**DEPARTMENT OF PHARMACY**

**MIT MUZAFFARPUR**

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**AFFILIATED TO**

**ARYA BHATT KNOWLEDGE UNIVERSITY,**

**MITHAPUR, PATNA**

**NAME OF FACULTY: DR. G. THAKUR**

**ASSISTANT PROFESSOR,**

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**M.I.T. MUZAFFARPUR**

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**Name of Course: PHARMACEUTICAL ANALYSIS-I**

**Course code (T): 091102**

**Course code (P): 091102P**

**Semester: I**

**Academic year : 2018-2019**

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**1. Vision**

**To generate competent Pharmaceutical human resources to serve society, industry and nation through personal development and professional excellence.**

**2. Mission**

* To inspire and in still the ethical values, leadership, and entrepreneurship skill in the students for betterment of the society and hence the nation.
* To offer state-of-art-undergraduate, postgraduate and the doctoral program.
* To excel in Pharmacy education, patient centered care, community engagement and research.

**3. Programme Educational Objectives (PEO’S)**

PEO-1 Students will be able to use their fundamental concepts and technical competence in field of pharmaceutical Analysis as and when required in Pharmaceutical Industry and /or institutes to achieve professional excellence

PEO-2 Students will acquire strong and well defined concepts in of Pharmaceutical analysis as per requirements of Pharmaceutical Industries, Community and Hospital Pharmacy.

PEO-3 They will be able to work in a team while being competent enough in solving complex problems in the area of Pharmaceutical Sciences.

PEO-4 Be ethical, professional and conscious of their environmental and social responsibilities.

PEO-5 Possess an attitude for continuous learning and practicing in the field of work.

4. Program Objectives (PO’S)

Pharmaceutical analysis is the subject which deals mainly with the quantitative analysis of those chemicals and dosage forms associated with the practice of pharmacy. It provides training ground for the accuracy expected from pharmacy graduates. The graduates of the program will acquire:

1. Knowledge and understanding outcome:

* Understand the significance of Pharmaceutical Analysis in the profession.
* Learn the various tools and techniques available for the analysis of drugs.
* Principles of various conventional analytical techniques

2. Practical outcome

* Expression of various concentrations and preparations.
* Application of Pharmacopoeial purity and identity tests for real life samples.
* Proper handling of laboratory equipments and glassware.

3. Intellectual outcome:

* Selection of an optimum analytical technique for a given sample.
* Converting the observations to meaningful results and drawing the inferences.
* Comparing various methods of analysis and their outcomes

5. Course Outcomes (COs)

On the completion of the course, students will be able to:

* Demonstrate adequate knowledge on basic principles and techniques of complexometric titration and non aqueous titration
* Execute Diazotisation titrations, Karl-Fischer titrations and Kjeldahl method of titration as when required.
* Discuss the fundamental of different techniques of separation such as TLC, Paper Chromatography, HPLC and GLC volumetric analysis, and significance of quality control in pharmaceutical.
* Learn Potentiometry, Conductometry, Coulometry, Polarography and Amperometry and will use above methods as when required in industry and research.
* Identify and apply the knowledge of Pharmaceutical Analysis as when required

**6. Mapping of CO’S & PO’S**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PO | CO1  | CO2 | CO3 | CO4 | CO5 |
| 1 | √ | √ | √ | √ | √ |
| 2 | √ | √ | √ | √ | √ |
| 3 | √ | √ | √ | √ | √ |
| 4 | √ | √ | √ | √ | √ |
| 5 | √ | √ | √ | √ | √ |

**7. Academic Calendar**

**Calendar (Odd Semesters**

**): 2018-19**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S.No | Events | B.Pharm 1stsem | B.Pharm 3 rdsem | B.Pharm 5thsem | B.Pharm 7thsem |
| 1 | Class Start Date |  | **16.7.2018** | **16.7.2018** | **16.7.2018** |
| 2 | First Sessional Exam start date |  |  |  |  |
| 3 | First Sessional Exam End date |  |  |  |  |
| 11 | Theory exam Date |  | **Dec -2018** | **Dec-2018** | **Dec- 2018** |
| 12 | Practical Exam Start Date/Final Presentation |  | **Jan-2019** | **Jan-2019** | **Jan-2019** |
| 13 | Practical Exam End Date/ Final Presentation |  | **Jan-2019** | **Jan-2019** | **Jan-2019** |

