.
2	IDENTIFICATION	Complies	Must complies as per IHS
	1 BY HPLC	In the Assay,the principal peak in the chromatogram obtained with the test solution is 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 should correspond to the peak in the chromatogram obtained with the reference solution.
3	AVERAGE WEIGHT OF TABLETS	313.5 mg	314.15 mg ± 3.0% of avg. weight
4	UNIFORMITY OF WEIGHT	HL:+3.12 % LL: -3.32 %	Within ± 5.0 % of avg. weight
5	THICKNESS	4.62 mm	4.40 mm ± 0.3 mm
6	HEIGHT	12.58 mm	12.60 mm ± 0.2mm
7	DISINTEGRATION TIME	05 minute 06 second in water medium 37°c	NMT 30 minute : in water medium 37°c
8	DISSOLUTION	94.46 %	NLT 70.00%
9	ASSAY BY HPLC	97.85 %	Each film coated tablet contains Udenafil 200MG [Limit :90.0 % to 110.0%]

Conclusion : The above sample complies as per IH
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
DIKESH QC CHEMIST	ASMITA Q.C IN CHARGE	PUSHPENDRA QA HEAD

DIKESH123 13-01-20 05:01 PM

LLOYD
LABORATORIES, INC.
QUALITY DEPARTMENT
#10 LLOYD AVE., FBIC, MALOLOS
BULACAN PHILIPPINES

CERTIFICATE OF ANALYSIS

COMPANY : [redacted] LOT NO. : 5SB01A

PRODUCT : Sildenafil + Vitamin B_1 + Vitamin B_{12} BATCH NO. : N/A

(UC SILDENAFIL PLUS 100mg) 100 mg / 400 mcg / 0.8 mcg Film Coated Tablet

MFG. DATE : 02/2025 EXPIRY DATE : 02/2027

[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
Appearance	Blue to dark blue film-coated tablet, round, biconvex, with break line on one side and plain on the other side.	Dark blue film-coated tablet, round, biconvex, with break line on one side and plain on the other side.
Identification (Sildenafil) By Liquid Chromatography	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay.	Complies
Weight / Tablet	433.0 mg ± 5% (411.4 mg – 454.7 mg)	429.3 mg
Diameter	10.10 mm + 0.30 mm (10.10 mm - 10.40 mm)	10.14 mm
Thickness	4.30 mm ± 0.30 mm (4.00 mm – 4.60 mm)	4.30 mm
Loss on Drying (at 60 °C)	Not more than 4.00%	0.64%
Hardness	12.00 kgF - 24.00 kgF	16.97 kgF
Disintegration Time	Not more than 30 minutes	9 minutes and 05 seconds
Uniformity of Dosage Units (By Weight Variation)	Not more than 2 of the tablets differ from the average weight by more than 10%	Complies
Dissolution	Not less than 85% of the labeled content of Sildenafil is dissolved in 30 minutes.	99%
Assay		
Sildenafil (As Citrate)	90.0% - 110.0% (90.00 mg - 110.00 mg)	102.4% (102.40 mg)
Vitamin B_1 (Thiamine Mononitrate)	90.0% - 150.0% (360.00 mcg - 600.00 mcg)	98.1% (392.40 mcg)
Vitamin B_{12} (Cyanocobalamin)	Identification	Positive
Microbial Limit Test		
Total Aerobic Microbial Count	Not more than 1,000 cfu/g	Less than 10 cfu/g
Total Combined Yeasts and Molds Count	Not more than 100 cfu/g	Less than 10 cfu/g
Salmonella spp.	Negative	Negative
E. coli	Negative	Negative

DISPOSITION: [X] RELEASED [ ] REJECTED [ ] OTHERS PASSED

Reviewed By:	Approved By:	Certified By:
03/25/2025	G Sudhakar 03/25/2025	
Catherine M. Centeno	Sudhakar Gudi	Joi Princess S. Sy
Quality Control Supervisor	Quality Control Manager	Authorized Person

LLOYD LABORATORIES PHILIPPINES

SOP-QCD-GN-15/Anx-Frm-06
Rev. 01

PHOENIX BIOLOGICALS PRIVATE LIMITED
THIRUVANDARKOIL, PUDUCHERRY, INDIA.

