M.Pharm.
Part-I 2007
Part-II 2008

Prospectus No. 081429

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SANT GADGE BABA AMRAVATI UNIVERSITY

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(FACULTY OF MEDICINE)

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¦ÉÉMÉ-1, 2008 ´É ¦ÉÉMÉ-2, 2009

PROSPECTUS

OF

MASTER OF PHARMACY (PHARMACEUTICS)

EXAMINATIONS PART-I, 2008 PART-II, 2009

2007

Price Rs. /-

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PUBLISHED BY

C.D.Deshmukh
Registrar
Sant Gadge Baba
Amravati University,
Amravati 444 - 602

SANT GADGE BABA AMRAVATI UNIVERSITY

SPECIAL NOTE FOR INFORMATION OF THE STUDENTS

(1) Notwithstanding anything to the contrary, it is notified for general information and guidance of all concerned that a person, who has passed the qualifying examination and is eligible for admission only to the corresponding next higher examination as an ex-student or an external candidate, shall be examined in accordance with the syllabus of such next higher examination in force at the time of such examination in such subjects, papers or combination of papers in which students from University Departments or Colleges are to be examined by the University.

(2) Be it known to all the students desirous to take examination/s for which this prospectus has been prescribed should, if found necessary for any other information regarding examinations etc. refer the University Ordinance Booklet the various conditions/provisions pertaining to examinations as prescribed in the following Ordinances-

Ordinance No. 1	:	Enrolment of Students.
Ordinance No.2	:	Admission of Students
Ordinance No. 4	:	National Cadet Corps
Ordinance No. 6	:	Examination in General (relevant extracts)
Ordinance No. 18/2001	:	An Ordinance to provide grace marks for passing in a Head of passing and Inprovement of Division (Higher Class) and getting Distinction in the subject and condonation of defficiency of marks in a subject in all the faculties prescribed by the Statute NO.18, Ordinance 2001.
Ordinance No.9	:	Conduct of Examinations (Relevant extracts)
Ordinance No.10	:	Providing for Exemptions and Compartments
Ordinance No. 19	:	Admission of Candidates to Degrees

Ordinance No.109	:	Recording of a change of name of a University Student in the records of the University
Ordinance No. 138	:	For improvement of Division.
Ordinance No.19/2001	:	An Ordinance for Central Assessment Programme, Scheme of Evaluation and Moderation of answerbooks and preparation of results of the examinations, conducted by the University, Ordinance 2001.

C.D.Deshmukh
Registrar
Sant Gadge Baba Amravati University

#* ORDINANCE NO.17 of 2002

Examination Leading to the Degree of ¦É¹ÉVÉÒ {ÉÉ®MÉiÉ

(Master of Pharmacy)

Whereas, it is expedient to provide ordinance leading to the degree of Master of Pharmacy, for the purpose hereinafter appearing; Management Council is hereby pleased to make the following Ordinance :

1. This Ordinance may be called "Examination leading to the degree of ¦É¹ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy), Ordinance, 2002".

2. This Ordinance shall come into force with effect from the Academic session 2002-03.

3. In this Ordinance unless the context otherwise requires the expression "Department" shall mean the Department of Pharmaceutical Sciences and "College" shall mean affiliated college approved for conducting M.Pharm.course.

4. The several courses leading to the Degree of ¦É¹ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy) shall be as follows, namely :

   I) Pharmaceutics
   II) Pharmaceutical Chemistry
   III) Pharmacology
   IV) Pharmacognosy & Phytochemistry
   V) Biotechnology
   VI) Quality Assurance
   VII) Industrial Pharmacy
   VIII) Bio pharmaceutics

5. There shall be two examinations leading to the Degree of ¦É¹ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy) namely the first examination and Final examination in each of the courses specified in paragraph 4 above. The duration of the course shall be of two Academic years with the M.Pharm. First Examination at the end of first academic year and the M.Pharm.Final Examination at the end of second academic year.

6. The Master of Pharmacy First Examination shall be held in March/ April and October/November, and the Final examination in March/ April and November/December at such places and on such dates as may be fixed by the Borad of Examination.

   Subject to the compliance with the provisions of this ordinance and of other ordinance in force from time to time, an applicant for admission to -

   A) The First M.Pharm. Examinee shall have passed not less than one academic year previously the B.Pharm.examination of this University or of any other university recognised as equivalent thereto and shall have prosecuted a regular course of studies in the department/college as prescribed in this ordinance.

   B) The Final M.Pharm. Examinee shall have passed the First M.Pharm. Examination of this university, and shall have prosecuted a regular course of study in the Department/College as prescribed in this ordinance. An applicant for the examination to the Final M.Pharm. shall not be allowed to take the examination if he/she fails to submit to his/her dessertation on or before the 20th December or 31st May of the calender year in which he/she has to take the examination.

7. A) Without prejudice to the other provision of ordinance No.6 relating to the examination in general, the provisions of paragraphs 5,8,10,26 and 31 of the said ordinance shall apply to every collegiate candidate.

