„"INDUSTRIAL TRAINING""

A REPORT SUBMITTED TO

SAVITRIBAI PHULE PUNE UNIVERSITY, PUNE

FOR THE DEGREE OF

MASTER OF SCIENCE

IN

ORGANIC CHEMISTRY

UNDER THE FACULTY OF SCIENCE

BY

Mr. Ajinkya Dattatray Lonare

Department of Chemistry, G. M. D.Arts,B.W. Commerce and Science College, Sinnar

UNDER THE GUIDANCE OF

Prof. :- Dr. M.R. Gaware

Head of

DEPARTMENT OF CHEMISTRY

G.M.D.ARTS, B.W.COMMERCE AND SCIENCE COLLEGE,

SINNAR 422103

APRIL 2023

Maratha Vidya Prasarak Samaj's

G.M.D. ARTS, COMMERCE AND SCIENCE COLLEGE,

SINNAR, DISTRICT- NASHIK

DEPARTMENT OF CHEMISTRY (PG)

CERTIFICATE

This is to certify that **Mr. Ajinkya Dattatray Lonare** studying in M.Sc.-II (Organic Chemistry) at **M.V.P. Samaj's G.M.D. Arts, B.W. Commerce and Science College , Sinnar** has successfully completed "Pharmaceutical Training Course in Analytical Techniques" **(CHO-453-Industrial Training)** from 07/12/2022 to 07/01/2023 conducted by Arni Analyticals, Nashik during the semester IV of academic year 2022-2023.

HOD Chemistry

HEAD
DEPARTMENT OF CHEMISTRY
G.M.D. Arts, B.W. Commerce
and Science college. Sinnar

Examiner

12-05-2023

Principal

PRINCIPAL
G.M.D.Arts, B.W.Commerce and
Science College, Sinnar, Dist. Nashik

CERTIFIED ISO 9001 CERTIFIED

ARNI ANALYTICAL

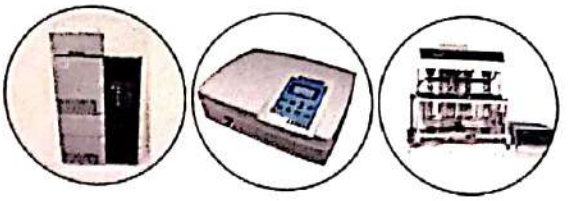
Add.: Pushpak Apartment, Flat No. 102, Lane No. 3, Near Neurocare Hospital, Pandit Colony, Nashik.
e-mail : arnianalyticals@gmail.com | Web Site : www.arnianalyticals.com

Certificate

This is to Certify that ..... *Ajinkya Dattatraya Lonare* .....
has Successfully Completed Pharmaceutical Training Course in
Analytical Techniques includes Practically Handling the
Instruments Like HPLC, UV - Spectrophotometer,
Dissolution Test Apparatus & Pharmaceutical
Instruments in the Training Period From *7 Dec. 2022* To *7 Jan. 2023*

Director

ARNI ANALYTICALS



: 9307686710

Certificate

"Pharmaceutical Training Course in Analytical Techniques"

This is to certify that Mr./Miss/ Mrs. **Ajinkya Dattatray Lonare** studying in **M. Sc.-II (Organic Chemistry)** at **M. V. P. Samaj's G. M. D. Arts, B. W. Commerce and Science College, Sinnar** has successfully completed **"Pharmaceutical Training Course in Analytical Techniques"** from 07/12/2022 to 07/01/2023 conducted by **Arni Analyticals, Nashik** and has obtained **"B"** grade.

Mr. Masum Deshmukh
Director

Add.: Pushpak Apartment, Flat No. 102, Lane No. 3, Near Neurocare Hospital, Pandit Colony, Nashik. | **e-mail :** arnianalyticals@gmail.com

ACKNOWLEDGEMENT

The success and final outcome of this training required a lot of guidance and assistance from many people. All that I have done is only due to such supervision and assistance and I would never forget to thank them.

I respect and thank Respected Dr. P.V. Rasal Sir for providing me an opportunity to do the training and giving all the support and guidance which made me complete the training successfully. I am extremely thankful to him for providing such a nice support and guidance.