CERTIFICATE OF ANALYSIS

Name of the Product	:	**VARDENA PLUS 20 mg**			
Manufacturer Name	:	**PHOENIX BIOLOGICALS PVT. LTD., PUDUCHERRY**	**A. R. Number**	:	**FP/ 01/142/25**
Batch Number	:	**PAI02**	**A. R. Date**	:	**29/01/2025**
[redacted]			**Mfg. Date**	:	**01/2025**
Sample Quantity	:	**60 TABLETS (6x 10 'S)**	**Exp. Date**	:	**12/2026**
			Sample Date	:	**25/01/2025**

S. No.	TESTS	RESULTS	SPECIFICATION
1.	Description	Dark Beige (Peach) colored circular shaped biconvex film coated tablet, plain on both sides.	Dark Beige (Peach) colored circular shaped biconvex film coated tablet, plain on both sides.
2.	Identification	Complies	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the respective Assay.
3.	Average weight	308.63 mg	308.0 mg ± 5.0%
4.	Uniformity of weight	Complies	Should be within the limit of ±5% of Average Weight.
5.	Diameter	9.60 mm	9.65 mm ±0.2 mm
6.	Thickness	4.31 mm	4.50 mm ± 0.3mm
7.	Disintegration Time	01 minutes 03 seconds	Not more than 30 minutes
8.	Dissolution Vardenafil	Average : 105.02% (Min: 96.24% and Max: 107.67%)	Not Less than 75 % in 30 minutes
9.	Assay: Each Film coated tablet contains: Vardenafil Hydrochloride USP equivalent to Vardenafil 20 mg Vitamin B1 USP 5mg Vitamin B12 USP 750 mcg	 20.82mg (104.1%) 6.94 mg (138.8%) 945.15 mcg (126.0%)	 19.0 mg to 22.0 mg (95.0 % to 110 .0%) NLT 4.5 mg (NLT 90.0%) NLT 675 mcg (NLT 90.0%)
10	Microbial Enumeration Test: (i) Total aerobic microbial count (ii) Total combined yeasts & molds count Escherichia coli	 30 CFU/g Less than 10 cfu/ g Absent/g.	 Not more than 1000 CFU/g Not more than 100 CFU/g Should be absent/g.

Remarks: The sample complies with the prescribed standards as per IN HOUSE

	Analysed by	Checked by	Approved by
Signature			
Date	29/01/25	29/01/25	29/01/25

PHOENIX BIOLOGICALS PVT. LTD. Puducherry 605 102.

PHOENIX BIOLOGICALS PRIVATE LIMITED
THIRUVANDARKOIL, PUDUCHERRY, INDIA.

CERTIFICATE OF ANALYSIS

Name of the Product	:	TADARA PLUS 20mg			
Manufacturer Name	:	PHOENIX BIOLOGICALS PVT. LTD., PUDUCHERRY	A. R. Number	:	FP/01/139/25
Batch Number	:	PAI01	A. R. Date	:	22/01/2025
[redacted]			Mfg. Date	:	01/2025
Sample Quantity	:	60 TABLETS (6x 10 'S)	Exp. Date	:	12/2026
			Sample Date	:	17/01/2025

S. No.	TESTS	RESULTS	SPECIFICATION
1.	Description	Dark Yellow colored circular shaped biconvex film coated tablet, plain on both sides.	Dark Yellow colored circular shaped biconvex film coated tablet, plain on both sides.
2.	Identification	Complies	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the respective Assay.
3.	Average Weight	292.51 mg	290.0 mg ± 5.0%
4.	Uniformity of weight	Complies	Should be within the limit of ±5% of Average Weight.
5.	Diameter	9.65 mm	9.50 mm ±0.2 mm
6.	Thickness	4.11 mm	4.00 mm ± 0.3mm
7.	Disintegration Time	1 minutes 58 seconds	Not more than 30 minutes
8.	Dissolution Tadalafil	Average : 99.37% (Min: 95.42% and Max: 102.56%)	Not Less than 80 % in 30minutes
9.	Assay: Each Film coated tablet contains: Tadalafil USP 20 mg Vitamin B1 USP 5mg Vitamin B12 USP 750 mcg	 20.90 mg (104.5 %) 6.72 mg (134.4%) 950.3 mcg (126.7%)	 18.0 mg to 22.0 mg (90.0 % to 110 .0%) NLT 4.5 mg (NLT 90.0%) NLT 675 mcg (NLT 90.0%)
10	Microbial Enumeration Test: (i) Total aerobic microbial count (ii) Total combined yeasts & molds count Escherichia coli	 25CFU/g Less than 10 cfu/ g Absent/g.	 Not more than 1000 CFU/g Not more than 100 CFU/g Should be absent/g.