   B) An unsuccessful examinee at the First M.Pharm.Examination, may be allowed to carry out his research work for dessertation for Final M.Pharm. examination but shall not be permitted to appear for the M.Pharm. examination unless he/she passes in all the papers and practicals prescribed for First M.Pharm. examination.

8. The fee for each examination shall be as fixed by the University.

9. The sessionals, papers, practicals, dessertation, and viva-voce, and 2 seminar if any, in which a candidate is to be examined, the maximum marks which each of the subject carries and the minimum marks which an examinee must obtain in order to pass the examination shall be as indicated in the respective annexures.

10. The scope of the subject shall be as indicated in the syllabus.

11. An examinee passing in a subject shall be exempted from appearing that subject at all subsequent examinations.

12. i) An examinee for the final M.Pharm. examination shall carry out research for not less than six months under an approved guide who shall be the internal examiner. A person from industry or Research Institute possessing Post-Graduate qualification in Pharmaceutical Science in appropriate subject and not less than 5 yrs. experience in an industry or Research Institute in a responsible capacity may also be considered for appointment as guide/co-guide/Internal/Extermal examiner

   ii) The examinee shall submit three copies of this dessertation to

the Head of the Department/Principal of the college not later than 30th December or 31st May of the calender year in which he/she has to take the examination, duly certified by the guide that the work has been done satisfactorily under his guidance.

iii) a) The examination based on the dessertation shall be carried out by

i) The Guide as Internal Examiner and

ii) One External Examiner.

b) The examiners may after conducting the viva-voce examination shall award the marks, out of the marks prescribed for dessertation. In case of any dispute, the decision of the External examiner shall be final. The marks shall be sealed under the signature of the External examiner & shall be handed over to the Principal for sending it to the University

c) If the dessertation is not found upto the marks & if the candidate fails in the dessertation, the External examiner shall give his suggestions / recommendations for re-submission / modification in the dessertation to the Principal alongwith a copy to the Controller of Examination of University for information.

iv) An examinee who fails to submit his/her dessertation within the prescribed date or whose dessertation has not be accepted or fails to present himself for Viva-voce, may subject to other provisions of this ordinance be readmitted to the examination at any subsequent examination provided,

a) he/she pays the prescribed fees as fixed by the University

b) his/her application is received by the registrar not later than one month before the date of commencement of the examination

c) he/she submits his dessertation on the same subject two weeks prior to the examination date. Examinee whose dessertation has not been accepted shall resubmit his/her work, with such additional work as may be directed at the next examination. However, an examinee wishing to submit dessertation on a fresh subject shall be required to join the department/college as a regular student.

13. Examinees who have passed in all the subjects prescribed for the first and final M.Pharm. examinations shall be eligible for the degree of Master of Pharmacy. Those obtaining 75% or more marks in aggregate shall be placed in the first division with distinction; those obtaining

60% and above but less than 75% in the first division, and all other successful examinees in the second division, examinees passing both the examinations leading to the Degree of ¦ÉÊÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy) in the minimum prescribed period and obtaining the first place shall be placed in Merit list.

14. Provision of ordinance no. 18 of 2001 relating to an ordinance to provide grace marks for passing in a Head of passing and improvement of division (Higher Class) and getting distinction in the subject and condonation of deficiency of marks in a subject in all the faculties prescribed by the Statute No.18, Ordinance 2001 shall apply to the examinations under this Ordinance.

15. An examinee who does not pass or who fails to present himself/ herself for the examination shall be eligible for admission to the same examination on payment of a fresh fee and such other fees as may be prescribed.

i) A candidate who has passed the M.Pharm. examination in any course specified in paragraph 4 may offer himself/herself in any other course as a candidate for the M.Pharm. examination. Such a candidate may be exempted from appearing in papers in which he/she has already passed under this ordinance at the first examination if there is equivalence in the syllabus. He/She shall, however, have to submit a fresh dessertation.

ii) An examinee passing the examination under subparagraph (i) shall not be eligible for the award of Division or for inclusion of his name in Merit List.

16. Notwithstanding anything to the contrary in this Ordinance, no person shall be admitted to an examination under this Ordinance if he has already passed the same examination in the course or an equivalent examination of any other statutory University.

17. The Degree in the prescribed form shall be signed by the Vice-Chancellor.

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* As amended by Ordinance No.10 of 2003. (Accepted by M.C. in its meeting dt.24.07.2003)

As amended by Ordinance Nos.10 of 2005, 23 of 2005, & 28 of 2005.