I owe my deep gratitude to Prof. Manoj Gaware Sir (Head of Chemistry Department) who took interest on my training and guided me all along, till the completion of training by providing all the necessary information .

I am thankful to Mr. Masum Deshmukh Sir for his guidance and suggestions during the training and thankful for giving all the knowledge during the training.

I am thankful to and fortunate enough to get constant encouragement, support and guidance from all Teaching Staffs of Department of Chemistry which helped me in successfully completing my training.

Sign:- 

Name:- Ajinkya Dattatray Lonare

INDEX

TENELIGLIPTIN

Introduction-

- Teneligliptin is a pharmaceutical drug for the treatment of type-2 diabetes mellidus.
- Teneligliptin belongs to the category of medicines called "anti-diabetic".
- It is used along or in combination with other drugs to lower blood sugar levels.
- Teneligliptin tablet contains the teneligliptin which belongs to class of dipeptidyl peptidase-4 inhibitors.
- It works by blocking the action of DPP-4 (an enzyme that destroys the harmone 'Incretin'). The enzyme 'Incretins' helps to produce more insulin only when required and reduces the liver's blood sugar level when not needed.

Chemical Formula- $C_{22}H_{30}N_6O_5$

Molar Mass- 426.58 gm/mol

- Teneligliptin significantly controls glycemic parameters with safety. No dose adjustment is required.
- As we all know that teneligliptin tablet contains only 20 mg active ingredient i.e. teneligliptin. Other layers or coatings are excepients.
- Once a tablet is formulated then directly it doesn't comes to market. First of all some of the random tablets are collected and forwarded for testing.

Testing have 2 types-

1. Physical
2. Chemical

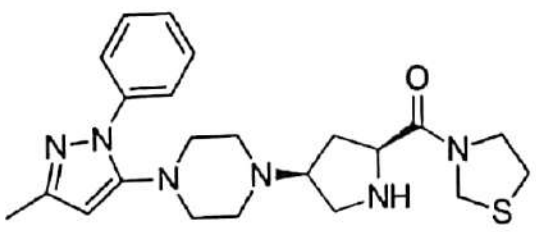
Physical Testing-

1. Average weight test
2. Uniformity of weight
3. Thickness
4. Dimensions
5. **Hardness**

Chemical Tests-

1. Dissolution Test
2. Separation Technique (HPLC)
3. Absorbance

Structure of Teneligliptin-



SPECIFICATION AND TESTS OF TENELIGLIPTIN TABLETS 20 MG

Sr. No.	Tests	Specification
1	Description	Yellow coloured, round shaped, film coated tablets, plain on both sides.
2	Identification	The retention time of the major peak in the chromatogram of assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the "Assay".
3	Average weight of Tablet	283 mg ± 7.5%
4	Uniformity of weight	283 mg ± 7.5% (Between 261.8 mg and 304.2 mg)
5	Dissolution	Not less than 80.00 % of labeled amount is dissolved in 45 minutes
6	Assay	Not less than 90.00% and Not more than 110.00% of Label Claim (Between 18.00 mg and 22.00 mg per tablet)

TEST METHOD

1) **Description:** White coloured, round shaped, film coated tablets, plain on both sides.

2) **Identification:**
The retention time of the principal peak in the chromatogram of sample preparation should correspond to that of the standard preparation as obtained in the "Assay".

3) **Average weight:**

TABLETS-1	:	285 mg	TABLETS-6	:	285
TABLETS-2	:	285	TABLETS-7	:	292
TABLETS-3	:	286	TABLETS-8	:	285
TABLETS-4	:	282	TABLETS-9	:	280
TABLETS-5	:	279	TABLETS-10	:	295

AVERAGE WEIGHT:- 286.8 mg **LIMIT: 283 MG ± 7.5%**

4) **Uniformity of Weight:**
Select randomly 10 tablets and weigh individual tablet. Calculate average, the minimum and maximum value.

