Mula Education Society's
ARTS, COMMERCE AND SCIENCE COLLEGE, SONAI
Tal. Newasa, Dist- Ahmednagar – 414105
Ph.: 02427-231384 Email: sonaicollege@yahoo.co.in, mesacsccollege@gmail.com Website:www.acssonaicollege.com
Affiliated to Savitribai Phule Pune University, Pune (I.D.PU/AN/ASC/031/1989)
NAAC Re-accredited with 'A' Grade, DBT Star College Scheme, ISO 9001: 2015 Certified, AISHE Code – C-42096

Additional Information for Metric No. 2.5.1

2.5.1Mechanism of internal assessment is transparent and robust in terms of frequency and mode.

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ISO 9001:2015 academic process manual clause no ACA.PR/o6

ACA/PR/06	Conduction of Internal, Midterm / Term-end Examination	
Rev.: 00 Date: 15.06.2018	Clause: 8.5.1, 8.6	Page: 01 / 01

Input	Brief abstracts, Time table, Syllabus coverage.

Sr. No.	Activity	Owner	Process Out put
1	Decide schedule for conduction of Internal, Midterm / Term-end examination	CEO	Faculty wise Examination Schedule
2	Issuing the notice of timetable to students	CEO	Notice
3	Preparation of examination's stationery	CEO	Stationery
4	Setting the question paper	Faculty	Question paper
5	Conduction of examination as per schedule	HoD	--
6	Assessment of the paper and preparation of results	Faculty	--
7	Communicate, Display and obtain acknowledgement of results from students	HoD & Faculty	Result sheet

Output	Identification of improvement areas and remedial measures

Process Monitoring & Measurement					
Parameter	**Indicator**	**Measurement Methodology**	**Frequency of Monitoring**	**Responsibility**	**Documented information**
Execution of Internal, Midterm / Term-end as per schedule	Plan V/s actual	Plan V/s actual of **Internal, Midterm / Term-end**	After every exams	CEO / HOD	Academic Calendar

1. Internal Exam Time Table (sample copy)

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Examination

ACA – R-28
Rev : 00
Date: 15.06.2018

Test Time Table
(Internal Assessment Test / Terminal Exam / Tutorial)

Academic Year: 2022-23
Annual /Semester:

Ref: MES ACSC ACA

Date: 4/11/2022

All the students of FY/SY/TY B.A. are hereby informed that the following is the schedule for the Internal Test- Semester I to be conducted from 14/11/2022 to 19/11/2022 . All Students should remain present compulsorily .

All Lectures will be conducted as per the time table except the test Period .

Day and Date	Class	Period I 8-00 to 8-50	Period II 8-50 to 9-40	Period III 9-50 to 10-40	Period IV 10-40 to 11-30
14/11/2022	F. Y . B A	Marathi	-----	------	-----
	S. Y. B . A.	-----	History G2	-----	All SEC-1
	T. Y. B. A	------	Geography G3	-------	Hindi G3 Eco -G3
15/11/2022	F. Y . B A	-------	Political Science	------	--------
	S. Y. B . A.	All.SEC/S 1	-------	-----	Political Science G2
	T. Y. B. A	History G 3	All DSE3/S3	-------	English G.3
16/11/2022	F. Y . B A	Com. English	------	-----	--------
	S. Y. B . A.	-----	Marathi G.2	-------	English G.2
	T. Y. B. A	------	-------	------	-----
17/11/2022	F. Y . B A	Hindi g-1/Eco G.1	------	Opp.English	--------
	S. Y. B . A.	DSE /S2	--------	-------	Hindi G2/Eco G2
	T. Y. B. A	Com. English	-------	-------	------
18/11/2022	F. Y . B A	------	------	Geography G1	-----
	S. Y. B . A.	-----	-----	Geography G2	-----
	T. Y. B. A	-----	DSE./S4	-----	Political Science G3
19/11/2022	F. Y . B A	-----	History G.1	------	-----
	S. Y. B . A.	------	Com .English	-----	-----
	T. Y. B. A	-----	-------	Marathi G3	-----

CEO
Mula Education Society's
Art's,Commerce & Science College
Sonai,Tal.Newasa Dist.Ahmednagar Pin 414105

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Tal.Newasa,Dist.Ahmednagar Pin 414105

Mula Education Society's
Arts, Commerce & Science College, Sonai

Time table of Internal Examination for B.Sc. Nov. 2022
Semester I/III/V

Day & Date	Class	Period I 8.00-8.50	Period II 8.50-9.40	Period III 9.50-10.40	Period IV 10.40-11.30
Monday 14.11.2022	FYBSc	Zoo-I/ Maths-I	Zoo-II/ Maths-II	--	--
	SYBSc	--	--	Che – I	Che – II
	TYBSc	--	--	Paper – I	Paper – II
Tuesday 15.11.2022	FYBSc	Phy – I/ Geo – I	Phy – II/ Geo – II	--	--
	SYBSc	--	--	Bot – I/ Maths – I	Bot – II/ Maths –II
	TYBSc	--	--	Paper – III	Paper – IV
Wednesday 16.11.2022	FYBSc	Che – I	Che – II	--	--
	SYBSc	--	--	Geo - I	Geo - II
	TYBSc	--	--	Paper – V	Paper – VI
Thursday 17.11.2022	FYBSc	Bot – I	Bot – II	--	--
	SYBSc	--	--	Zoo – I/ Phy – I	Zoo – II/ Phy – II
	TYBSc	--	--	SEC – I	SEC – II
Friday 18.11.2022	SYBSc	Marathi/ English	--	--	--

Important instructions:

1) **It is compulsory to all the students to attend internal examination as per above time table, as there will be no second internal examination.**
2) The obtained marks in above internal examination will be treated final and submitted to University.
3) All the papers will be of 10 marks each.
4) Answers are to be written on the question paper itself.
5) Pattern of question paper will be as per guidelines of University.
6) For any clarification, students should contact their subject teachers.
7) The examination will be held in regular classrooms.

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Mula Education Society's
Arts, Commerce & Science College, Sonai
Department of Botany (P.G.)

ACA – R-28
Rev : 00
Date: 15/06/2018

Test Time Table

Academic Year: 2022 – 23 (Term-II)

Semester: II & IV

Ref: MES/ACSC/ACA/

Date: 06/05/2023

M.Sc. Part –I & -II Botany (Credit Pattern 2019)
Internal Theory Examination Time Table

Students of M.Sc. Part –I & -II Botany (Credit Pattern 2019) are informed that their ***Internal Theory Examination*** will be conducted from **8th May to 10th May. 2023.** The Examination will be conducted according to the norms of Savitribai Phule Pune University Examination.

- ***Instructions to the Students:***

- Students should be present half an hour before the exam.
- Students will not be allowed for exam without Identity card & dress code.
- No Rexam will be conducted for the absent students.
- Examination will be of **10 marks; Time: 1 hr.**

- **Pattern of Question Paper:**

Each paper of 10 marks and the pattern of question paper shall be:

Question 1 (1 Marks)	5 compulsory sub-questions, each of 1 mark; (such as define, short problem, / neat labeled diagram, short reasons, characteristics, applications, etc.)
Question 2 (2.5 Marks)	2 out of 3 –descriptive answer type questions of 2.5 marks each; answerable in sufficient length like write notes

Sr. No.	Date	Time	M.Sc.-I	M.Sc.-II
1	**08/05/2023**	10.00 am to 11.00 am	BOUT 121 (Plant Systematic II)	BOUT 241 (Botanical Techniques)
		11.00 am to 12.00 noon	BOUT 122 (Molecular Biology)	BOUT 241 (Advance Ecology)
2	**09/05/2023**	10.00 am to 11.00 am	BOUT 123 (Biochemistry)	BODT 243 (Seed Technology)
3		10.00 am to 12.00 noon	BODT 124 b (Mushroom Cultivation and Bio-pesticide technology)	BODT 244 (Plant Tissue culture technology)
4	**10/05/2023**	12.00 pm to 01.00 pm	Cyber Security - II	Cyber Security-IV
5		02.00 pm to 03.00 pm	Human Rights - II	Skill Development-II

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Mula Education Society's
Arts, Commerce & Science College, Sonai

Time table of Internal Examination for B.Sc. (April 2023)

Semester II/IV/VI

Day & Date	Class	Period I 8.00-8.50	Period II 8.50-9.40	Period III 9.50-10.40	Period IV 10.40-11.30
Wednesday 26.04.2023	FYBSc	Zoo-I/ Maths-I	Zoo-II/ Maths-II	--	--
	SYBSc	--	--	Che – I	Che – II
	TYBSc	Paper – I	Paper – II	--	--
Thursday 27.04.2023	FYBSc	Phy – I/ Geo – I	Phy – II/ Geo – II	--	--
	SYBSc	--	--	Bot – I/ Maths – I	Bot – II/ Maths –II
	TYBSc	Paper – III	Paper – IV	--	--
Friday 28.04.2023	FYBSc	Che – I	Che – II	--	--
	SYBSc	--	--	Geo - I	Geo - II
	TYBSc	Paper – V	Paper – VI	--	--
Saturday 29.04.2023	FYBSc	Bot – I	Bot – II		--
	SYBSc	--	--	Zoo – I/ Phy – I	Zoo – II/ Phy – II
	TYBSc	SEC – III	SEC – IV	--	--
Tuesday 02.05.2023	SYBSc	Marathi/ English	--	--	--

Important instructions:

1) **It is compulsory to all the students to attend internal examination as per above time table, as there will be no second internal examination.**
2) The obtained marks in above internal examination will be treated final and submitted to University.
3) All the papers will be of 10 marks each.
4) Answers are to be written on the question paper itself.
5) Pattern of question paper will be as per rules of University.
6) For any clarification, students should contact their subject teachers.
7) The examination will be held in regular classrooms.