ANNEXURE-I

MASTER OF PHARMACY
IN INDUSTRIAL PHARMACY

I. FIRST EXAMINATION

Sr.No.		Subject/Paper	Maximum marks			Minimum marks for passing
			Sessional	Paper	Total	
1	CP-1	Biostatistics & Research Methodology	20	80	100	50
2	CP-2	Product Development and Formulation	20	80	100	50
3	IP-1	Advanced Industrial Pharmacy-I	20	80	100	50
4	IP-2	Advanced Industrial Pharmacy-II	20	80	100	50
5	IP-3	Industrial Process Validation and Production Management	20	80	100	50
6	IP-4	Selected Topics in Industrial Pharmacy	20	80	100	50
7	IP-5	Practicals in Industrial Pharmacy	20	80	100	50
					700	

II. FINAL EXAMINATION :

IP-6	Dessertation & Viva-voce		250	125
IP-7	Seminar		50	25
			300	

Note :

1) All theory papers shall be of three hours duration.
2) All practical examination shall be of 12 to 16 hr.spread over two days.
3) The sessional marks in the theory will normally based on one test conducted at the end of Academic year but before the final examination and in practicals on evaluation of the experiments done during the academic year (10 marks) and tests conducted (10 marks) at the end of the academic year but before the final examination by the teachers in the department/college.
4) In Order to pass, the examinee must obtain the minimum pass marks as above.
5) The dessertation shall commence in the first year and shall be evaluated during the second year.

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ANNEXURE-II

Master of Pharmacy
Pharmacognosy and Phytochemistry

I. FIRST EXAMINATION

Sr.No.		Subject/Paper	Maximum marks			Minimum marks for passing
			Sessional	Paper	Total	
1.	CP-1	Biostatistics & Research Methodology	20	80	100	50
2.	CP-2	Product Development and Formulation	20	80	100	50
3.	PG-1	Advanced Pharmacognosy I	20	80	100	50
4.	PG-2	Advanced Pharmacognosy II	20	80	100	50
5.	PG-3	Standardization of Herbal Products	20	80	100	50
6.	PG-4	Selected topics in Pharmacognosy & Phytochemistry	20	80	100	50
7.	PG-5	Practicals in Pharmacognosy & Phytochemistry	20	80	100	50
					700	

II. FINAL EXAMINATION:

PG-6	Dessertation & Viva-voce		250	125
PG-7	Seminar		50	25
			300	

Note:

1. All theory papers shall be of three hours duration.
2. All Practical exanimation shall be of 12 to 16 hrs spread over two days.
3. The Sessional marks in the theory will normally based on one test conducted at the end of Academic year but before the final examination and in Practicals on evaluation of the experiments done during the academic year (10 marks) and tests conducted (10 marks) at the end of the academic year but before the final examination by the teachers in the department / college.
4. In Order to pass, the examinee must obtain the minimum pass marks as above.
5. The dessertation shall commence in the first year and shall be evaluated during the second year.

DIRECTION

No.: 1 / 2007 Date : 18 /01/ 2007

Subject : Scheme of Examination for M.Pharm. (Pharmaceutics)

Whereas, the Ordinance No.17 of 2002 in respect of Examination leading to the Degree of ¦É¼ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy) is in existance.

AND

Whereas, the Govt. of Maharashtra of Maharashtra, Department of Higher and Technical Education, vide its letter No./Ê]<B¨É 2006/(287/06)/iÉÉÉ¶É-1, Dt. 22.06.2006 has granted permission to start the above said course at Pataldhamal Wadhwani College of Pharmacy, Yavatmal.

AND

Whereas, the B.O.S. in Pharmaceutical Sciences in its emergent meeting held on 04.10.2006 has provided the scheme of examination, and syllabi for the said course.

AND

Whereas, the Academic Council in its meeting held on 29th December, 2006 vide item No.65, has granted first time affiliation to the aforesaid course from the Academic Session 2006-2007, at Pataldhamal Wadhwani College of Pharmacy, Yavatmal.

AND

Whereas, the scheme of examination for M.Pharm. (Pharmaceutics) is to be made available from the Academic Session 2006-2007.

AND

Whereas, the Hon'ble Vice-Chancellor has accepted the scheme of examination and syllabi for M.Pharm. (Pharmaceutics) under sub-section (7) of section 14 of the Maharashtra Universities, Act, 1994, on 13/1/2007.

AND

Whereas, the scheme of examination is a part of Ordinance in respect of Examination leading to the Degree of ¦É¼ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy), Ordinance 2002, i.e. Ordinance No.17 of 2002, in which necessary amendment is to be made.

AND

Whereas, making amendments in the said ordinance i.e. Ordinance No.17 of 2002 in respect of Examinations leading to the Degree of ¦É¼ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy), Ordinance 2002, is a time consuming process.

Now, therefore, I, Dr. Kamal Singh , Vice Chancellor of Sant Gadge Baba Amravati University, in exercise of powers conferred upon me under sub-section (8) of section 14 of the Maharashtra Universities Act., 1994, do hereby direct as under:

1. This Direction may be called "Examinations leading to the Degree of ¦É¼ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy), Direction, 2007".
2. This direction shall come into force from the date of its issuance.
3. The Scheme of examination for the Examination leading to the Degree of ¦É¼ÉVÉÒ {ÉÉ®MÉiÉ (Master of Pharmacy) i.e. M.Pharm. (Pharmaceutics), shall be as per Annexure-I, appended with this Direction.