TABLETS-1	:	285 mg	TABLETS-6	:	285 mg
TABLETS-2	:	285 mg	TABLETS-7	:	292 mg
TABLETS-3	:	286 mg	TABLETS-8	:	285 mg
TABLETS-4	:	282 mg	TABLETS-9	:	280 mg
TABLETS-5	:	279 mg	TABLETS-10	:	295 mg

MINIMUM WEIGHT :-
MAXIMUM WEIGHT :-

LIMIT: 283 MG ±7.5% (BETWEEN 261.8 MG AND 304.2 MG)

5) Dissolution (By HPLC):

Dissolution Parameters :					
Medium	:	Water	Rotatory Speed	:	75 RPM
Volume	:	900 ml	Temperature	:	37°C ± 0.5°C
Apparatus	:	USP Type II (Paddle)	Time	:	45 min

Standard Weight :-

Potency:-

Calculations: Teneligliptin (% Drug Release) $= \frac{At}{As} \times \frac{Ws}{100} \times \frac{900}{LC} \times \frac{P}{100} \times \frac{426.57}{628.86} \times 100$

Tablet 1= $\frac{0.6045}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 89.95 %

Tablet 2= $\frac{0.5994}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 89.19 %

Tablet 3= $\frac{0.6237}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 92.81 %

Tablet 4= $\frac{0.5951}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 88.55 %

Tablet 5= $\frac{0.5808}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 86.43 %

Tablet 6= $\frac{0.6084}{0.6642} \times \frac{32.43 \times 5}{100 \quad 50} \times \frac{900}{20} \times \frac{99.85}{100} \times \frac{426.57}{628.86} \times 100 =$ 90.53 %

$89.95 + 89.19 + 92.81 + 88.55 + 86.43 + 90.53 = 89.57$ %

6

Average:- 89.57 %

Limits: Not less than 80.00 % of labeled amount is dissolved in 45 minutes

6) Assay (By HPLC):

Chromatographic Conditions:

Column	:	C_{18}, (150mm X 4.6mm), 5 µm
Pump mode	:	Isocratic
Mobile Phase	:	Buffer :- Acetonitrile (65:35)
Flow rate	:	1.00 mL/min
Injection volume	:	20 µL
Column Temperature	:	30°C
Wavelength	:	1.5 times of retention time of principle peak (2.5 min) (5 min)

Preparation of solutions:

- **Standard preparation:**

Dissolved 0.1M potassium dihydrogen orthophosphate in 300ml of wate

Prepare a mix. of Buffer, Acetonitrile (65:30 v/v). filter through 0.45 µ filter & degas.

- **Sample preparation:**

Standard Weight :- 20mg
Sample Weight :- 286.8 mg
Average Weight :- 286.8 mg
Potency :- 99.85%.

- **Calculations:**

$$\% \text{ of Teneligliptin} = \frac{At}{As} \times \frac{Ws}{100} \times \frac{100}{Wt} \times \frac{P}{100} \times Aw \times \frac{426.57}{628.86} \times \frac{100}{LC}$$

1) $\frac{11960800}{11135986} \times \frac{29.43}{100} \times \frac{100}{286.8} \times \frac{P}{100} \times 286.8 \times \frac{426.57}{628.86} \times \frac{100}{20} = 104$

=

2) $\frac{11947512}{11135986} \times \frac{29.43}{100} \times \frac{100}{286.8} \times \frac{P}{100} \times 286.8 \times \frac{426.57}{628.86} \times \frac{100}{20} = 106$

=

Average :- 105.92%.

Limit: Not less than 90.00 % and not more than 110.00 % of the label claim

	ARNI ANALYTICALS	
TITLE	**HPLC DATA SHEET**	
Instrument Name :-	HIGH PERFORMANCE LIQUID CHROMATOGRAPHY	**Page No**
Instrument Make :-	SHIMADZU	
Instrument Model No. :-	LC 2010 CHT	1 of 1
Instrument ID : -	ARNI/INS-001	

DATA SHEET

NAME OF TEST :- SYSTEM SUITABILITY

SYSTEM SUITIBILITY CHECK BY INJECTING 3 REPLICATE INJECTIONS OF CAFFEINCE

- **Chromatographic Conditions:**

Column	A stainless steel column **Dimentions :-** **Length** :- 15 cm × **Diameter**:- 4.6 mm ; **Particle size** :-5µm **Length** :- 150 mm × **Diameter**:- 4.6 mm ; **Particle size** :-5µm **Stationary Phase** :- Packed with octadecylsilyl (C18) silica gel
Data Aquisitation Time	7 Minutes
Pump (Flow Rate)	1.00 ml/min
Port	A
Detector (Wavelength)	273nm
Column Oven Temperature	30°C
Degasser	Off
Autosampler Temperature	Off

- **MOBILE PHASE PREPARATION :-**

Prepare a Mixture of 80 volumes of Water and 20 volumes of Methanol. Mix well.