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2. Internal Exam Question paper **(sample copy)**

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Chemistry

ACA – R -29
Rev : 00
Date: 15.06.2018
Class: M.Sc. Organic Chemistry
Sub.: CHO-452(A)

Internal Test
CHO-452A
Concepts and Applications of Medicinal Chemistry.

Academic Year: 2022-23
Semester: II
Date: 09/05/2023
Time: 12:00To :01:00
Max. Marks: 20

Section - I

Q.1) Define / Explain *3M*

1. Define: Protein.
2. Define: Medicinal Chemistry.
3. Define: Coenzyme.

Q.2) Write a Short Note On (Attempt any TWO) **4M**

i) Protein as a biological catalyst

ii) Solid phase peptide synthesis

iii) Biological Application of Folic Acid

iv) Write Hansch equation and explain terms involved in it.

Q.3) Answer the Following (Attempt any One) *3M*

i) Draw structure of oxamniquine and explain its mechanism of action.

ii) Explain Proton Pump Inhibitor

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Chemistry

ACA – R -29
Rev : 00
Date: 15.06.2018
Class: M Sc. I.
Sub.:CHI 130

Question Paper
Internal test

Academic Year: 2022-23
Annual /Semester: I
Date: 22/11/2022 Time:12.00
Max. Marks: 20 marks

Section-I

Instructions: 1. all questions are compulsory

Q1. Attempt the following (compulsory) 03 Marks

1. Which principal axis is present in $NiCl_4$?
2. Define Improper axis of symmetry?
3. Define Symmetry elements?

Q2. Attempt the following (any TWO) 04 Marks

1. Explain all symmetry elements and symmetry operations in NH_3?
2. Explain all symmetry elements and symmetry operations in $XeOF_4$?
3. Determine the point group of Ethylene molecule?
4. Determine the point group of Boric Acid molecule?

Q3. Attempt the following (any ONE) 03Marks

1. Explain all symmetry elements and symmetry operations in CH_4 molecule?
2. Explain all symmetry elements and symmetry operations in SF_6 molecule?

Section-II

Q4. Attempt the following (compulsory) 03 Marks

1. Define Electron Deficient Compound?
2. Define Electron Rich Compound?
3. Define Electron Precise Compound?

Q5. Attempt the following (any TWO) 04 Marks

1. Define acid by arrenius theory?
2. Define Interhalogen Compound?
3. Define Pseudohalogens?
4. Explain in brief about Diamond allotrope?

Q6. Attempt the following (any ONE) 03Marks

5. Explain Interhalogen Compound with suitable examples?
6. Explain Pseudohalogen Compound with suitable examples?

3. Internal Exam Attendance sheet **(sample copy)**

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Physics

ACA – R -29
Rev : 00
Date: 15.06.2018
Class: M.Sc. - II

Internal Exam March/April - 2023

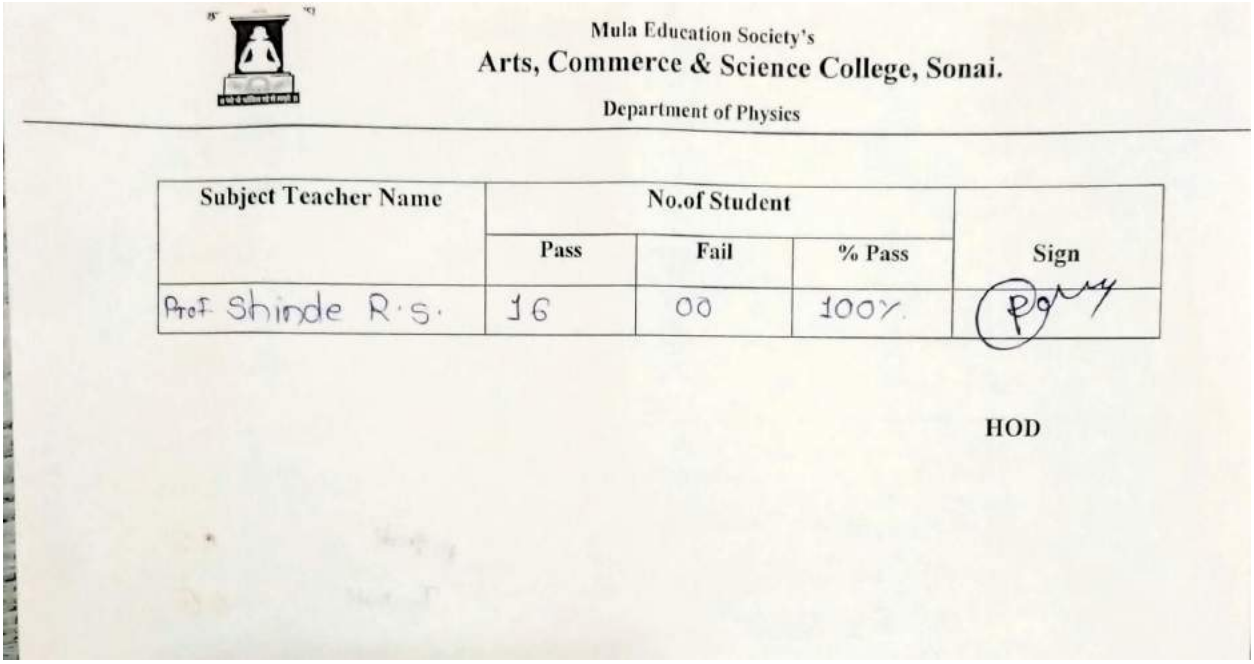
Academic Year: 2022-23
Annual /Semester: IV
Time: 12:00 pm to 01:00 pm
Marks: 10
Date :- 09 /05/2022

Sub.: PHOT – 244H4
Energy Studies - II

Sr. No.	Roll No.	Name of Student	Student Sign	Marks
1.	01	Aghade Rutuja Vilas		05
2.	02	Barhate Rutuja Eknath	Barhate	06
3.	03	Darandale Uday Patilba		07
4.	04	Dhere Akash Bapurao		05
5.	05	Gade Ankita Shashikant		06
6.	06	Gawali Shivani Jayant		06
7.	07	Ghodechor Dyaneshwari Namdev		06
8.	08	Kajale Shital Abasaheb	Bajale	08
9.	09	Kardile Pranali Satish		07
10.	10	Lande Pratiksha Dinkar		06
11.	11	Latpate Rushikesh Ramkisan		07
12.	12	MisalVaishnavi Janardhan		05
13.	13	Sawai Sarita Mohan		07
14.	14	Tekale Vaishnavi Sambhaji		07
15.	15	Toge Ganesh Ashok		05
16.	16	Devtarse kaveri Babasaheb		08

Supervisor's Name	No. of Student			Sign
	Appeared	Present	Absent	
Miss. Darandale A.A.	16	16	00	DarandaleAA.

Test Co-ordinator



Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Physics

Subject Teacher Name	No.of Student			Sign
	Pass	Fail	% Pass	
Prof Shinde R.S.	16	00	100%	

HOD

4. Internal marks with signs (sample copy)

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Chemistry

ACA – R -30 Rev : 00 Date: 15.06.2018 Class: M.sc-II(organic Chemistry) Sub- CHO-452(A)	Mark List CHO-452(A) Concepts and Application of Medicinal Chemistry	Academic Year: 2022-23 Semester: IV Max. Marks: 30

Ref: Ref: MES/ACSC/ACA/ /

Sr. No.	Name of The students	Internal (Mark-10)	Seminar and PPT (Mark-10)	Assignment (Mark-5)	Short Quize (Mark-5)	Total (Out of 30)	Sign.
1.	AUTI MANISHA RAMKISAN	06	05	03	04	18	
2.	BACHKAR SACHIN ASHOK	04	04	03	05	16	
3.	BANKAR JAYASHRI BABASAHEB	07	08	04	05	24	
4.	BANKAR PRATIKSHA RANGNATH	04	04	02	05	15	
5.	BELHEKAR VAISHNAVI RAMESH	06	04	03	05	18	
6.	BHAGWAT MANGESH SANJAY	04	05	03	05	17	
7.	BHALERAO SNEHAL VITTHAL	04	04	03	03	14	
8.	BHAWAR SANKET VIJAY	04	07	04	05	20	
9.	BORHADE MAYUR ASHOK	04	07	04	05	20	
10.	CHAVAN SHUBHANGI NITIN	07	03	03	05	18	
11.	DAHATONDE RUTUJA SANJAY	04	04	03	04	15	
12.	DARANDALE NAVNATH NAMDEV	04	04	02	03	13	
13.	DARANDALE VAIBHAV SUNIL	04	04	02	05	15	
14.	DESHMUKH AARTI RAJENDRA	06	08	04	05	23	
15.	DEVHARE SAGAR GORAKSHNATH	04	02	02	04	12	
16.	DHALE SAGAR ASHOK	06	04	03	05	18	
17.	DHANWATE AKSHDA ANNASAHEB	07	08	04	05	24	
18.	DHUMAL GAYATRI SANDIP	05	04	03	05	17	
19.	GADAKH KSHITIJA ANIL	04	04	03	04	15	
20.	GADAKH SHRIKRUSHNA SANJAY	04	03	02	05	14	
21.	GADAKH SUDARSHAN BABASAHEB	04	03	02	05	14	
22.	GAIKWAD SAURABH RAMESH	08	08	05	05	26	
23.	GAIKWAD SHITAL BABASAHEB	09	08	05	05	27	
24.	GITE RAHUL BHAGWAN	04	03	02	04	13	