**8. List of Holidays**

|  |  |  |  |
| --- | --- | --- | --- |
| S.No | Day | Date | Day |
| 1 | Independence Day | 15.08.2018 | Wednesday |
| 2 | Bakrid | 22.08.2018 | Wednesday |
| 3 | Sri Krishna Janmasthami | 03.09.2018 | Monday |
| 4 | Muharam | 21.09.2018 | Friday |
| 5 | Gandhi Jayanti | 02.10.2018 | Tuesday |
| 6 | Durga Puja | 13.10.2018-21.10.2018 | Saturday to Saturday |
| 7 | Chehallum | 30.10.2018 | Tuesday |
| 8 | Deepabali | 07-11,2018 -16.11.2018 | Wednesday to Friday |
| 9 | Hazarat Mohamad sahib Birthday | 21.11.2018 | Wednesday |
| 10 | Christmas | 25-12-2018 -31.12.2018 | Tuesday To Monday |

9. Sample Time Table

|  |
| --- |
| MUZAFFARPUR INSTITUTE OF TECHNOLOGY |
| ODD SEM (JULY- DEC 2018) TIME TABLE FOR 3 rd , 5 th&& 7 th SEMESTER, B.PHARM, WITH EFFECT FROM 16.07.2018. |
| DAY | SEMESTER |  9 AM TO 10 | 10 -11 AM | 11- 12 AM | 12 -1 PM | 2 TO 5 PM |
| MON | THIRD SEM | APHE II SK | PHARM ANAL II GT | PHARMACEUTICS III AB | PHARMACOGNOSY II NRB | CLASS TEST |
| FIFTH SEM | PHARMACEUTICS V RKC | PHARMACEUTICS V LAB RKC | CLASS TEST |
| SEVENTH SEM | PHARMA. BIOTECH SNS | PHARM CHEM VII RP | PHARMA. INDUST. MANAG. | PHARMACOLOGY III RP | CLASS TEST |
| TUES | THIRD SEM | PHARMACEUTICS III AB | PHARM CHEM IV SW | PHARMACEUTICS III AB(T) | PHARM ANAL II GT(T) | PHARMACEUTICS III LAB AB |
| FIFTH SEM | PHARM CHEM V SNS | PHARMACEUTICS VI AB | PHARMA CEUTICS V RKC | PHARMACOLOGY I SK | PHARM CHEM V LAB SNS |
| SEVENTH SEM | PHARMACEUTICS VIII RKC | PHARM CHEM VII RP | PHARMACOLOGY III RP | PHARMACEUTICS VIII RKC(T) | PHARMACOLOGY III LAB RP |
| WED | THIRD SEM |   | PHARMACOGNOSY II NRB(T) | PHARMACOGONOSY II NRB | PHAR ANAL II GT | PHARMACOGONOSY II LAB NRB |
| FIFTH SEM | PHARMACOLOGY I SK | PHARM CHEM V SNS  | PHARMACEUTICS VI AB | PHARMACOLOGY I SK(T) | PHARMACOLOGY I LAB SK |
| SEVENTH SEM | PHARM CHEM VII RP(T) | PHARMACEUTICS VIII RKC | PHARM CHEM VII RP | ELECTIVE OPT | PHARM CHEM VII RP |
| THURS | THIRD SEM | APHE II SK(T) | PHARM CHEM IV SW | APHE II SK | PHARM CHEM IV SW(T) | PHARM ANAL II LAB GT |
| FIFTH SEM | PHARM CHEM V SNS | PHARMACEUTICS VI AB | PHARMACOGONOSY IV SW |   | PHARMACOGONOSY IV LAB SW |
| SEVENTH SEM | PHARMACEUTICS VIII RKC | PHARMA. BIOTECH SNS(T) | PHARMACOLOGY III RP  | ELECTIVE OPT | ELECTIVE LAB-OPT |
| FRI | THIRD SEM | APHE II SK | PHARMACUTICAL CHEMISTRY IV LAB SW | APHE II LAB SK |
| FIFTH SEM | PHARMACOGONOSY IV SW | PHARMACEUTICS V RKC | PHARMACOGONOSY IV SW(T) | PHARMACEUTICS V RKC(T) | PHARMACEUTICS VI LAB OPT AB |
| SEVENTH SEM |   | ELECTIVE OPT (T) | ELECTIVE OPT  | PHARMA. BIOTECH.SNS | PHARMACEUTICS V III RKC LAB |
| SAT | THIRD SEM | PHARMACOGONOSY II NRB | PHARM CHEM IV SW | PHAR ANAL II GT | PHARMACEUTICS III AB |   |
| FIFTH SEM | PHARM CHEM V SNS(T) | PHARMACOLOGY I SK | PHARMACEUTICS VI AB | PHARMACOGONOSY IV SW |   |
| SEVENTH SEM | PHARMACOLOGY III RP(T) | PHARMA. INDUST. MANAG. | PHARMA. BIOTECH SNS |   |   |