Sd/-

Amravati (Dr.Kamal Singh)
Dated : 17/01/2007 Vice-Chancellor

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ANNEXURE-I

SANT GADGE BABA, AMARAVATI UNIVERSITY
Master of Pharmacy
Pharmaceutics

I. FIRST EXAMINATION

S.N.	Code	Subject/Paper	Maximum marks			Minimum marks for passing
			Sessional	Paper	Total	
1	CP1	Biostatistics and Research Methodology	20	80	100	50
2	CP2	Product Development and Formulation	20	80	100	50
3	P1	Advanced Physical Pharmacy	20	80	100	50
4	P2	Biopharmaceutics and Pharmacokinetics	20	80	100	50
5	P3	Pharmaceuticals Dosage Form Technology	20	80	100	50
6	P4	Selected Topics in Pharmaceutics	20	80	100	50
7.	P5	Practicals in Pharmaceutics	20	80	100	50
					700	

II. FINAL EXAMINATION

P6	Dissertation and Viva-voce	250	125
P7	Seminar	50	25
		300	

Note:

1. All theory papers shall be of three hours duration.
2. All practical examination shall be of 12 to 16 hours spread over two days.
3. The Sessional Marks in the theory will normally based on the test conducted at the end of academic year but before final examination and Practicals on evaluation of experiments done during academic year (10 Marks) and test conducted (10 Marks) at the end of academic year but before the final examination by the teachers in department/college.
4. In order to pass, the examinee must obtain the minimum pass marks as above.
5. The dissertation shall commence in the first year and shall be evaluated during second year.

SYLLABUS PRESCRIBED FOR THE EXAMINATION OF THE DEGREE OF

MASTER OF PHARMACY IN PHARMACEUTICS

I. FIRST EXAMINATION

CP-1 : BIOSTATISTICS AND RESEARCH METHODOLOGY.

SECTION-A

The following topics in the subject covered by Sanford Bolton in Pharmaceutical Statistics-Practical and Clinical Applications, Marcel Dekker, Inc., New York,1990, will be dealt with:

Basic Definations and concepts, Data Graphics, The Binomial and Normal probability Distributions, Sampling, Estimation and Hypothesis Testing, Sample size and power, Linear Regression and Correlation, Analysis of variance, Factorial Designs, Transformations and outliers, Experimental Design in Clinical Trials, Quality Control, Validation, Consumer Testing, Nonparametric Methods and Optimization Techniques.

COMPUTER APPLICATIONS IN PHARMACY :

Introduction to computers, Programming languages, flow charting and system analysis-A review, Applications of LOTUS 1-2-3 and dBASE (III,IV) Strategy for building of Pharmacokinetic models, study of Computer software like AUTOAN 1, AUTOAN 2, CSTRIP, NONLIN, MACDOPE, etc., An approach to computer aided drug design.

Reference Books :

1. Buncher, C.R. and Jia-Yeong Tsay, Statistics in the Pharmaceutical Industry, Marcel Dekker Inc.
2. Peace,K.E., Biopharmaceutical Statistics for Drug Development. Marcel Dekker Inc.
3. Berry,D.A.,Statistical Methodology in pharmaceutical Sciences, Marcel Dekker Inc.
4. Peace, K.E., Statistical Issue in Drug Research and Development, Marcel Dekker Inc.
5. Bergman, S.W., Statistical Methods for Pharmaceutical Research and planning, Marcel Dekker Inc.
6. Daniel, W.W., Biostatistics.
7. Fassett, W.E. and Christensen, D.B.,Computer Applications in Pharmacy.
8. Gilbert, C and Williams, L., The ABC's of 1-2-3, B.P.B. Publications.
9. Simpson, Introduction to dBASE III +; B.P.B. Publications.

10. Naiman, An Introduction to Wordstar; B.P.B. Publications.

CP-1 **SECTION-B**

I Research

1. Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) - Objective of research-
2. Literature Survey- Use of Library, books & journals-Medline-Internet, getting patents and reprints of articles as sources for literature survey.
3. Selecting a problem and preparing research proposal for different types of research mentioned above.
4. Methods and tools used in Research.

   - Qualitative studies,Quantitative Studies
   - Simple data organisation, Descriptive data analysis
   - limitations and sources of Error
   - Inquiries in form of Questionnaire, Opinionnaire or by interview.
   - Statistical Analysis of data including variance, standard deviation, student't' test and annova, correlation data and its interpretation, computer data analysis

5. Documentation

   - "How" of Documentation
   - Techniques of Documentation
   - Importance of Documentation
   - Uses of Computer packages in Documentation

6. The Research Report/Paper writing/thesis writing

   -Different parts of the Reseach paper

   1. Title-Title of project with author's name
   2. Abstract-Statement of the problem, Background list in brief and purpose and scope.
   3. Key-words-
   4. Methodology - Subject, Apparatus/Instrumentation, (if necessary) and procedure.