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Department of Chemistry

25.	GOSAVI MAHESH SUNIL	04	07	04	05	20	
26.	GUDADHE SHWETA MITTHU	05	06	04	03	18	
27.	JADHAV RUSHIKESH DHARMARAJ	04	03	03	04	14	
28.	JARE DIGAMBAR BHAUSAHEB	04	04	03	05	16	
29.	JARE PANKAJ BABASAHEB	04	03	00	05	12	
30.	KALE SNEHAL SUBHASH	09	08	05	05	27	
31.	KUNDE SHEETAL RAMRAO	08	08	04	05	25	
32.	KURHE JAYDIP DILIP	04	04	02	04	14	
33.	KURHE SAURABH ASHOK	04	05	02	05	16	
34.	MAGAR PRAVIN HARIBHAU	05	05	04	04	18	
35.	MARADE ARPIT BANDU	05	05	05	05	20	
36.	MORE MANGESH BALASAHEB	04	04	00	04	12	
37.	MORE PRATIKSHA SARJERAO	07	07	04	05	22	
38.	MUSMADE AMRUTA ASHOK	07	04	03	05	19	
39.	ROTHE SACHIN NANASAHEB	06	04	03	05	18	
40.	SANAP AMOL BHAUSAHEB	04	03	02	04	13	
41.	SAPTE AMOL DNYANDEO	04	03	01	04	12	
42.	SATRE MAHESH VISHNU	05	04	03	05	17	
43.	SHINDE SHUBHAM SADANAND	05	04	03	05	17	
44.	SOMVANSHI NILAM GANESH	07	07	04	05	23	
45.	TARAWADE ARTI SANJAY	Ab	Ab	Ab	Ab	Ab	–
46.	TODMAL GANESH DILIP	05	07	04	05	21	
47.	TUWAR KIRAN RAMBHAU	05	07	04	05	21	
48.	~~WAGH VAISHNAVI BABASAHEB~~ Wakade Rahul Ramkrishna	04	07	02	02	12	
49.	ZINE PRITI PRAKASH	04	04	03.	05	16	

Mula Education Society's
Arts, Commerce & Science College, Sonai.
Department of Chemistry

Supervisor's Name	No of students			Sign
	Appeared	Present	Absent	
Miss. Kank P. S.	49	48	01	
Total	49	48	01	

Subject Teacher Name	No of students			Sign
	Pass	Fail	% Pass	
Miss. Kank P. S.	48	01		

Test Coordinator

HOD

Head
Department of Chemistry
Arts,Commerce & Science
College,Sonai,Tal.Newasa,
Dist.Ahmednagar - 414105

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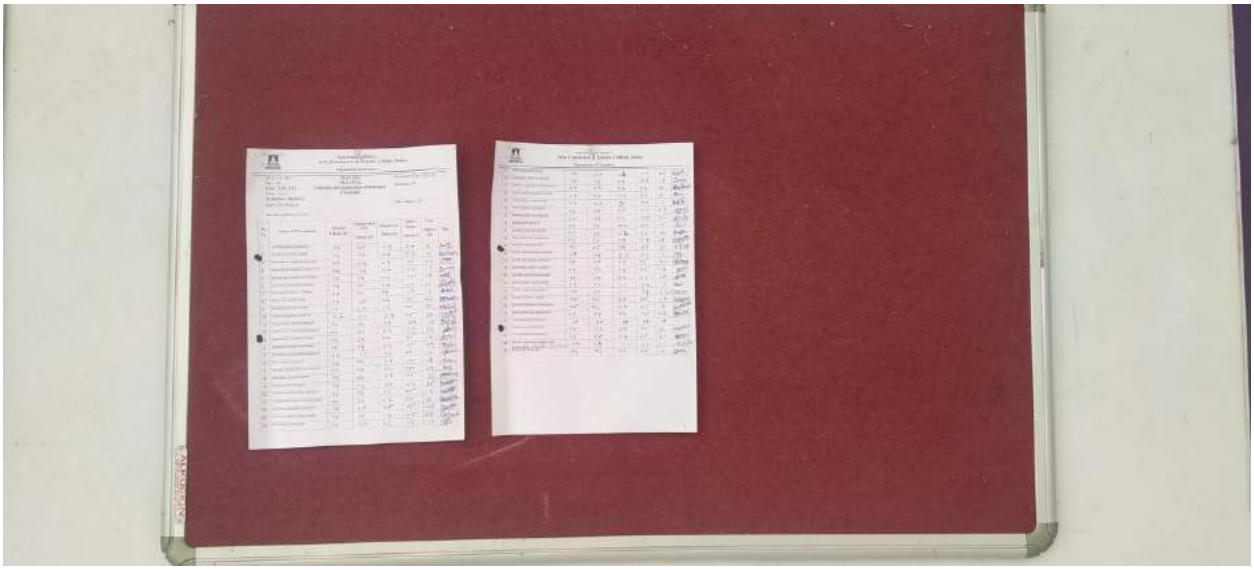

Internal marks displayed on noticeboard

Mula Education Society's
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Tal. Newasa, Dist- Ahmednagar – 414105
YASH GROUP
Ph.: 02427-231384 Email: sonaicollege@yahoo.co.in, mesacsccollege@gmail.com Website:www.acssonaicollege.com
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Internal marks uploaded on university portal for final result

Savitribai Phule Pune University
Examination Session 2023
Marks Inward System for Colleges

2306270251228

6/27/2023

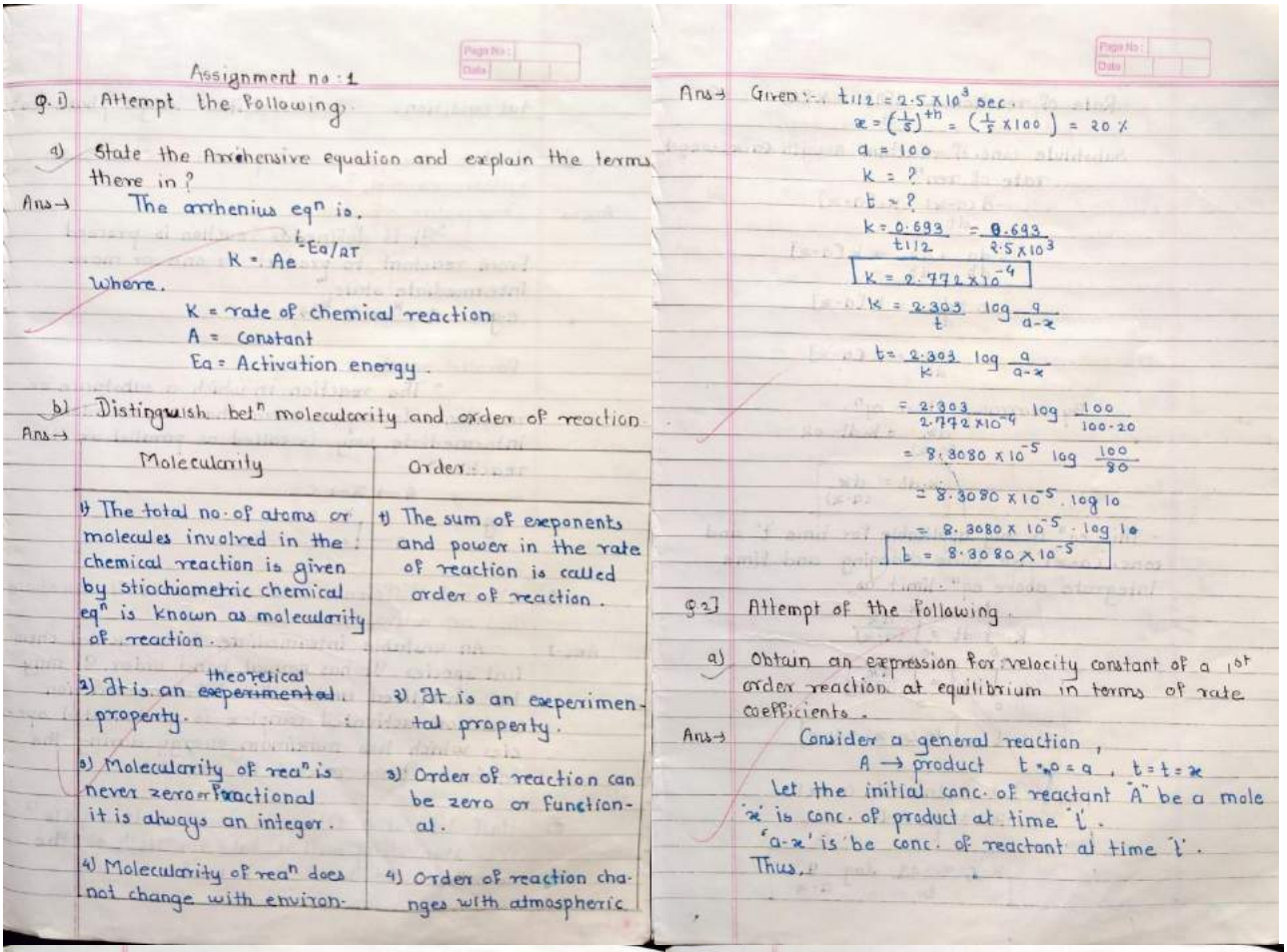
College Name	CAAA016340 - MULA EDUCATION SOCIETY'S ARTS, SCIENCE & COMMERCE COLLEGE		
Pattern Name	22519 - M.Sc. ORGANIC CHEMISTRY (REV.2019)	**Batch No**	202304088489
Subject Name	33423A - CBOP-4 CHO-452 A)MEDICINAL CHEMISTRY	**Exam Type**	INTERNAL OUT OF 30
Teacher Name	Kank Pratiksha Sanjay (Mob. No.: 8625018191) - Internal Examiner		