70 30 Acetonitrile

- **STANDARD PREPARATION :-**

Weigh accurately 20mg of Caffeine standard to a 100ml volumetric flask. Add 60ml of HPLC grade wate and shake to dissolve completely. Slowly makeup the volume upto the mark. Mix well. Further dilute 5ml of the above solution to 50ml volumetric flask, dilute with water to makeup volume.

	ARNI ANALYTICALS	
TITLE	HPLC DATA SHEET	
Instrument Name :-		Page No
Instrument Make :-		
Instrument Model No. :-		1 of 1
Instrument ID : -		

NAME OF STUDENT :-

DATA SHEET

NAME OF TEST :- SYSTEM SUITABILITY

SYSTEM SUITIBILITY CHECK BY INJECTING 3 REPLICATE INJECTIONS OF CAFFEINCE

- **Chromatographic Conditions:**

Column	A stainless steel
Data Aquisitation Time	5 minutes
Pump (Flow Rate)	1.00 ml/min
Port	A
Detector (Wavelength)	273 nm
Column Oven Temperature	30°C
Degasser	off
Autosampler Temperature	off

- **MOBILE PHASE PREPARATION :-**

Prepare a mixture of 70 volumes of water & 20 volumes of Acetonitrile & Mix well.

- **STANDARD PREPARATION :-**

Weigh accurately 20 mg of caffiene standard to 100ml volumetric flask. Add 60 ml HPLC grade water & shake it make up the volume & further dil. 5 ml of above soln to 50ml vol. flask & dilute to make up volume.

- **SEQUENCE OF INJECTION :-**

Name of Solution	No. Of Injection
Blank	1
Standard	2

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HPLC DATA SHEET

- **HPLC Parameter settings:**
  - **Make a purging of the mobile phase of all ports & injection port to remove the air bubble from the line.**
  - **Create a new method by using below parameter.**
  - **Save the Method Parameters with a file name.**
  - **Download the method to the instruments.**

- **CHROMATOGRAPHIC PARAMETERS-1**

INSTRUMENT PARAMETERS		Set Parameters
Data Aquisitation Time	:	10 min
Pump	:	1.00 ml/min
Port	:	A
Detector (Wavelength)	:	210 nm
Column Oven Temperature	:	30°C
Degasser	:	On
Autosampler Temperature	:	10°C

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- **CHROMATOGRAPHIC PARAMETERS-2**

INSTRUMENT PARAMETERS		Set Parameters
Data Aquisitation Time	:	13 min
Pump	:	0.80 ml/min
Port	:	C
Detector (Wavelength)	:	222 nm
Column Oven Temperature	:	40°C
Degasser	:	Off
Autosampler Temperature	:	4°C

- **CHROMATOGRAPHIC PARAMETERS-3**

INSTRUMENT PARAMETERS		Set Parameters
Data Aquisitation Time	:	22 min
Pump	:	1.20 ml/min
Port	:	A
Detector (Wavelength)	:	260 nm
Column Oven Temperature	:	30°C
Degasser	:	off
Autosampler Temperature	:	15°C

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ARNI ANALYTICALS

TITLE	HPLC DATA SHEET	
Instrument Name :-		Page No
Instrument Make :-		
Instrument Model No. :-		3 of 3
Instrument ID : -		
Name Of Student :-		

- **CHROMATOGRAPHIC PARAMETERS-4**

INSTRUMENT PARAMETERS		Set Parameters
Data Aquisitation Time	:	15 min
Pump	:	0.70 ml/min
Port	:	B
Detector (Wavelength)	:	225 nm
Column Oven Temperature	:	35°C
Degasser	:	on
Autosampler Temperature	:	12°C