Remarks: The sample complies with the prescribed standards as per IN HOUSE

	Analysed by	Checked by	Approved by
Signature	SAH	SE	TJK
Date	22/01/25	22/01/25	22/01/25

PHOENIX BIOLOGICALS PVT. LTD. Puducherry 605 102.

LLOYD
LABORATORIES, INC.
QUALITY DEPARTMENT
#10 LLOYD AVE., FBIC, MALOLOS
BULACAN PHILIPPINES

CERTIFICATE OF ANALYSIS

COMPANY : [redacted]

LOT NO. : 5SB22A

PRODUCT : Dutasteride + Zinc
(UC DUTA PLUS) 0.5 mg / 1 mg Film Coated Tablet

BATCH NO. : N/A

MFG. DATE : 02/2025

EXPIRY DATE : 02/2027

[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
Appearance	White to off-white, film-coated tablet, round, biconvex, plain on one side and bisected on the other side	Off-white film-coated tablet, round, biconvex, plain on one side and bisected on the other side
Identification Test	The retention time of the major peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the assay	Complies
Weight / Tablet	103.0 mg ± 7.5% (95.3 mg–110.7 mg)	105.0 mg
Thickness	3.00 mm ± 0.30 mm (2.70 mm – 3.30 mm)	3.07 mm
Diameter	6.30 mm + 0.30 mm (6.30 mm – 6.60 mm)	6.41 mm
Loss on Drying (at 60°C)	Not more than 2.00%	0.69%
Hardness	4.00 kgF – 8.00 kgF	6.51 kgF
Disintegration	Not more than 30 minutes	3 minutes
Uniformity of Dosage Units; Content Uniformity	L1: Acceptance value of first 10 dosage units should be less than or equal to 15.0, test the next 20 units and calculate the acceptance value. L2: The final acceptance value of the 30 dosage units should be less than or equal to 25.0.	Dutasteride – 15.0 Zinc – 12.7
Assay		
Dutasteride	90.0% - 110.0% (0.45 mg – 0.55 mg)	102.1% (0.51 mg)
Zinc	90.0% - 125.0% (0.90 mg – 1.25 mg)	114.5% (1.14 mg)
Microbial Limit Test		
Total Aerobic Microbial Count	Not more than 1,000 cfu/g	Less than 10 cfu/g
Total Combined Yeast and Mold Count	Not more than 100 cfu/g	Less than 10 cfu/g
Salmonella coli	Negative	Negative
Escherichia coli	Negative	Negative

DISPOSITION : [X] RELEASED [ ] REJECTED [ ] OTHERS PASSED

Reviewed By:	Approved By:	Certified By:
03/31/2025 Catherine M. Centeno **Quality Control Supervisor**	G. Sudhakar 03/31/2025 Sudhakar Gudi **Quality Control Manager**	03/31/2025 for Princess S. Sy **Authorized Person**

LLOYD LABORATORIES, INC. PHILIPPINES

SOP-QCD-GN-15/Anx-Frm-06
Rev. 01

LLOYD
LABORATORIES, INC.
QUALITY DEPARTMENT
#10 LLOYD AVE., FBIC, MALOLOS
BULACAN PHILIPPINES

CERTIFICATE OF ANALYSIS

COMPANY : [redacted]
PRODUCT : Minoxidil (UC MINOXIDIL) 2.5 mg Tablet
MFG. DATE : 01/2025
LOT NO. : 54SL04A
BATCH NO. : N/A
EXPIRY DATE : 01/2028

[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
Appearance	White to off-white, circular tablet, biconvex, with break line on one side and plain on the other side.	Off-white, circular tablet, biconvex, with break line on one side and plain on the other side.
Identification A. by Chromatography	The retention time of the Minoxidil peak of the *Sample solution* corresponds to that of the *Standard Solution*, as obtained in the *Assay*.	Complies
B. by Ultraviolet Absorption	The UV absorption spectra of the Minoxidil peak of the *Sample solution* correspond to that of the *Standard solution*, as obtained in the *Assay*.	Complies
Weight / Tablet	122.5 mg ± 7.5% (113.3 mg – 131.7 mg)	123.6 mg
Thickness	3.00 mm ± 0.50 mm (2.50 mm – 3.50 mm)	2.85 mm
Diameter	7.00 mm + 0.30 mm (7.00 mm – 7.30 mm)	7.10 mm
Hardness	3.00 kgF – 7.00 kgF	4.35 kgF
Friability	Not more than 1.00% (54 tablets, 25 rpm, 4 minutes)	0.12%
Disintegration	Not more than 15 minutes	52 seconds
Dissolution Test	Not less than 75% (Q) of the labeled amount of Minoxidil ($C_9H_{15}N_5O$)is dissolved in 15 minutes.	89%
Uniformity of Dosage Units; Content Uniformity	L1: Acceptance value of first 10 dosage units should be less than or equal to 15.0. If acceptance value is greater than 15.0. test the next 20 units and calculate the acceptance value. L2: The final acceptance value of the 30 dosage units should be less than or equal to 25.0.	11.0
Loss on Drying (at 60°C)	Not more than 3.00%	1.18%
Assay	90.0% - 110.0% (2.25 mg - 2.75 mg)	102.2% (2.56 mg)
Microbial Limit Test		
Total Aerobic Microbial Count	Not more than 1,000 cfu/g	Less than 10 cfu/g
Total Combined Yeasts and Molds Count	Not more than 100 cfu/g	Less than 10 cfu/g
E. coli	Negative	Negative