Total Students	Present Students	Absent Students	Not Applicable	Detained
49	48	1	0	0

Seat No	Marks/Grade	Seat No	Marks/Grade
334568	18	334593	16
334569	16	334594	13
334570	24	334595	27
334571	15	334596	25
334572	18	334597	15
334573	17	334598	16
334574	14	334599	18
334575	20	334600	20
334576	20	334601	13
334577	18	334602	22
334578	15	334603	19
334579	14	334604	18
334580	15	334605	13
334581	23	334606	13
334582	13	334607	17
334583	18	334608	17
334584	17	334609	23
334585	15	334610	(AB)
334586	14	334611	21
334587	14	334612	21
334588	26	334613	12
334589	13	334614	16
334590	20	334615	24
334591	18	334616	27
334592	15		

Head
Department of Chemistry
Arts,Commerce & Science
College,Sonai,Tal.Newasa,
Dist.Ahmednagar - 414105
Stamp & Authorized Signatory

5. Sample of Assignment Submission



Assignment no : 1

Q.1) Attempt the following.

a) State the Arrhenius equation and explain the terms there in?

Ans→ The arrhenius eqⁿ is.

$$K = Ae^{-Ea/RT}$$

Where.

K = rate of chemical reaction
A = Constant
Ea = Activation energy.

b) Distinguish betⁿ molecularity and order of reaction

Ans→

Molecularity	Order
1) The total no. of atoms or molecules involved in the chemical reaction is given by stiochiometric chemical eqⁿ is known as molecularity of reaction.	1) The sum of exponents and power in the rate of reaction is called order of reaction.
2) It is an ~~experimental~~ theoretical property.	2) It is an experimental property.
3) Molecularity of reaⁿ is never zero or fractional it is always an integer.	3) Order of reaction can be zero or fractional.
4) Molecularity of reaⁿ does not change with environmental condition.	4) Order of reaction changes with atmospheric condition in gas phase reaⁿ

Ans→ Given :- $t_{1/2} = 2.5 \times 10^3$ sec.

$x = \left(\frac{1}{5}\right)^{th} = \left(\frac{1}{5} \times 100\right) = 20\%$

$a = 100$

$k = ?$

$t = ?$

$k = \frac{0.693}{t_{1/2}} = \frac{0.693}{2.5 \times 10^3}$

$k = 2.772 \times 10^{-4}$

$k = \frac{2.303}{t} \log \frac{a}{a-x}$

$t = \frac{2.303}{k} \log \frac{a}{a-x}$

$= \frac{2.303}{2.772 \times 10^{-4}} \log \frac{100}{100-20}$

$= 8.3080 \times 10^{-5} \log \frac{100}{80}$

$= 8.3080 \times 10^{-5} \log 10$

$= 8.3080 \times 10^{-5} \cdot \log 10$

$t = 8.3080 \times 10^{-5}$

Q.2] Attempt of the following.

a) Obtain an expression for velocity constant of a 1st order reaction at equilibrium in terms of rate coefficients.

Ans→ Consider a general reaction,

$A \rightarrow$ product $\quad t=0 \; a, \quad t = t \; x$

Let the initial conc. of reactant 'A' be a mole 'x' is conc. of product at time 't'.
'a-x' is be conc. of reactant at time 't'.
Thus,

Rate of reaction $= -\frac{d[A]}{dt} = k[A] \quad \cdots (1)$

Substitute conc. of reactant A with (a-x) we get rate of reaⁿ

$\frac{-d(a-x)}{dt} = k \cdot [a-x]$

$-\frac{da}{dt} + \frac{dx}{dt} = k[a-x]$

$0 + \frac{dx}{dt} = k[a-x]$

$\frac{dx}{dt} = k[a-x]$

By rearrange above eqⁿ.

$\frac{dx}{(a-x)} = k \cdot dt$ OR

$k \cdot dt = \frac{dx}{(a-x)}$

- This eqⁿ is only applicable for time 't' and conc. '(a-x)' for wide changing and time Integrate above eqⁿ limit as.

$k \cdot \int_0^t dt = \int_0^x \frac{dx}{(a-x)}$

$k \left[dt\right]_0^t = \left[\frac{dx}{a-x}\right]_0^x$

$k \cdot t = \left[-\ln(a-x) + \ln a\right]$

$k \cdot t = \ln a - \ln(a-x)$

$k = \frac{1}{t} \ln \frac{a}{a-x}$

$k = \frac{2.303}{t} \log \frac{a}{a-x}$

c] Define consequative and parallel reaction with suitable example?

Ans→ Consequative reaction :-

"It is defined as reaction is proceed from reactant to product to one or more intermediate state."

e.g :- $A \xrightarrow{K_1} B \xrightarrow{K_2} C$

Parallel reaction :-

"The reaction in which a substance or reactant decompose more than one or more intermediate way is called as parallel or side reaction".

$A \rightarrow B \rightarrow C$

e.g :- $A \begin{cases} \xrightarrow{K_1} B \\ \xrightarrow{K_2} C \end{cases}$

d] What is difference between unstable intermediate and an activated complex.

Ans→ An unstable intermediate is an actual chemical species. It has normal, band order. It may be stabilized under the different reaction condition activated complex is postualated species which has maximum energy during the inversion from reacted to parallel.

e] Half-life of a 1st order reaction is 2.5×10^{13} sec. How long will it take for 1/5th of the

$$\therefore \frac{x}{a} = e^{-k_1 t} \quad \ldots\ldots (3)$$

eqⁿ (3) is called exponential eqⁿ. i.e. conc of reactant A. fall exponential with time B.

1) For rate of formation, $\frac{dY}{dt} = k_1 x$

2) For rate decomposition, $\frac{dY}{dt} = -k_2 Y$

∴ Net reaction.

$$\frac{dY}{dt} = k_1 x - k_2 Y.$$

Multiply above eqⁿ with -ve sign.

$$-\frac{dY}{dt} = -k_1 x + k_2 Y.$$

$$-\frac{dY}{dt} = k_2 Y - k_1 x \quad \ldots\ldots (4)$$

put eqⁿ (3) in eqⁿ (4)

$$-\frac{dY}{dt} = k_2 Y - k_1 a e^{-k_1 t} \quad \ldots\ldots (5)$$

Eqⁿ (5) is called linear differential eqⁿ of 1st order eqⁿ is.

$$Y = \frac{k_1 a}{k_2 - k_1}\left(e^{-kt} - e^{-k_2 t}\right) \quad \ldots\ldots (6)$$

- If there is no change in no. of moles. i.e sum of moles A, B, and C = Initial moles of reactant at time t A of time t = 0.

$$x + Y + z = a$$

$$z = a - x - Y \quad \ldots\ldots (7)$$

put eqⁿ (6) in eqⁿ we get.

Where 'k' is the velocity constant.
These eqⁿ is known as integrated form of first order reaction".

b] Derive the expression for the half life of an nth order reaction?