- **CHROMATOGRAPHIC PARAMETERS-5**

INSTRUMENT PARAMETERS		Set Parameters
Data Aquisitation Time	:	22 min
Pump	:	1.20 ml/min
Port	:	A
Detector (Wavelength)	:	260 nm
Column Oven Temperature	:	30°C
Degasser	:	off
Autosampler Temperature	:	15°C

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	ARNI ANALYTICALS	
TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-	Analytical Balance	Page No
Instrument Make :-	WENSAR	
Instrument ID : -	ARNI/INS-004	1 of 3

MONTHLY CALIBRATION RECORD

1. **Calibration by using Weights:**

Observation Table:

Sr. No.	Reference Weight in g	Observed Weight in g	Weight in g (Limit: ± 0.1%)
1	200.0000	200.065	199.8000 to 200.2000
2	100.0000	98.790	99.9000 to 100.1000
3	50.0000	50.714	49.9500 to 50.0500
4	20.0000	19.055	19.9800 to 20.0200
5	10.0000	10.002	9.9900 to 10.0100
6	5.0000	5.083	4.9950 to 5.0050
7	2.0000	1.329	1.9980 to 2.0020
8	1.0000	0.925	0.9990 to 1.0010
9	0.5000	0.152	0.4995 to 0.5005
10	0.2000	0.105	0.1998 to 0.2002
11	0.1000	0.058	0.0999 to 0.1001
12	0.0500	0.088	0.0499 to 0.0501
13	0.0200	0.014	0.0199 to 0.0200
14	0.0100	0.013	0.0099 to 0.0100
15	0.0050	0.008	0.0049 to 0.0051

Conclusion: The observed weights are **within limit/ out of limit.**

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	ARNI ANALYTICALS	
TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-		Page No
Instrument Make :-		
Instrument ID : -		2 of 3

2. Test for Linearity:

Sr. No.	Selected Weights in g	Observed Weight in g
1	50	50.714
2	100	98.790
3	200	200.067

Conclusion: The observed weights are **Consistent/not Consistent.**

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3. Test for Eccentricity:

1	2
A	
3	4

Sr. No.	Weight Observed in g		Difference in g	Limit
1.	At Centre- (A)	50.714		± 0.1 %
2.	At Corner 1 (B)	50.710.	B-A = −0.004	
3.	At Corner 2 (C)	50.710	C-A = −0.004	
4.	At Corner 3 (D)	50.708	D-A = −0.006	
5.	At Corner 4 (E)	50.709	E-A = −0.005	

Conclusion: The maximal Differential Eccentricity error is **within limit/~~out of limit~~** of Std. deviation.

ANALYSED BY **CHECKED BY**

ARNI ANALYTICALS

TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-		Page No
Instrument Make :-		
Instrument ID : -		3 of 3

4. Test for Repeatability :

Selected Weight in g: 100 g

Sr. No.	Observed Weight in g	Sr. No.	Observed Weight in g	Limit
1	98.790	6	98.796	± 0.1 %
2	98.792	7	98.793	
3	98.794	8	98.794	
4	98.795	9	98.794	
5	98.793	10	98.794	

Conclusion: Individual measurement deviation from average value **exceeds/ does not exceed** standard deviation

Remark: The instrument is found **Satisfactory/ unsatisfactory** for its use.

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	ARNI ANALYTICALS	
TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-	Analytical Balance	Page No.
Instrument Make :-	Wensar	
Instrument Model No. :-	DS 8000	1 of 3
Instrument ID : -	ARNI/INS-004	

NAME OF STUDENT:-

MONTHLY CALIBRATION RECORD

1. Calibration by using Standard certified weights:

Observation Table:

Sr. No.	Reference Weight in g	Observed Weight in g	Weight in g (Limit: ± 0.1%)
1	200.0000	200.022	199.8000 to 200.2000
2	100.0000	98.770	99.9000 to 100.1000
3	50.0000	50.699	49.9500 to 50.0500
4	20.0000	19.051	19.9800 to 20.0200
5	10.0000	9.997	9.9900 to 10.0100
6	5.0000	5.080	4.9950 to 5.0050
7	2.0000	1.280	1.9980 to 2.0020
8	1.0000	0.923	0.9990 to 1.0010
9	0.5000	0.191	0.4995 to 0.5005
10	0.2000	0.106	0.1998 to 0.2002
11	0.1000	0.057	0.0999 to 0.1001
12	0.0500	0.035	0.0499 to 0.0501
13	0.0200	0.014	0.0199 to 0.0200
14	0.0100	0.008	0.0099 to 0.0100
15	0.0050	0.005	0.0049 to 0.0051