7. Results- Tables,Graphs, Figures and statistical presentation

8. Discussion - Support or non-support of hypothesis

   - practical & theoretical implications,

   - conclusions

9. Acknowledgements

10. References

11. Errata

12. Importance of spell check for Entire project.

13. Use of footnotes

II. Presentation (specially for oral)

Importance, types, different skills.

- Content of presentation, format of model.

  Introduction and ending

- Posture, Gestures, Eye contact, facial expressions, stage fright

- Volume-pitch, speed, pause & language

- Questionnaire

III. Protection of patents and trade marks. Designs and copyrights

- The patent system in India - Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents.

- Advantages

- The science in law. Turimetrics (Introduction)

- What may be patented

- Who may apply for patent

- Preparation of patent proposal

- Registration of patents in foreign countries and vice-versa

IV. Cost Analysis of the Project

- Cost incurred on Raw Material

- Cost incurred on Procedure

- Cost incurred on Instrumentation

- Cost incurred on Clinical trials

V. Sources for procurement of Research Grants

VI Industrial-Institution Interaction

- Industrial projects- Their feasibility reports

Books

1. Research in Education - John V. Best, James V. Kahn
2. Presentation skills - Michael Halton - Indian Society for Institute Education.
3. A Practical Introduction to copy right - Gavin Mcfarlane
4. Thesis projects in Science and Engineering - Richard M.Davis
5. Scientists in legal system - Ann labor science
6. Thesis and Assignment wirting - Jonathan Anderson
7. Writing a technical paper - Donald Menzel
8. Effective Business Report writing - Leland Brown
9. Protection of Industrial property rights- Purushottam Das and Gokul Das
10. Spelling for the millions - Edna Furmess
11. Preparing for publication - King Edwards Hospital fund for London
12. Information technology - The Hindu speaks
13. Documentation - Genesis & Development 3792
14. Manual for evaluation of Industrial projects - United Nations
15. Manual for the preparation of Industrial feasibility studies

CP-2 : PRODUCT DEVELOPMENT AND FORMULATION

INTRODUCTION OF NEW DRUGS:

Steps involved in the development of a new drug, obstacles to its evaluation, limitations of screening procedures, animal toxicity tests. Extrapolation of laboratory data to man, placebo, New drug application as per WHO norms and proforma. Requirement and guidelines on clinical trials for import and manufacture of new drugs in India.

PREFORMULATION STUDIES :

Investigation of physical and chemical problems inherent in the development of new formulations.

PHYSICAL PROPERTIES :

Organoleptic properties, microscopy, intrinsic solubility and dissolution rate; powder flow and compression, properties and physical stability.

CHEMICAL PROPERTIES :

Chemical properties : Purity, physico-chemical parameters affecting absorption, solid state and solution-phase stability and compatibility with excipients. Formulation additives : Studies on all excipients to be incorporated in the development of liquid orals, solid dosage forms. Stability data : Advanced studies on stability and development of stability data on different formulations.

PROCESS VALIDATION :

Development of validation data on different formulations, Quality assurance and GMP : A Detailed study of current good manufacturing practices in manufacturing, processing, packaging and holding of drug.

Product development approach on following formulations :

LIQUID ORALS :

Cough and multivitamin syrup, antiflatulant and laxative emulsions, antacid and antidiaroheal suspensions.

TOICALS :

Antibiotic ointment, analgesic gels.

TABLETE :

Common cold, multivitamin, chewable antacid, soluble asirin and dispresible/kid tablets.

STERILE DOSAGE FORMS :

B-comlex injection, antibiotic eye and ear drops, antihistaminic nasal drops.

Reference Books :

1. Gennaro, Remingtons Pharmaceutical Sciences, Mack Publishing Co.
2. Lachman, Theory and practice of Industrial pharmacy, Lea and Febiger.
3. Ansel.,Pharmaceutical Dosage Forms & Drug Delivery Systems, Lea & Febiger.
4. Banker, Modern Pharmaceutics, Marcel Dekker Inc.
5. Racz, Drug Formulation, John Wiley and Sons.
6. Aulton, Pharmaceutics : The Science of Dosage Forms Design, ELBS, London
7. Wells, Pharmaceutical preformulation: The physico-chemical properties of Drug Substance, Ellis Horwood Ltd.
8. Florence, Atwood, physico-chemical Principles of pharmacy, Chapman and Hall NY.
9. Welling and Tuckerman, Good Manufacturing practices : A plan for Total Quality Control, Bhalani Publishing House, Bombay.
10. Connors, Chemical stability of pharmaceuticals : A Handbook for pharmacists, Wiley Inter-Science.
11. Carstensen, Drug Stability : Principles and practices, Marcel Dekker Inc.

P-1 : ADVANCED PHYSICAL PHARMACY

Thermodynamics of Drug Molecules: Introduction, Role of thermodynamics of solution behaviour in pharmacy and biology. The group contribution concept, activity co-efficient, solubility and solubility of hydrocarbons in water. Partition coefficient study of work of Hansch and co-workers (concepts in pharmaceutical sciences) hydrophobic interactions like confirmaition. The application of group contribution of proteins, co-relation of biological activity with physicochemical parameters. Thermodynamics analysis of SAR. The transport of drug molecules across membranes through bio-phases. The interaction of drug with micro-molecules. Drug metabolism and elimination.