Ans→ Half-life period - $(t_{1/2})$

We know that

$$k = \frac{1}{t(n-1)}\left[\frac{1}{(a-x)^{n-1}} - \frac{1}{a^{n-1}}\right]$$

By rearrange above equation we get.

$$t = \frac{1}{k(n-1)}\left[\frac{1}{(a-x)^{n-1}} - \frac{1}{a^{n-1}}\right]$$

For 50% reaⁿ, t = $t_{1/2}$ and than above eqⁿ $x = a/2$ becomes.

$$\therefore t_{1/2} = \frac{1}{k(n-1)}\left[\frac{1}{(a-a/2)^{n-1}} - \frac{1}{a^{n-1}}\right]$$

$$\therefore t_{1/2} = \frac{1}{k(n-1)}\left[\frac{1}{(a/2)^{n-1}} - \frac{1}{a^{n-1}}\right]$$

$$\therefore t_{1/2} = \frac{1}{k(n-1)}\left[\frac{2^{n-1}}{a^{n-1}} - \frac{1}{a^{n-1}}\right]$$

$$\therefore t_{1/2} = \frac{1}{k(n-1)a^{n-1}}\left[2^{n-1} - 1\right]$$

$$\therefore t_{1/2} = \left[\frac{2^{n-1}-1}{k(n-1)}\right] \cdot \frac{1}{a^{n-1}}$$

$$\therefore t_{1/2} \propto \frac{1}{a^{n-1}}$$

c] How does the concentration of intermediate be obtained in the case of consecutive reaction $A \rightarrow B \rightarrow C$

* Ans→ Consecutive reaction -

- The reaction which proceed from reactant to product into one or more intermediate stage
- Consider a reaⁿ.

$$A \xrightarrow{k_1} B \xrightarrow{k_2} C$$

Initial time (t=0)	a	0	0
time (t)	x	y	z

∴ The rate of decomposition of reactant A. $\therefore \frac{dx}{dt} = -k_1 x$

Multiply above eqⁿ with -ve sign E

$$-\frac{dx}{dt} = k_1 x.$$

By rearrange the eqⁿ.

$$-\frac{dx}{x} = k_1\, dt$$

Integrate above eqⁿ without limit,

$$-\int \frac{dx}{x} = k_1 \int dt + c$$

$$-\ln x = k_1 \cdot t + c \quad \ldots\ldots (1)$$

Hence at time t=0, x = a then

∴ eqⁿ (1) become.

$$-\ln a = k_1 \cdot 0 + c$$

$$c = -\ln a \quad \ldots\ldots (2)$$

put eqⁿ (2) in eqⁿ (1)

$$\therefore -\ln x = k_1 t - \ln a$$

$$\therefore -\ln x + \ln a = k_1 t$$

∴ multiply with -ve sign.

$$\ln x - \ln a = -k_1 t$$

$$\ln\left(\frac{x}{a}\right) = -kt$$

$$\therefore z = a - ae^{-k_1 t} - \frac{k_1 \cdot a}{k_2 - k_1}\left(e^{-k_1 t} - e^{-k_2 t}\right) \ldots$$

Q.3. Solve the Following

1) In the arrhenius eqⁿ for a certain reaction the values of A & Ea are 4×10^{13} sec^{-1} and 98.6 kJ mol^{-1} respect. If the reaction is of the 1st order at what temp will it's half life be 10 minutes?

Ans→ Given :-

$A = 4 \times 10^{13}\ sec^{-1}$

$Ea = 98.6\ kJ\ mol^{-1}$

$t_{1/2} = 10$ minutes $= 10 \times 60 = 600$ sec.

$$K = \frac{0.693}{t_{1/2}}$$

$$K = \frac{0.693}{600}$$

$$K = 1.155 \times 10^{-3}$$

$$K = A \cdot e^{-Ea/RT}$$

$$\log K = A - \frac{Ea}{RT}$$

$$\log(1.155 \times 10^{-3}) = 4 \times 10^{3} - \frac{98.6}{8.314 \times T}$$

$$-2.9374 = 4 \times 10^{3} - \frac{98.6}{8.314 \times T}$$

$$T = \frac{4 \times 10^{3} - 98.6}{8.314 \times (-2.9374)}$$

$$T = \frac{4 \times 10^{3} - 98.6}{-24.4216}$$

$$T = 4 \times 10^{3} + 4.0374$$

$$T = 400\,40$$

$$T = 400.40$$

(b) In a 1st order reaction the reactant conc. reactant concentration by two third in a millisecond. In how much time will it be reduced to one nineth?

Ans→ Given :-

t = millisecond = 1000 sec

$a = 1$

$a - x = 2/3$

Formula -

$$K_1 = \frac{2.303}{t} \log \frac{a}{a-x}$$

$$= \frac{2.303}{1000} \log \frac{1}{2/3}$$

$$= 2.303 \times 10^{-3} \log 3/2$$

$$= 2.303 \times 10^{-3} \log 1.5$$

$$= 2.303 \times 10^{-3} \times 0.1760$$

$$K_1 = 4.0532 \times 10^{-4}$$

$(a-x) = 1/9$ $\quad t = ?$

$$K_1 = \frac{2.303}{t} \log \frac{a}{a-x}$$

$$t = \frac{2.303}{4.0532 \times 10^{-4}} \log \frac{9 \cdot 1}{1/9}$$

$$t = \frac{2.303}{4.0532 \times 10^{-4}} \log 9$$

$$= 5681.98 \times 0.9542$$

$$t = 5421 \text{ sec.}$$

(c) Chlorofluro oxide (CℓFO) decays according to the second order rate law If the initial conc^n is 2.5×10^{-5} mol^{-1}. Calculate the half life and conc^n after 4 minutes.

[Rate conctant $K = 2.25 \times 10^{-7}$ mol^{-1} s^{-1}]

Ans→ Given :-

$a = 2.5 \times 10^{-5}$ mol^{-1}

$K = 2.25 \times 10^{-7}$ l mol^{-1} s^{-1}

t = 4 minute

$= 4 \times 60 = 240$ sec

$t_{1/2} = ?$

$x = ?$

Formula.

i) $t_{1/2} = 1/a \cdot k$

$$t_{1/2} = \frac{1}{2.5 \times 10^{-5} \times 2.25 \times 10^{-7}}$$

$$t_{1/2} = \frac{1}{662.5}$$

$$t_{1/2} = 1.777 \times 10^{-3} \text{ sec.}$$

ii) $K = \frac{1}{a \cdot t} \cdot \frac{x}{(a-x)}$

$x = (a-x) \times a \cdot t$

$x = 2.5 \times 10^{-5}$

Assignment no. 2

Q.1 Attempt the Following.

1) For the parallel reaction, $A \xrightarrow{k_1} B$, $A \xrightarrow{k_2} C$ $A \rightarrow D$. Determine the concentration of B, C and D

Ans→ Parallel reaction :-

"The reaction in which a substance or reactant decompose than one way is called as parallel or side reaction."

- such reaction gives more than one independent product.

$$A \begin{cases} \xrightarrow{k_1} B \\ \xrightarrow{k_2} C \end{cases}$$

- If one of the reaction utilize major portion of the reactant it is called main reaction and other is called side reaction.

$k_1 >>> k_2$ then,

$A \rightarrow B$ ..... main reaction —— ①

$A \rightarrow C$ ..... side reaction —— ②

From above eq^n

- The rate eq^n for 1st reaction becomes, hence,

$$\frac{d[A]}{dt} = -k_1 [A] \text{ or}$$

$$-\frac{d[A]}{dt} = + k_1 [A] \quad \ldots\ldots\ldots (3)$$

For second reaction

$$\frac{d[A]}{dt} = -k_2 [A] \text{ or}$$

$$-\frac{d[A]}{dt} = k_2 [A] \quad \text{——} (4)$$

From eq^n ③ & ④ the net reaⁿ becomes.

$$-\frac{d[A]}{dt} = k_1 [A] + k_2 [A] \quad \text{——} (5)$$

Here both reaction follows simple first order differential form in,

$$[A] = a \cdot e^{-(k_2 - k_2)t} \quad \ldots\ldots\ldots (6)$$

For product B & C

$$\frac{d[B]}{dt} = k_1 [A] \quad \ldots\ldots\ldots (7)$$

$$\frac{d[C]}{dt} = k_2 [A] \quad \ldots\ldots\ldots (8)$$

put eq^n (6) in eq^n (7) and (8)

$$\frac{d[B]}{dt} = k_1 \cdot a \cdot e^{-(k_1 + k_2)t} \quad \ldots\ldots\ldots (9)$$

$$\frac{d[C]}{dt} = k_2 \cdot a \cdot e^{-(k_1 + k_2)t} \quad \ldots\ldots\ldots (10)$$

by rearrange and integrate (9) and (10)

$$[B] = \frac{k_1 \cdot a}{k_1 \cdot k_2} \left(1 - e^{-(k_1 + k_2)t}\right) \quad \ldots\ldots (11)$$

Similarly,

$$[C] = \frac{k_2 \cdot a}{k_1 \cdot k_2} \left(1 - e^{-(k_1 + k_2)t}\right) \quad \ldots\ldots (12)$$

by taking reaction of eq^n (11) and (12) we get.

$$\frac{[B]}{[C]} = \frac{k_1}{k_2} \quad \ldots\ldots\ldots (13)$$

2) Consider the reaction mechanism.

$A + B \xrightleftarrow{k_1} C$ ..... ①

$C \xrightarrow{k_2} D$ ..... ③

Write the expression of $\frac{d[P]}{dt}$ the rate of product formation, assuming equation is establi-

shed in the 1st order reaction before any appreciable amount of product is formed - OR
Explain pre-equilibria approximation show that $\frac{d[P]}{dt} = K_P [A]^2 [B]$ For the following reaction.

$A + B \xrightarrow{dt} I$, $I + B \xrightarrow{K_P} P$ where I is an Intermediate?

Ans → The rate formation of equilibrium and rate of decomposition eq^m is faster than rate of formation of product.

Consider a rea^n.

$$A + B \underset{k'a}{\overset{ka}{\rightleftharpoons}} AB \xrightarrow{kb} P.$$

here, pre-equilibria arises.

i.e. $\frac{ka}{k'a} > kb$.