**10. COURSE DESCRIPTIONS: PHARMACEUTICAL ANALYSIS-I**

**B. PHARM –FIRST SEMESTER**

1. Course Syllabus

Module:-1

* Significance of quantitative analysis in quality control, Different techniques of analysis, Preliminaries and definitions, Significant figures, Rules for retaining significant digits, Types of errors, Mean deviation, Standard deviation, Statistical treatment of small data sets, Selection of sample, Precision and accuracy. Fundamentals of volumetric analysis, methods of expressing concentration, primary and secondary standards.

Module:-2

* Acid Base Titrations**:**Acid base concepts, Role of solvent, Relative strengths of acids and bases, Ionization, Law of mass action, Common-ion effect, Ionic product of water, pH, Hydrolysis of salts, Henderson-Hessel bach equation, Buffer solutions, Neutralization curves, Acid-base indicators. Theory of indicators, Choice of indicators, mixed indicators, Polyprotic system, Polyamine and amino acid systems, Amino acid titration, applications in assay of Hl04, NaOH, CaC03 etc. .

Module :-3

* Precipitation Titrations**:** Precipitation reactions, Solubility products, Effect of acids, temperature and solvent upon the solubility of a precipitate. Argentometric titrations and titrations involving ammonium or potassium thiocyanate, mercuric nitrate, and barium sulphate, Indicators, Gay-Lussac method, Mohr’s method, Volhard's method and Fajan's method.

Module:-4

* Oxidation Reduction Titrations**:**Concepts of oxidation and reduction, Redox reactions, Strengths and equivalent weights of oxidizing and reducing agents, Theory of redox titrations, Redox indicators, Cell representations, Measurement of electrode potential, Oxidation-reduction curves, Iodimetry and Iodometry, Titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate; titanous chloride and Sodium 2, 6-dichlorophenol indophenol.

Module:-5

* Gravimetric Analysis**:**Precipitation techniques, Solubility products; The colloidal state, Supersaturation co-precipitation, Postprecipitation, Digestional washing of the precipitate, Filtration, Filter papers and crocibles, Ignition, Thermogravimetric curves, Specific examples like barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesiumas magnesium pyrophosphate, Organic precipitants.