Solid State: Introduction to states of matter, transformation of matters, concepts of force, pressure, energy. Review of work and heat, heat capacity, enthalpy, varieties of enthalpy, entropy change, Gibbs function, changes of state. Physical transformation of pure material, Review of solid state, symmetry of crystal lattice and unit cells, space group and properties of crystals, diffraction, electron diffraction, rate of solution and solubility crystal growth, methods of studying solid microscopic studies,etc.

Reaction kinetics: The apparent zero order and first order rate constants, complex reactions, effect of temperature, specific acid base catalysis, general acid base catalysis, ionic strength, die electric constant and solvolysis on the reaction rate, derivation and applications of relevant kinetic equations. prediction of stability of drug in dosage forms by accelerated stability techniques.

Interfacial Phenomenon: liquid-liquid interphase, insoluble monolayers, surface pressure, surface potential, surface rheology, and their measurement, structure and state of monolayers, mixed monolayers, micromolecular films, biological membranes, liquid-solid interphase, detailed study of wetting, detergency and water repellancy.

Solubility and solubilization: recent development in different pharmaceutical aspects of solubility and drug solubilization techniques including their theories and mechanism and role of surfactants, solubilization of phenolic disinfectants, iodophores, vitamin preparation, hormone solutions, steriods flavours etc.

Theories of Dispersion Techniques: General basic physical considerations, adsorption and interfacial energetic, and study of relevant equations, adsorption on solid surfaces, Electrical phenomenon at interfaces. Particle-particle interactions, Influence of polymer adsorption of particle-vehicle interaction. Flocculation kinetics, controlled flocculation. Application of dispersion techniques in formulation of emulsions and suspensions.

Emulsions: Electrical theories of stabilization of emulsions, Assessment and prediction of emulsion shelf life, equations involved in emulsion stability, Stress conditions and physical parameters employed to evaluate emulsion stability.

Preservation of emulsion, Interaction between preservative and emulsion ingredients like surface active agents, hydrophilic polymers, packaging materials etc. Prediction of preservative efficiency.

Rheology: Theoretical considerations, Thixotriopy, Spurs and bulges in the hysteresis loop, continuous shear rheometry of semi-solids, viscolasicity, the creep test, study including principle of operation and applications of cone and plate, Stormer, Mac-Michael, Brookefield viscometers, Chemical and physical factors affecting rheological properties, Rheology and product, design, Rheology and Pharmaceutical Processing, Rheology and Biological applications.

Complexation: Forces operative in complex, classification of types of complexes, Experimental methods of determination of complex formation Determination of stability Micromeritics : Adsorption, air permeability, techniques and coulter-counter in determining the surface area and size of particles, Classification of some basic properties, of powders, evaluation of the fundamental properties of powders in relation to flow properties, flow properties of various powder systems.

REFERENCE BOOKS:

1. Bean, Beckett and Carless, Advances in Pharmaceutical Sciences Vols I, II, III and IV
2. Martin, Physical Pharmacy, Lea and Febiger.
3. Gennaro, Remingtons Pharmaceutical Sciences, Mack Publishing Co.
4. Rawlins, Bently's TB of Pharmaceutics, ELBS
5. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
6. S.H. Yalkowsky, Techniques of Solubilization of Drug, Marcel Dekker Inc.
7. K.C. James, Solubility and related properties, Marcel Dekker Inc.
8. Florence and Atwood, Surfactant systems- Their Chemistry, pharmacy and biology, Blackwell Scientific publications.

P-2 : BIOPHARMACEUTICS AND PHARMACOKINETICS

Review of drug dissolution absorption and disposition.

Prodrugs: Goals of prodrug, design of prodrug to overcome pharmaceutical and Pharmacokinetics problems and for targeted delivery of drugs.

Pharmacokinetics: Rates and orders of physiologic processes, rate constants, approaches to pharmacokinetic modelling: compartmental, non-compartmental and physiologic, types of Compartment models : mammillary and catenary.

Compartmental Analysis: Rate equations for absorption and disposition of drugs, determination of rate constants and other parameters following drug administration by i.v. infusion and extra vascular route by considering open one compartment and multi-compartment models.

Pharmacokinetic Parameters: Concept of drug clearance and apparent volume of distribution, their relationship with elimination half-life, absorption and disposition rate constants, AUC, etc. Determination of Ka by blood concentration and urinary excretion data.

Non-linear Pharmacokinetics: Study of processes demonstrating saturation kinetic, Michaelis-Menten kinetics, one and two compartment open model with M.M. Kinetics, determination of Km and Vm. Kinetics of P-D binding, determination of binding constants and binding sites.