Conclusion: The observed weights are **within limit/ out of limit.**

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CHECKED BY:-

	ARNI ANALYTICALS	
TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-		Page No.
Instrument Make :-		
Instrument Model No. :-		2 of 3
Instrument ID : -		

2. Test for Linearity:

Sr. No.	Selected Weights in g	Observed Weight in g
1	5	5·081
2	10	10·002
3	20	18·375

Conclusion: The observed weights are **Consistent/not Consistent.**

ANALYSED BY **CHECKED BY:-**

3. Test for Eccentricity:

1	2
A	
3	4

Sr. No.	Weight Observed in g	Difference in g	Limit
1.	At Centre- (A) 10·000		
2.	At Corner 1 (B) 9·999	B-A = −0·001	
3.	At Corner 2 (C) 9·998	C-A = −0·002	± 0.1 %
4.	At Corner 3 (D) 10·000	D-A = 0·000	
5.	At Corner 4 (E) 9·997	E-A = −0·003	

Conclusion: The maximal Differential Eccentricity error is **within limit/~~out of limit~~** of Std. deviation.

ANALYSED BY **CHECKED BY:-**

	ARNI ANALYTICALS	
TITLE	MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE	
Instrument Name :-		Page No.
Instrument Make :-		
Instrument Model No. :-		3 of 3
Instrument ID : -		

4. Test for Repeatability :

Selected Weight in g: 10 gm

Sr. No.	Observed Weight in g	Sr. No.	Observed Weight in g	Limit
1	9.997	6	9.998	± 0.1 %
2	9.998	7	9.996	
3	10.000	8	9.997	
4	9.999	9	9.997	
5	9.998	10	9.998	

Conclusion: Individual measurement deviation from average value ~~**exceeds/**~~ **does not exceed** standard deviation.

Remark: The instrument is found **Satisfactory/** ~~**unsatisfactory**~~ for its use.

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	ARNI ANALYTICALS	
TITLE	DAILY CALIBRATION RECORD OF pH-METER	
Instrument Name :-	pH Meter	Page No
Instrument Make :-	LABMAN	1 of 1
Instrument Model No. :-	LMPH-10	
Instrument ID : -	ARNI/INS-00	

DAILY CALIBATION RECORD

- **Procedure: Refer SOP No. : SOP/ARN/INS-005**
- **Preparation Of Solutions:**

- **pH-4.01 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 4.0 ±0.05 at 25°C.

- **pH-7.00 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 7.0 ±0.05 at 25°C.

- **pH-9.20 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 9.20 ±0.05 at 25°C.

- **Observation Table:**

Sr. No.	Date	pH	
		4.00 (± 0.05)	7.00 (± 0.05)
1	16/12/2022	3.95	6.77

Slope = 95 %.

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	ARNI ANALYTICALS	
TITLE	DAILY CALIBRATION RECORD OF pH-METER	
Instrument Name :-		Page No
Instrument Make :-		1 of 1
Instrument Model No. :-		
Instrument ID : -		

DAILY CALIBATION RECORD

- **Procedure: Refer SOP No. : SOP/ARN/INS-005**
- **Preparation Of Solutions:**

- **pH-4.01 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 4.0 ±0.05 at 25°C.

- **pH-7.00 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 7.0 ±0.05 at 25°C.

- **pH-9.20 :-**
  - Transfer the capsule content in a 100ml volumetric flask using a funnel.
  - Dissolve the contents in 10 ml of distilled water and then make it up to 100 ml with distilled water.
  - This solution will have a pH of 9.20 ±0.05 at 25°C.

- **Observation Table:**

Sr. No.	Date	pH	
		4.00 (± 0.05)	7.00 (± 0.05)
01.	10/12/2022	3.99	6.88

Slope = 97 %

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	ARNI ANALYTICALS	
TITLE	DISSOLUTION TEST APPARATUS WORKSHEET	
Instrument Name :-	DISSOLUTION TEST APPARATUS	Page No.
Instrument ID : -	ARNI / INS - 003	
Instrument Model No. :-	DS-8000	1 of 1
Name Of Students	Lonare Ajinkya Dattatraya	

NAME OF TEST :-

TRIAL FOR DISSOLUTION TEST.