**11. TEXT BOOKS/ REFERENCE BOOKS**

1. R. M. VERMA, ANALYTICAL CHEMISTRY THEORY AND PRACTICE, C.B.S. PUBLICATIONS.

 2. DR. A.V. KASTURE, PHARMACEUTICAL ANALYSIS, VOL-I, NIRALI PUBLICATION.

3. PHARMACEUTICAL ANALYSIS: VOL-I ; ASHOTOSH KAR: CBS PUBLISHERS ANA DISTRIBUTORS

4, PHARMACEUTICAL DRUG ANALYSIS:; ASHOTOSH KAR: NEW AGE INTERNATIONAL (P) LIMITED PUBLISHERS

5.MEITES, L., ED. HANDBOOK OF ANALYTICAL CHEMISTRY, NEW YORK, MCGRAW-HILL, 1963.

6.PIETRZYK, DJ, AND CW FRANK, ‘ANALYTICAL CHEMISTRY’, LONDON, ACADEMIC PRESS, 2ND ED., 1979.

7.HARGIS, L.G., ‘ANALYTICAL CHEMISTRY’, NEW JERSEY, PRENTICE HALL, 1988.

8.JEFFREY, G.H. J. BASSETT., J. MENDHAM AND R.C. DENNEY, **‘**VOGEL’S TEXTBOOK OF QUANTITATIVE CHEMICAL ANALYSIS**\*,’**

5TH ED., NEW YORK, LONGMAN SCIENTIFIC AND TECHNICAL, 1989.

9.SCHIRMER, R.E., **‘**MODERN METHODS OF PHARMACEUTICAL ANALYSIS**,** 2ND. VOL. 1, BOSTON, CRC PRESS 1991.

**12. Assessment Methods for CO’S; Theory & Practical**

12.1. Theory

|  |  |  |  |
| --- | --- | --- | --- |
| S.No | Assessment Tools | Marks | Outcomes |
| 1 | Sessional Examination | 20 | CO1 CO2 CO3 CO4 |
| 2 | Assignment  | 02 | CO1 CO2 CO3 CO4 |
| 3 | Presentation | 02 | CO1 CO2 CO3 CO4 |
| 4 | Quizzes | 01 | CO1 CO2 CO3 CO4 |
| 5 | Attendance | 05 | NA |
| 6 | University Examination | 70 | NA |

12.2. Practical

|  |  |  |  |
| --- | --- | --- | --- |
| S.No | Assessment Tools | Marks | Outcomes |
| 1 | Attendance | 05 | CO1 CO2 CO3 CO4 |
| 2 | Experiment valuation  | 10 | CO1 CO2 CO3 CO4 |
| 3 | Internal Viva- voce | 05 | CO1 CO2 CO3 CO4 |
| 4 | University Practical Exam | 30 | CO1 CO2 CO3 CO4 |

**13 Delivery Methodologies**

|  |  |  |
| --- | --- | --- |
| Outcomes | Methods | Supporting Tools |
| CO 1 | Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning | Board, Laptop, Projector, You Tube, Whatsapp, Google,  |
| CO2 | Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning | Board, Laptop, Projector, You Tube, Whatsapp, Google,  |
| CO3 | Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning | Board, Laptop, Projector, You Tube, Whatsapp, Google,  |
| CO4 | Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions,, Web based learning | Board, Laptop, Projector, You Tube, Whatsapp, Google,  |
| CO5 | Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning | Board, Laptop, Projector, You Tube, Whatsapp, Google,  |