Bioavailability and Bioequivalence: Purpose of bioavailability studies methods of assessing bioavailability, general issues to be considered in conducting bioavailability studies. Bioequivalence studies, determination of bioequivalence, evaluation and design of single-dose bioequivalence study. Correlation of in-vitro dissolution and in-vivo bioavailability. Biopharmaceutic classification system and its significance in drug formulation development and bioavailability.

Clinical Pharmacokinetics: Design of dosage regimen, determination of route of drug administration, dose, dosage interval and frequency of administration, multiple dose regimen, adjustment dose in renal failure and relationship between pharmacokinetic and pharmacologic response.

Separation, purification and analysis of drugs and their metabolites in various biological samples.

REFERENCE BOOKS

1. Milo Gibaldi, Pharmacokinetics Marcel Dekker Inc.
2. Abdou, Dissolution, Bioavaliability and Bioequivalence, Mack Publishing Co.
3. Smith and Stewart, T.B. of Biopharmaceutic Analysis, Lea and Febiger.
4. Sharjel, Applied Biopharmaceutics and Pharmacokinetics, Appleton Century Crofts.

5. Jenner and Testa, Concepts in Drug Metabolism, Part I and II, Marcel Dekker.
6. Wagner, Fundamentals of Clinical Pharmacokinetics, Drug Intelligence Publishing.
7. Gibaldi and Prescott, Handbook of Clinical Pharmacokinetics, ADIS Health Science.
8. Robinson and Lee, Controlled Drug Delivery: Fundamentals and Applications, Marcel Dekker.
9. Brahmankar and Jaiswal, Biopharmaceutics and Pharmacokinetics – A Treatise, Vallabh Prakashan, Delhi.

P-3 : PHARMACEUTICAL DOSAGE FORM TECHNOLOGY

Controlled Drug Delivery System: Rationale, design and fabrication of following, controlled drug release systems: oral, ocular, intravaginal and intrauterine transdermal, parenteral and implantable controlled drug delivery systems, other specialized controlled drug systems like: liposomes, nanoparticles, microparticulates and macromolecule drug carriers, and antibodies for drug delivery.

Lipoproteins: Lipoproteins in biological fluids, cellular interactions with vascular endothelium, lipoproteins and microemulsions as carriers of therapeutic and chemical agents.

Non-Traditional Topical Drug Delivery Systems: Microsponges, liposome, surfactant, association colloids, gels, silicones.

Biodegradable Polymers for Controlled Drug Delivery: Introduction, general consideration, design and formulation options, drug release kinetics.

Pharmaceutical Liquids: Manufacturing considerations, industrial processing, production equipments and machines used for large-scale manufacture of solutions, suspensions and emulsions.

Tablets: Tablet formulation and design, formulation aspects of tablets prepared by different techniques, formulation and evaluation of compression coated, layered, effervescent, chewable and specialty tablet and medicated lozenges.

Compression: Consolidation, compaction and compression characteristics of different materials with special emphasis on directly compressible vehicles, mechanisms of bonding and properties of tablets problems and their rectification. Tablet-Coating, Sugar and film coating formulations, equipments used, mechanisms of film formation, factors affecting quality of films, polymers useful in film coating with comparative film forming and drug-releasing efficiency, controlled and aqueous polymeric coatings. Problems encountered in sugar and film coating and their solutions.

Tablet Stability and Kinetics: Reaction kinetics in solid dosages forms, solid-drug and solid-dosage form degradation, mechanisms that affect tablet stability.

Microencapsulation: Core and coating properties; microencapsulation techniques, coacervation-phase-separation using aqueous and nonaqueous vehicles, congealing, spray embedment and polycondensation, polymerization process for nanoparticles, ion-exchange resins and other methods.

Mechanisms of drug release from microcapsules.

Pelletization Technology: Rationale for pelletization mechanism of pellet formation and growth, pelletization equipments; coating pans, fluid bed equipments, extruder spheronizer and centrifugal equipment, pelletization process, solution suspension and dry powder layering and extrusion and spheronization, formulation variables in pelletization.

Sterile Dosage Forms: Sterilization and disinfection, relative efficiency of different methods, kinetics of sterilization, sterility assurance and equipment function tests and exposure verification tests.

Facilities, environment control and personnel in the production of sterile dosage forms, formulation and processing of LVP, SVP and related sterile products, parenteral devices.

Topical Drug Delivery System: Percutaneous absorption, factors affecting, types of topical preparations, vehicles, enhancers, quality control, stability and precaution on industrial scale.

Pilot Plant Scale-up Techniques: Purpose and functions, concepts of pilot plant for development and control, Planning for pilot plant, size of pilot plant. Organization and personnel, basic consideration in developing the process for production of pharmaceutical dosage forms. Pilot plant study design for tablets, tablet coating, capsules, liquid orals and semi-solids.

Biodegradable Polymers for controlled drug delivery: Introduction, general consideration, design and formulation options, drug release kinetics.