From above rea^n rate for forword reaction

$$\frac{d[A]}{dt} = -ka\,[A]\cdot[B]$$

Rate for backword reaction

$$\frac{d[A]}{dt} = k'a\,[AB]\ eq^m$$

The net reaction are

$$\frac{d[A]}{dt} = ka'\,[AB]\ eq^m - ka\,[A][B]$$

hence, above eq^n. becomes,

$$ka\,[AB]\ eq^m = ka\,[A]\cdot[B] = 0$$

$$k'a\,[AB]\ eq^m = ka\,[A]\cdot[B]$$

$$\frac{ka}{k'a} = \frac{[AB]}{[A][B]}\ eq^m$$

$$k = \frac{[AB]\ eq^m}{[A][B]} \quad \cdots\cdots\cdots (1)$$

$[AB]\ eq^m = k = [A]\cdot[B]$, where $\frac{ka}{k'a} = k$.

Thus, rate For product formation becomes,

$$\frac{d[P]}{dt} = K_b\,[AB]\ eq^m \quad \cdots\cdots (3)$$

$$\frac{d[P]}{dt} = kb\cdot k\,[A][B]$$

put eq^n in (2) and (1)

$$\therefore \boxed{\frac{d[P]}{dt} = k\cdot[A]\cdot[B]} \quad \cdots\cdots (5)$$

Where, $kb\cdot k = k$

in eq^n (3) eq^m is not involve hence, pre-equilibria is follows 2nd order kinetics.

3] Obtain the expression For rate constant For 2nd order reaction. When reactants in concentrations.

Ans → Consider a reaction :

$A + B \longrightarrow$ product

rate of reaction $= \frac{-d[A]}{dt} = k\cdot[A]\cdot[B]$ — (1)

- If $(a-x)$ and $(b-x)$ are the concentration of reactant time 't' then above eq^n becomes.

rate of reaction $= \frac{-d(a-x)}{dt}$

$$\frac{dx}{dt} = k(a-x)\cdot(b-x) \quad \cdots\cdots (2)$$

by rearranging eq^n...

$$k\cdot dt = \frac{dx}{(a-x)(b-x)} \quad \cdots\cdots (3)$$

by rearranging eq^n.

$$k\cdot dt = \frac{dx}{(a-b)}\left[\frac{1}{(b-x)} - \frac{1}{(a-x)}\right]$$

$$k\cdot dt = \frac{1}{(a-b)}\left[\frac{dx}{(b-x)} - \frac{dx}{(a-x)}\right] \quad \cdots\cdots (4)$$

For wide change in concentration integrate above eq' with limit, we get,

$$k\int_0^t dt = \frac{1}{(a-b)}\left[\int_0^x \frac{dx}{(b-x)} - \int_0^x \frac{dx}{(a-x)}\right]$$

$$k\cdot dt = \frac{1}{(a-b)}\left[\left[-\ln(b-x)\right]_0^x - \left[-\ln(a-x)\right]_0^x\right]$$

$$kt = \frac{1}{(a-b)}\left[-\ln(b-x) + \ln b + \ln(a-x) - \ln a\right]$$

$$k\cdot t = \frac{1}{(a-b)}\left[\ln b + \ln(b-x) + \ln b + \ln(a-x) - \ln a\right]$$

$$k\cdot t = \frac{1}{(a-b)}\left[\ln b + \ln(a-x) - \ln a - \ln(b-x)\right]$$

$$k\cdot t = \frac{1}{(a-b)}\left[\ln \frac{b(a-x)}{a(b-x)}\right]$$

$$k = \frac{1}{t(a-b)}\ln\frac{b(a-x)}{a(b-x)}$$

$$\boxed{k = \frac{2.303}{t(a-b)}\log\frac{b(a-x)}{a(b-x)}} \quad \cdots\cdots (5)$$

eq^n (5) is a expression For velocity constant with unequal initial concentration.

Q2 Solve the Following.

a) Calculate energy of activation For a reaction if rate of the reaction is doubled by changing the temperature From 27°c to 37°c ?

Ans → Given :

$T_1 = 27°C = 27 + 273 = 300\,k$

$T_2 = 37°C = 37 + 273 = 310\,k$

if rate of reaction is doubled

$k_2 = 2k_1$

$E_a = ?$ / $R = 8.314\,J$

Formula :

$$\log\frac{k_2}{k_1} = \frac{E_a}{2.303R}\left[\frac{T_2 - T_1}{T_1 - T_2}\right]$$

$$\log\frac{2k_1}{k_1} = \frac{E_a}{2.303}\left[\frac{310 - 300}{300\times310}\right]$$

$$\log 2 = \frac{E_a}{2.303}\left[\frac{10}{93000}\right]$$

$$0.3010 = \frac{E_a}{2.303}\left[\frac{10}{93000}\right]$$

$$0.3010 = \frac{E_a}{2.303}\times 1.0752\times10^{-4}$$

$$E_a = \frac{0.3010\times2.303}{1.0752\times10^{-4}}$$

$$E_a = \frac{0.693205}{1.0752\times10^{-4}}$$

$$\boxed{E_a = 6447.20}$$

b) Show that in every 1st order rea^n time required For 75% completion of reaction is double the half life period.

Ans → Given :-

$a = 100$

$x = 75\%$, $t_{1/2} = 0.693/k$ ... (1)

$\therefore a - x = 100 - 75 = 25\%$

Formula :-

$t_{1/2} = \frac{2.303}{k} \log \frac{a}{a-x_{1/2}}$

$t_{1/2} = \frac{2.303}{k} \log \frac{a}{a-x_{1/2}}$

$t_{1/2} = \frac{2.303}{k} \log$

$\therefore t_{75\%} = \frac{2.303}{k} \log \frac{100}{25}$

$= \frac{2.303}{k} \log 4$

$= \frac{2.303}{k} \times 0.6020$

$\therefore t_{75\%} = \frac{1.386}{k}$ (2)

Take ratio of eq^n (2) and (1)

$\frac{t_{75\%}}{t_{50\%}} = \frac{1.386/k}{0.693/k}$

$= 2.00$

c) In a reaction the decrease in reactant concentration is 20% in 20 min and 40% in 40 min. Calculate of reaction and rate constant?

Ans→ Given.

$T_1 = 20\%$

$T_2 = 40\%$

$t_1 = 20 \text{ min} = 20 \times 60 = 1200$

$t_2 = 40 \text{ min} = 40 \times 60 = 2400$

$a = 100$

1) $a - x = 100 - 80\% = 80\%$

2) $a - x = 100 - 40\% = 60\%$

1) $K_1 = \frac{2.303}{t} \log \frac{a}{a-x}$

$K_1 = \frac{2.303}{1200} \log \frac{100}{80}$

$K_1 = \frac{2.303}{1200} \log (1.25)$

$K_1 = 1.919 \times 10^{-3} \times 0.0969$

$K_1 = 1.859 \times 10^{-4} \text{ s}^{-1}$

2) $K_2 = \frac{2.303}{t} \log \frac{a}{a-x}$

$K_2 = \frac{2.303}{2400} \log \frac{100}{60}$

$K_2 = 9.595 \times 10^{-4} \log (1.66)$

$K_2 = 9.595 \times 10^{-4} \times 0.220$

$K_2 = 2.1109 \times 10^{-4} \text{ s}^{-1}$.

Assignment No - 1

Q1) What are the essical principal of method transfer ? Dissus in deatal documental. Commocation Assentance criteri. Implimeation & method Varitation & modification?

→ There are five essential principles which will esure suressful method transfer documenication Communcation, acceptance Contend implementation & method modificate & revalidation

i) Documentation: method trinsfered from devalopment laboratory to designated labrat ory The essential element are

A) a written procedure - Step by desoncation of manipulation specific regent, equipment instrumentsetting & Critical parameters each step of procedure instruction give one possible interpretation It distinguishes method transfer from method radation The Proced are is correct provied & recived

B) Method Validation Report- It contain experimental design & data that justify the conditi the analytical method written, performs as intende

C) System suitabicity criteria - It defins the minimum accept+ance criteria prior to

ii) Communication - The R&D & Qc Staff's Should meet before trinifer to discuss relevant practical aspect of the method a particulary manipulative steps These discussion should be initiated before Validati

vi) Method modification & revalidation:-

It significant modification to an method are incorporated at the time of transfer revalidation may be necessary to ensure that the modification have not invalidation previous. Consulsion in the method validation report that all change in method required revalidation the examples of method Validation give above represent method Regression required revalidation of the method. The Version of method is being empoyed for product analysis method Validati & method tranfer It includes

d) Automation :- The use of robotic appropriates calibrated repents indesfically all manipulations of previous manual method only precissior experiment need to be repeated occour in the laboratorikony after method transfer.

b) Sample preparation :- It would be desire to use whole table instead of ground - table composition. The modificati Solvent - solvent or Solvent solid ratio's are changed in the eraction step

C) Dilution: It Solvent ratio are maintain identical to those in the original method & the analytical concentration are also the same only the precision is likely to be affted & these experiment repeat