14. Teaching plan

14.1. Theory

|  |  |
| --- | --- |
| Lecture No. | Contents |
| 1 | Significance of qualitative analysis in quality control |
| 2 | Different techniques of analysis |
| 3 | Preliminaries and definitions |
| 4 | Significance of figures. Rules for retaining significant digits |
| 5 | Types of errors, minimization of error |
| 6 | Selection of sample |
| 7 | Precision and accuracy, fundamentals of volumetric analysis |
| 8 | Methods of expressing concentration |
| 9 | Primary and secondary standards |
| 10 | Class Test |
| 11 | Acid Base Titration: Acid base concepts, role of solvents |
| 12 | Relative strength of acids and bases |
| 13 | Law of mass action |
| 14 | Lonization, Common ion effect |
| 15 | Ionic product of water, ph |
| 16 | Hydrolysis of salts |
| 17 | Henderson-Hesselbalch equation, Buffers solutions |
| Class test |
| 18 | Neutralization curves |
| 19 | Neutralization curves |
| 20 | Acid-base indicators |
| 21 | Theory of indicators |
| 22 | Choice of indicators, Mixed indicators |
| 23 | Polyamine and amino acid systems. Amino acid titration |
| 24 | Applications in assay, H3PO4, NaOH, CaCO3 |
| 25 | Class Test |
| 26 | Precipitation Titrations: Precipitation reactions |
| 27 | Solubility product |
| 28 | Effect of acids, temperature and Solvent upon the solubility of a precipitate |
| 29 | Argentometric titration and titrations involving ammonium or Potassium thiocyanate |
| Class test |
| 30 | Mercuric nitrate orthophosphoric acid, sodium hydroxide, calcium carbonate and Barium sulphate |
| 31 | Indicators , Mohr’s method |
| 32 | Volhard’s method |
| 33 | Gay-Lussac method; and Fajan’s Method |
| 34 | Class Test |
| 35 | Gravimetric Analysis: Precipitation techniques, |
| 36 | Solubility products. The colloidal state, supersaturation |
| 37 | Co-precipitation, post precipitation, Digestion |
| 38 | Washing of the precipitate, Filtration, Filter papers and Crucibles, Ignition |
| 39 | Thermo gravimetric curves |
| 40 | Specific examples like barium sulphate, aluminum as Aluminum oxide, |
| 41 | Calcium as calcium oxalate and magnesium as magnesium pyrophosphate, organic Precipitants |
| 42 | Class Test |
| 43 | Oxidation Reduction Titrations**:** Concepts of oxidation and reduction, Redox reactions, |
| 44 | Strengths and equivalent weights of oxidizing and reducing agents, Theory of redox titrations |
| 45 | Redox indicators, Cell representations, Measurement of electrode potential, Oxidation-reduction curves, Iodimetry and Iodometry |
| 46 | Titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate |
| 47 | Titanous chloride and Sodium 2, 6-dichlorophenol indophenol |

14.2. Practical

|  |  |
| --- | --- |
| Exp. No | Experiment |
| 1 | Standardization of 0.1 NaOH |
| 2 | Standardization of 0.1 HCl. |
| 3 | Standardization of 0.1 H2SO4. |
| 4 | Assay of NaHCO3. |
| 5 | Standardization of 0.1 N AgNO3. |
| 6 | Assay of NaCl. |
| 7 | Estimation of barium. |
| 8 | Estimation of chloride |

**15. Sample Theory Handouts**

|  |  |
| --- | --- |
| Institute  | M.I.T., MUZAFFARPUR |
| Program Name | B.PHARM |
| Course Code | 091102 P |
| Course Name | PHARMACEUTICAL ANALYSIS -I |
| Labs (per week) | 1 | **Course Credits** | 2 |
| Course Coordinator Name | Dr G Thakur |

1. **Scope and Objectives of the Course**

Pharmaceutical analysis is the subject which deals mainly with the quantitative analysis of those chemicals and dosage forms associated with the practice of pharmacy. It provides training ground for the accuracy expected from pharmacy graduates. The graduates of the programme will acquire knowledge and skill the various tools and techniques available for the analysis of drugs.

**16.** Sample Lab. Course Handouts

|  |  |
| --- | --- |
| Institute  | M.I.T., MUZAFFARPUR |
| Program Name | B.PHARM |
| Course Code | 091102 P |
| Course Name | PHARMACEUTICAL ANALYSIS -I |
| Labs (per week) | 1 | **Course Credits** | 2 |
| Course Coordinator Name | Dr G Thakur |

1. **Scope and Objectives of the Course**
* To understand the importance of analysis in pharmaceutical industry
* To understand the knowledge about assay of pharmaceutical substance and product
* To develop basic practical skills using instrumental techniques
* To inculcate theoretical knowledge on various instrumental techniques adopted for analysis of pharmaceuticals
* To develop various methodologies for assay of drugs and pharmaceuticals with the skills and knowledge gained
* To understand and gain knowledge on trouble shooting in adopting various methodologies using instrumental techniques