DISSOLUTION CONDITIONS:-

Dissolution Media	WATER
Media Volume	900 mL
Apparatus	USP TYPE II PADDLE
RPM	100
Temperature	37.0 ± 0.5°C
Time	45 Minutes

PREPARATIONS:-

Pour 900 mL of dissolution medium in each vessel. Allow sufficient time for the dissolution medium to equilibrate at 37°C ± 0.5°C. Adjust stirring element speed to 100 rpm. Place one capsule in each of six paddle and adjust the paddle in the dissolution medium so that there is a distance of 25 mm ± 2 mm between the bottom of the paddle and inside bottom of the vessel. Start the apparatus. At the end of specified time interval, withdraw 10 mL aliquot from a zone midway between the surface of the dissolution medium and at top of the rotating paddle. Further dilute 2ml of the above solution to 25ml with dissolution medium.

ANALYSED BY

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	ARNI ANALYTICALS	
TITLE	DISSOLUTION TEST APPARATUS WORKSHEET	
Instrument Name :-		Page No.
Instrument ID : -		
Instrument Model No. :-		1 of 1
Name Of Students		

NAME OF TEST :-

TRIAL FOR DISSOLUTION TEST.

DISSOLUTION CONDITIONS:-

Dissolution Media	Water
Media Volume	900 ml
Apparatus	USP Type II paddle
RPM	100
Temperature	37.0 ± 0.5°C
Time	45 min

PREPARATIONS:-

Pour 900 ml of dissolution medium in each vessel. Allow sufficient time for the dissolution medium to equilibrate at 37°C ± 0.5°C. Adjust stirring element speed at 100 rpm. Place one capsule in each of six paddle & adjust it in medium so the dist of 25 mm ± 2 mm betn bottom of paddle & inside bottom of vessel. Start the apparatus. At end of specified time, withdrawn 10 ml aliquot from zone midway. Further diluted 2 ml above solution to 25 ml dissolution medium.

Aijaya
ANALYSED BY

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ARNI ANALYTICALS

TITLE	UV-SPECTROPHOTOMETER WORKSHEET	
Instrument Name :-	UV-Spectrophotometer	Page No.
Instrument ID : -	ARNI/INS-002	
Instrument Model No. :-	LMSP-UV100B	1 of 1
Name Of Students	Lonare Ajinkya Dattatraya	

NAME OF TEST :-

1) **PHOTOMETRIC ANALYSIS**
2) **WAVELENGTH SCAN**

PREPARATIONS:-

STANDARD PREPARATION :-

Weigh accurately 10mg of Caffeine standard in a 100ml volumetric flask, add 60ml of water sonicate for 5 minutes to completely dissolve, makeup the volume with water.

Further dilute 5mlof the above solution to 50ml with water.

UV-SPECTROPHOTOMETER WAVELENGTH :- **273nm** (Maxima)

ANALYSED BY

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ARNI ANALYTICALS

TITLE	UV-SPECTROPHOTOMETER WORKSHEET	
Instrument Name :-		Page No.
Instrument ID : -		
Instrument Model No. :-		1 of 1
Name Of Students		

Date:-

NAME OF PRODUCT	:	Caffiene
WORKING STANDARD NO.	:	—
POTENCY	:	—
INSTRUMENT ID	:	ARNI / INS-002

NAME OF TEST :- 1) Photometric Analysis
2) Wavelength Scan

PREPARATIONS:-

STANDARD PREPARATION :-

Weigh accurately 10 mg of caffiene standard in 100 ml volumetric flask, add 60 ml water & sonicate for 5 min. dissolve it & makeup volume. Further dilute 5 ml of soln to 50 ml of water.

UV-SPECTROPHOTOMETER WAVELENGTH :- 273 nm (maxima)
246 nm (minimum)

OBSERVATIONS:-

MAXIMUM ABSORPTION WAVELENGTH

273 nm.

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ANALYSED BY

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