Complete It is possible to introduce any desirable change modification into ARD Validation report prior registration Inter departmental communication allows time to generate data to justify alternative to prepare method Validation report include included in registration package e.g Chages in Sample. Preparation automent requirment, dviability, cost-effectiveness of required reagent

iv] Acceptance criteria:- The designated laboratory is responsible for issuing & following sops define the critical for accepting an analytical method. The data generated by sops basic of method transfer report. The designated laboratory responsible for data session resulting form the use of the method most of sops proble & acceptable. For unique criteria for define a method acceptable e.g different statistical approaches for data evaluation, different scheme for evaluting operator to operator or day to day variability

v] Implemetation:- The dessignation laboratory must follow the procedure written to ensur that method submitted by data base to be included in the method validation report to add additional data at the time of method transfer

d) Alternative use of Chromatographic technique - The change in specificity & resolution as well as quantitative aspect of the method This type of modification require all method validation parameters to be reassed ie specificity linearie accuracy prusion & time of La

2) Write a short note on ILC Processe:
→ i) The method transfer - It involves more designated laboratory obtain result expected after carrying a sample of respresentative product. Alone will not assur sencient performance of the method over time & actually mask erroneus results arising from compensting errors

ii) laboratory :- Each laboratory in the method tranfer process should define, independently, an experimental protocol to be followed for every method transfered to most efficiently way, to take advantages of the scientific datas base already established & included in the method validation report

iii) function :- a) The designated laboratory should conform the linearity & recovery for the analyte alone & in presence of the known product components by Designing the experimental Protol for the

ILC so that it resemable as much as possible that is carried out by the

① Advantages:
a) Allow comparsion of the result raw data & calculated results with these already in the method validation report by the tranfer report to be reviewed by regulatory agency as a complementary package

⑥ method development & designted lab:- Should test a common sample Paplulation that should be represent of the intented product. comparsion of data provides an additive level of inter-laboratory information as well as forming basis of inter-laboratory qualification (ILC) pro

⑦ Experimental design:- allows bias to be traced to an instrument in one laboratory the method itself and specific operator reason beings that both lab will be analysed both analytical prepared & representative product sample

⑧ Bias / impresion:- associated with the assay of the former are clearly method

⑨ Anamalous result:- It is associated only with the assay of the former are clearly indicate a problem with the conduction of the method in dergnated laboratory corrected by additional insmuti into the method or by training

⑩ Result conclusion:- The experimental summarised in the method transfer report overall objective of the results should be decumentation that the method is acceptable, it is the responsibility of the designated laboratory

⑪ The Method tranfer Report:- It remains in the files of the designted laboratories along with the method validation report to support subsequent audits

3) Dissuces fundamental defination of Variation & inter laboratory transfer
→ i) Introduction:- It is necessary to introduce fundamental defination is nessary to distinguish the responsibicity of the laboratory that develop a method from those of laboratory who will use the method the "gap" between the two laboratories is bridged by the method transfer process

ii) Pharmaceutical industrial setting, the Analytical research & development group group usually provides validated analytical methods

iii) Method Validation report - Is submitted to regulatory agency, a method & the supporting data in the report are viewed by both manufacturing & control reviewing chemists & one / more validation laboratories at the agency.

iv) Validation of the analytical procedure - The assessments the validation laboratory refered to as the validation of the analytical procedure. If use of term validation in all the above situation is

v) ARD group - normally develop the original method, who validates analytical methods & who transfer them depend upon circumstance.

vi) Most of Pharmaceutical companies - API ARD group are responsible for the development of analytical method & their chaiter is to prode appropriate test method, specification & stability data

4) What is different between method transfer & validation write a note on method validation report.

→ Introduction - There are five essential principal which will ensure successful method tranfer: documention, communication acceptance criteria, implimentation & method modification & revalidation

i) Documentation - method transfered form development laboratory to designated laboratory The essential elements are -
(A) a written procedure - step by step description of manipulation, specific regent, equipment interresting & critical parameters
(B) method validation report - It contains experimental degin & data that justify the conclusion the analytical method written perform as intended
(C) System suitability criteria - It defines the minimum acceptance criteria to analysis

Method Validation report:-
i) The essential principle of method tranfer emphasis the importance of distinguishing between validation & method transfer & established the scientific qulification of a specific analytical method validation report
ii) Tranfer of a validated method is governed by the SOP establishes by the designated laboratory which defined their acceptance performance criteria
iii) Method validation report is a pivotal document for any regulatory submission because it forms the basis for any subsequent qualification of the method.

iv) It is appropriate to reviewcertain aspects of the method validation report which relates directly to the method tranfer process & there by qualify acceptable performance in the designated lab
(A) Specificity (Selectivity)
I) It defines abicity of the method to decribe / measure the analyte to the exculsion to revelant components, which might interere
II) Experiment:- to establish method specificty include evaluating matrix component any known related components such as synthesis - relates impurities & degradation on products
III) less relvent component such as metabolite or isomers, which might help to define the limits of a method resolution may also evaluated
IV) A similar assessment is repeated after stressing the drug to accelrate degradation under the influence of heat, light oxidation & acid & base hydrolysis
b) Chromatographic parameters:
i) It is used as the minimum standard of performance in system suitabcity
ii) The resolution of a cruicial pairs of peak's in the chromatogram defines minimum seperation requirment
iii) The minimum resolution factor in the system suitabicity testes is generally used in the conjuction.

5) Define i) linearality ii) spespecity
→ linearality:- It is defined the actual analytical reponse as a function of analytical concentration & range. Precribes a region over which acceptable linerity presion & accuracy are achieved

spespecity:- It defins abicity of the method to describe measure the analyte to the exclusion of revelant componen which might interfer is called spespcity

5) Give the differency between Aquecny & persition
→ Accuracy:-
I) The recovery of the analyte of inter from the given matrix can be used as a measure of the accuracy or bias of the method.
II) The same range of concentration as employed in the linerity studi
III) The linenty of experiment is repeated in the presence of matrix constituents; in corporation of impur & destration products may also appro

Precision:
I) It refers to the variabity of an analytical result as a function of operator, method maunpulation & day to to day enviroment.

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II) The statistical data generated to demonstrate assay precisions essential
III) for efficiency, analys can be both linenity & recovery data for the statistic assesment.
IV) To include additional their of comparative analyses of the sample of repesatiativ -e product usually a minimum of ten replication.

7) Explain the termes chromatographic parameters

→ A) Linernity - It is defined the actual analytical response as a function of analytical concentration & range prescribes a region over which acceptable linearity, precision & accuracy are achie

d) Accuracy - The recovery of the analyte of interst from the given matrix can be used as a measuser of the accuracy or bias of the method

e) Precision - It refers to the variability of an analytical result as function of operator, method manipulation & day to day enviroment. To include additional their of comparative analyses of the sample of reporsentitive product usually a minimum of replication

Assignment No-2

1) Write a short note on overview of world wide regulation use for the validation methods used in pharamaceu analysis

→ (A) The European community guidlines -
i) In July 1989 & them in 1992 the EC issued an analytical validation guid in their publication "The Rules Governing medicinal product in European communi
ii) The European Gidelines indicate that are applicable to the following section of the Chemical pharmaceutical & biological documentation
ii A Development pharamceties
ii B In-process control during manfactur
ii C control tests on intermediate produc
ii E control testes on the finished produ
ii F Stabicity
iii) The guidlines state that revalidati of the procedure may be necessary in certain circumstances such as transfer form analytical development qualifi control or when significant changes in the manfacturing process of the starting material or in the composition of the finished product have occured. The degr of revalidation depends upon the nature of the changes it inuced as
a) Identification · Specificity
b) Impurity content test · Specificity limit of dectection or limit of quantit

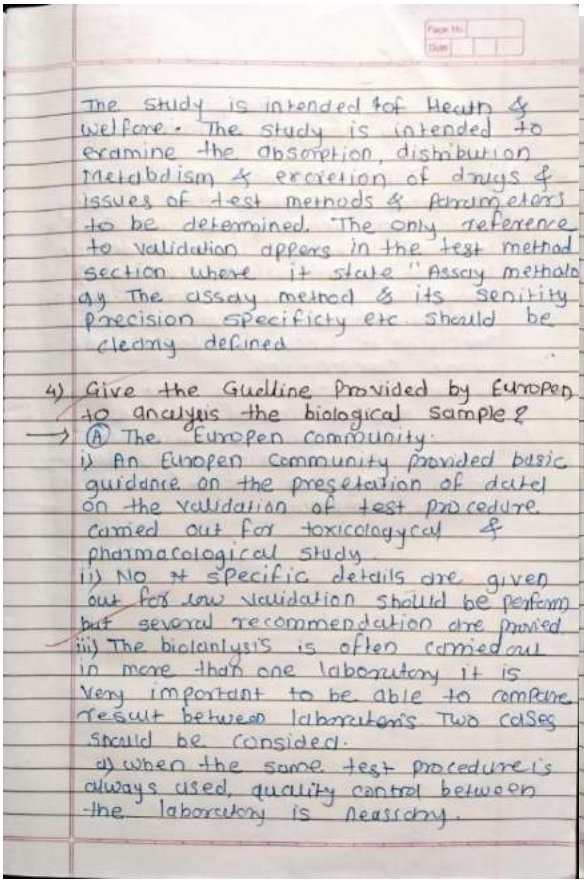
iv) General recommendation are given which require that that the procedure includes method principles & are described in such away that they may be repeated by regulatory authority or state laborat ories
v) In a chromatographic system a system suitabaity test should be provided the details formulas for result calculation should be given to gether with precise descriptions of equipment of commercially avidable The details of a method as similar as possible using standard equipment should be given. method found in pharma copoeia are concisdered to be validated provied that they are used for the intended application similarly, reference substance should be evaluated for their intended purpose. Complete data showing valluality should be indicated.
B) The Japanese minisiry of Health and welfare (MHW):- i) The Japanese regulatory Drug Approval & licensing procedure in Japan 1992 do not give sepecific guidan on the requirments for Japan 1992 analytical method validation This has been entrusted to the scientific judgeme of each individual pharamecutical company. Validation is mentioned only matter mentioned as the matter to be adderssed in the setting.