**Experiment:-1. Preparation of 0.1 N Ammonium Ceric Sulphate Solution**

**Materials Required:** Ceric ammonium sulphate : 66 g ; sulphuric acid (conc.) : 30 ml.

**Procedure:** Dissolve 66 g of ceric ammonium sulphate, with the help of gentle heat, in a mixture of 30 ml of sulphuric acid and 500 ml DW. Cool, filter the solution through a fine-porosity sintered-glass crucible, dilute to 1 litre mark in a volumetric flask and mix thoroughly.

Since the oxidation reaction is given by:

Ce4+ + e →Ce3+

Therefore, 632.57 g Ce(SO4)2 2(NH4)2SO4.2H2O ≡1000 ml N

or 63.26 g Ce(SO4)2 2(NH4)2 SO4.2H2O ≡1000 ml 0.1 N ammonium ceric sulphate

**Experiment:-2. Stadardization of 0.1 N Ammonium Ceric Sulphate Solution**

**Materials Required:**

Arsenic trioxide: 0.2 g ; sodium hydroxide solution (8.0% w/v) : 25 ml ; diluted sulphuric acid (10% w/v) : 30 ml ; osmic acid solution (1.0% w/v in water) : 0.15 ml ; ferroin sulphate solution (dissolve 0.7 g of ferrous sulphate in 70 ml of DW and add 1.5 g of 1, 10-phenanthroline and sufficient water to produce 100 ml) : 0.1 ml.

**Procedure:**

Weigh accurately about 0.2 g of arsenic trioxide previously dried at 105°C for 1 hour and transfer to a 500 ml conical flask. Wash down the inner walls of the flask with 25 ml of sodium hydroxide solution, swirl to dissolve, add 100 ml of water and mix. Add 30 ml of diluted sulphuric acid, 0.15 ml of osmic acid solution, 0.1 ml of ferroin sulphate solution and slowly titrate with ceric ammonium sulphate solution until the pink colour is changed to a very pale blue. Each 4.946 mg of arsenic trioxide is equivalent to 1 ml of 0.1 N ammonium ceric sulphate or 0.06326 g of Ce(SO4)2. 2(NH4)2SO4. 2H2O.

**Equations:**

As2O3 + 6NaOH → 2Na3AsO3 + 3H2O

2Ce (SO4)2 + Na3AsO3 + H2O → Ce2 (SO4)3 + Na3AsO4 + H2SO4

It is evident from the above equations that 4 equivalents of ceric sulphate is required to oxidise 1 moleof arsenic trioxide, hence, 1 equivalent weight of arsenic trioxide is 1/4 mole or 197.84/4 or 49.46 g and1 milliequivalent shall contain 49.46 mg or 0.04946 g.

**Calculations:**

Therefore, the normality of ammonium ceric sulphate solution may be expressed as

follows :

N =wt. of arsenic trioxide/ml × 0.04946

**17. Sample Assignment: I,& II**

Sample Assignment -1

1. What is the importance of ‘Purity’ in pharmaceutical chemicals for manufacturing drugs? Discuss with suitableexamples.

2. Elaborate the following statistical methods with suitable examples:

 (*i*) Students *t*-test

 (*ii*) F-test (Variance-Ratio Test).

Sample Assignment -2

**1.** Describe the theory of ‘**Acids and Bases**’ with respect to the following aspects:

 (*a*) Lowry-Bronsted’s Theory

 (*b*) Lewi’s Theory

2. Explain the following:

 (*i*) Precipitation reactions governing ‘**argentometric methods**’.

 (*ii*) Role of ‘**solubility product**’ in precipitation reactions.

 (*iii*) Various cardinal parameters required for a feasible argentometric analysis.

**18. Students List**

**19. Previous Arya Bhatt Knowledge University Questions**