DISPOSITION: [X] RELEASED [ ] REJECTED [ ] OTHERS PASSED

Reviewed By:	Approved By:	Certified By:
01/23/2025	01/23/2025	01/23/2025
Catherine M. Centeno	Sudhakar Gudi	For Klaire Marie B. Gallanosa
Quality Control Supervisor	**Quality Control Manager**	**Authorized Person**

SOP-QCD-GN-15/Anx-Frm-06
Rev. 01

LLOYD
LABORATORIES, INC.
QUALITY DEPARTMENT
#10 LLOYD AVE., FBIC, MALOLOS
BULACAN PHILIPPINES

CERTIFICATE OF ANALYSIS

COMPANY : [redacted]
PRODUCT : Minoxidil (UC MINOXIDIL) 5 mg Tablet
MFG. DATE : 09/2024
LOT NO. : 4SH11A
BATCH NO. : N/A
EXPIRY DATE : 09/2027

[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
Appearance	White to off-white, circular tablet, biconvex, with break line on one side and plain on the other side.	Off-white, circular tablet, biconvex, with break line on one side and plain on the other side.
Identification A. by Chromatography B. by Ultraviolet Absorption	The retention time of the Minoxidil peak of the *Sample solution* corresponds to that of the *Standard Solution*, as obtained in the *Assay*. The UV absorption spectra of the Minoxidil peak of the *Sample solution* correspond to that of the *Standard solution*, as obtained in the *Assay*.	Complies Complies
Weight / Tablet	125.0 mg ± 7.5% (115.6 mg – 134.4 mg)	125.6 mg
Thickness	3.00 mm ± 0.50 mm (2.50 mm – 3.50 mm)	2.92 mm
Diameter	7.00 mm + 0.30 mm (7.00 mm – 7.30 mm)	7.11 mm
Hardness	4.00 kgF – 8.00 kgF	5.13 kgF
Dissolution	Not less than 75% (Q) of the labeled amount of Minoxidil ($C_9H_{15}N_5O$) is dissolved in 15 minutes.	102%
Friability	Not more than 1.00% w/ no capped tablets (52 tablets, 25 rpm., 4 minutes)	0.14%
Disintegration	Not more than 15 minutes	10 minutes and 12 seconds
Loss on Drying	Not more than 3.00%	1.07%
Uniformity of Dosage Units; Content Uniformity	L1: Acceptance value of the first 10 dosage units should be less than or equal to 15.0. If acceptance value is greater than 15.0, test the next 20 units and calculate the acceptance value. L2: The final acceptance value of the 30 dosage units should be less than or equal to 25.0.	9.1
Assay	90.0% - 110.0% (4.50 mg - 5.50 mg)	98.5% (4.93 mg)
Microbial Limit Test		
Total Aerobic Microbial Count	Not more than 1,000 cfu/g	Less than 10 cfu/g
Total Combined Yeasts and Molds Count	Not more than 100 cfu/g	Less than 10 cfu/g
E. coli	Negative	Negative

DISPOSITION : [X] RELEASED [ ] REJECTED [ ] OTHERS PASSED

Reviewed By:	Approved By:	Certified By:
10/08/2024 Catherine M. Centeno **Quality Control Supervisor**	G. Sudhakar 10/08/2024 Sudhakar Gudi **Quality Control Manager**	10/08/2024 Klaire Marie B. Gallanosa **Authorized Person**

LLOYD LABORATORIES INC. PHILIPPINES

SOP-QCD-GN-15/Anx-Frm-06
Rev. 01