2) How the biological sample study by USA guidlines

→ (A) The united states food & Drug administration:- The report was intende to provide a framwork of the further development of us guidline on the subject some principles & requirments for established avalid method are described & include (1) each step should be investigated to determine the extent to which matrix & environmental variab could affect the determination of the analyte. type. (2) A method validation repeat should be provided. The same biological matrix should be used for validation as in the intended real samples (3) The stability of the drug sample matrix should determined. The concentration range must be defined in the method anlay standard curve. derived (5) An adequate no of standard must be used to define adquately the relationship between concentration & response. (7) The accuracy & precision with which known concentration & analyte in the biological matrix can be determine must be demonstrated

3) What are the Japan Gudline use to the study biological sample

→ The Japan minsitry of Health & welfare



The study is intended for Heath & welfare. The study is intended to examine the absorption, distribution Metabdism & excretion of drugs & issues of test methods & parameters to be determined. The only reference to validation appears in the test method section where it state "Assay methods by The assay method & its senitity precision specificty etc should be clearly defined.

4) Give the Gudline provided by Europen to analysis the biological sample?

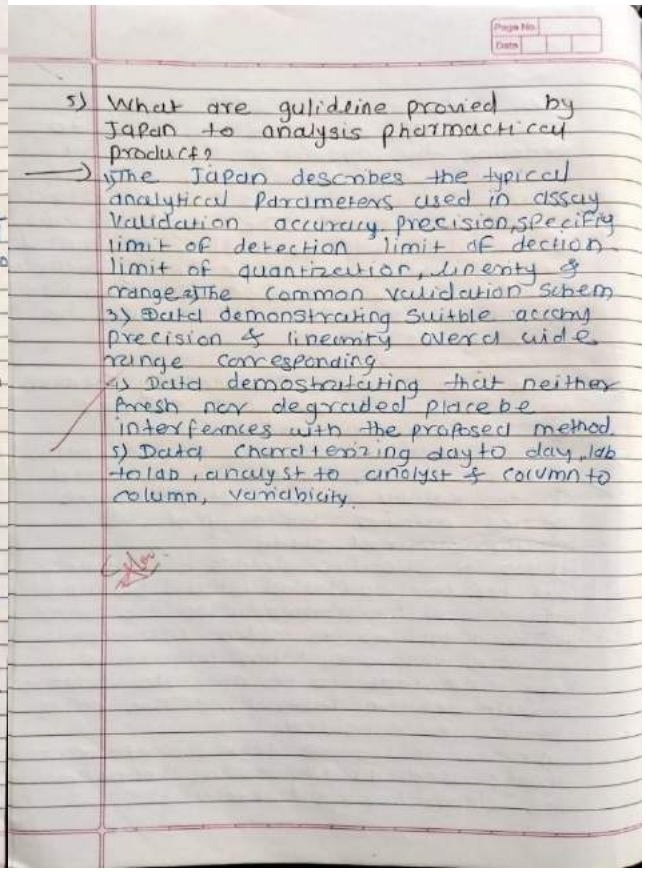
→ (A) The Europen community.

i) An Europen community provided basic guidance on the presetation of data on the validation of test procedure carried out for toxicologycal & pharmacological study.

ii) No # specific details are given out for low validation should be perform but several recommendation are provied.

iii) The bioanlysis is often carried out in more than one laboratory it is very important to be able to compare result between laboratoris. Two cases should be consided.

a) when the same test procedure is always used, quality control between the laboratory is nessisary.



5) What are gulideine provied by Japan to analysis pharmacticay product?

→ i) The Japan describes the typical analytical parameters used in assay validation accuracy precision, specifig limit of detection limit of dection limit of quantizeation, linenty & range. ii) The common validation schem

3) Data demonstrating suitble accuny precision & linearity overal wide range corresponding

4) Data demostrating that neither fresh nor degraded placebe interfernces with the proposed method.

5) Data charactenizing day to day, lab to lab, analyst to analyst & column to column, variabicity.

6. Sample of Offline Seminars Conducted

(Seminar by Department of Chemistry Conducted on 10/03/2023)

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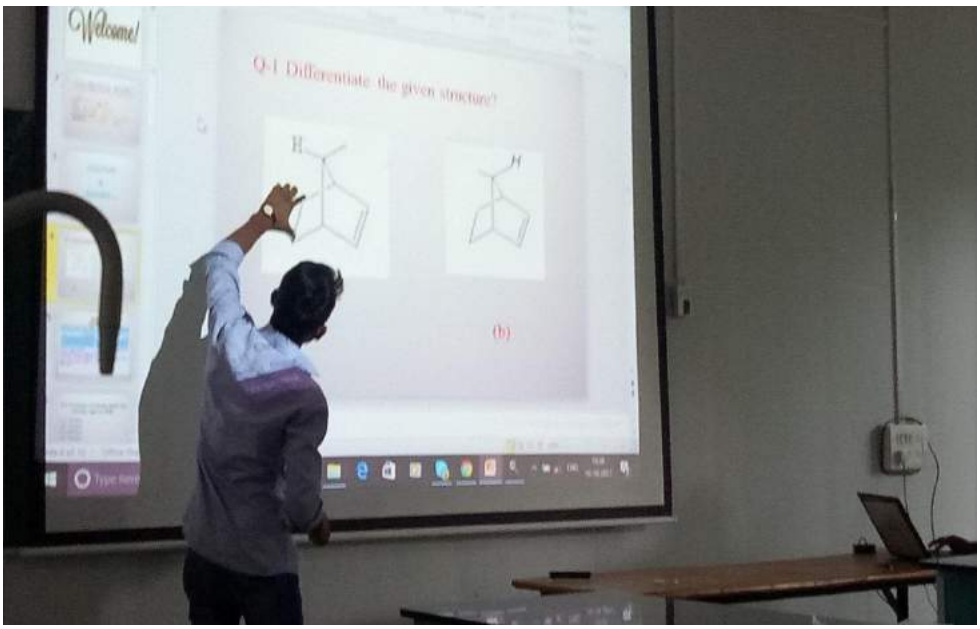

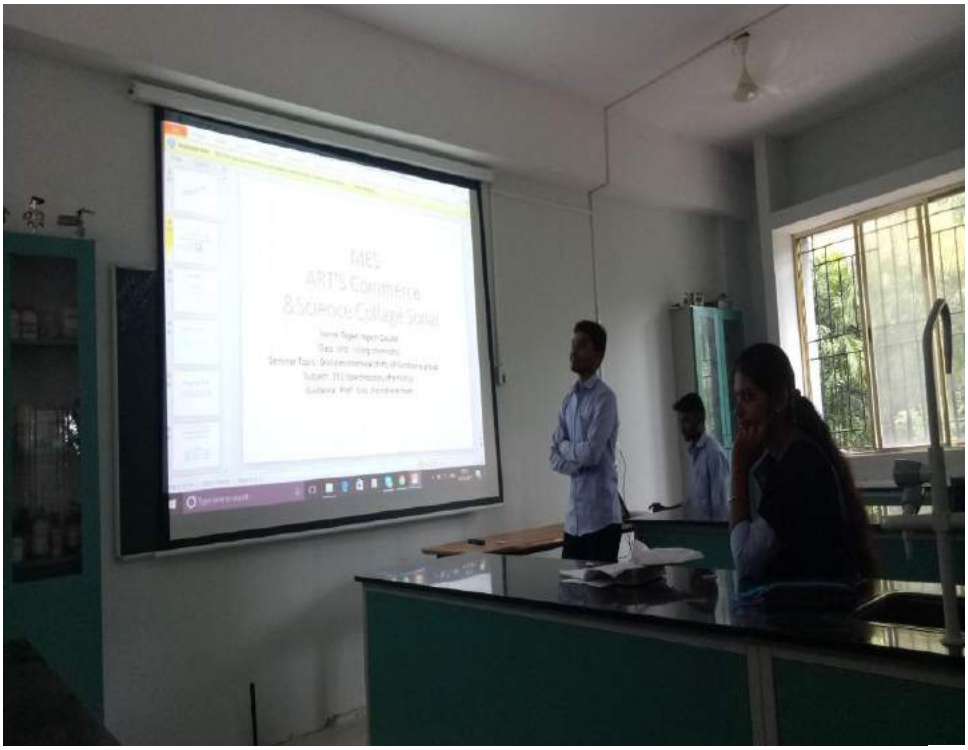

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