Packaging Materials : Cosmetics and their relation to drugs comparison on the basis of composition, on the basis of safety and performance, formulation aspects for skin, hair, face preparation, colours and perfumes, dentrifrices and mouth washes.

REFERENCE BOOKS :

1. G.S. Banker, Modern Pharmaceutics, Marcel Dekker Inc.
2. Gennaro, Remingtons Pharmaceutical Sciences, Mack Publishing Co.
3. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
4. Lachman, Reiger and Banker, Pharmaceutical Dosage Forms: Disperse Systems, Vols. I and II, Marcel Dekker Inc.
5. Lieberman, Lachman and Schwartz, Pharmaceutical Dosage Forms: Tablets, Vols. I, II and III Marcel Dekker Inc.
6. Lieberman, Lachman and Avis, Pharmaceutical Dosage Forms: Parenteral Medications, Vols. I and II Marcel Dekker Inc.

7. King and Turco, Sterile Dosage Forms, Lea and Febiger.
8. Russell, Hugo and Ayliffe, Principles and Practice of Disinfection, Preservation and Sterilization, Blackwell Scientific Publising Co.
9. J.R. Nixon, Microencapsulation, Marcel Dekker Inc.
10. Robinson and Deasy, Microencapsulation and Related Drug Processes, Marcel Dekker Inc.
11. D. W. Osborne, Antone, H. Amann, Topical Drug Delivery Formulation Marcel Dekker Inc.
12. Vinod P. Shah, Howard I. Maibach, Topical Drug, Bioavailability, Bioequivalence and Penetration, Plenum Press.
13. Ghebre-Sellasie, Pharmaceutical Pelletization Technology, Marcel Dekker Inc.
14. Bean, Beckett and Carless, Advances in Pharmaceutical Sciences Vols I, II, III and IV.
15. Martin, Physical Pharmacy, Lea and Febiger.
16. Rawlins, Bentley's T.B. of Pharmaceutics, ELBS
17. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
18. S.H. Yalkowsky, Techniques of Solubilization of Drug, Marcel Dekker Inc.
19. K.C. James, Solubility and Related Properties, Marcel Dekker Inc.
20. Florence and Atwood, Surfactant Systems – Their Chemistry, Pharmacy and Biology, Blackwell Scientific Publications.
21. Robinson and Lee, ControlleDelivery: Fundamentals and Applications, Marcel Dekker Inc.
22. Y.W. Chien, Novel Drug Delivery Systems, Marcel Dekker Inc.
23. S.D. Bruck, Controlled Drug Delivery Vols. I and II, CRC Press.
24. David Illum, Polymers in Controlled Drug Delivery, Wright Publishing Co.
25. Michal Shaw, Lipoproteins as Carriers for Pharmacological Agents, Marcel Dekker Inc.
26. Mark Chasin, Robert Langer, Biodegradable Polymers as Drug Delivery Systems, Marcel Dekker Inc.
27. James Swarbrick, James Boylan, Encyclopaedia of Pharmaceutical Technology, Vol. I to III, Marcel Dekker Inc.

P4: SELECTED TOPICS IN PHARMACEUTICS

1. **General Consideration**, Preparation of Master Manufacturing Procedures: Material Handling, Blending, Granulation, Drying, Slugging, Compression, Coating Liquid Dosage Forms, Contract Manufacturing.
2. **Project, Production and Planning Management:** Space allocation, environmental factors, manufacturing materials, management, sales forecasting, cost control.
3. **Drug Regulatory Methods:** Definitions, federal food Drug and cosmetic act, Kafaurver Harres amendment, New Drug application, Drug efficacy Study, Implementation review, OTC drug review, Drug listing, Drug Amendments, Patents, Copy rights, trade marks, Drug recalls, Product liability, Clinical trials.
4. **Patents and Copyrights - Indian and International Laws and Act:** Various Laws and acts, Indian and International Patent systems.
5. **Review of advances in chromatographic techniques and troubleshooting applications of techniques to test cases.**
6. **Introduction of advanced techniques and their instrumentation.**
   1. FTIR and its applications in polymorphsim in bulk drug and particulate.
   2. Automatic dissolution testing of solid dosage forms.
   3. Chiral chromatography.
   4. Ion exchange chromatography.
   5. Mass spectroscopy, fragmentation pattern, rearrangements of fragmentation & interpretation of results.
   6. NMR, chemical shift, spin-spin coupling, decoupling, interpretation of results.
   7. DSC (differential scanning calorimetry)
   8. DTA (differential thermal analysis)
   9. X-ray diffraction & X-ray emission methods.
7. **Applications of analytical principles and procedures to –**
   1. Stability studies
   2. Construction of (stability chambers) walking chambers for accelerated temperature studies.
   3. Selection of analytical method using stability indicating procedures
   4. Forced degradation
   5. Synthesis of degradation products
   6. FDA guidelines
   7. Global harmonization, ICH guidelines
   8. Sequential overview of stability functions

Solid state stability

- Kinetics of solid state decomposition

- Pharmaceutical Examples of solid state Decomposition
- Pure drugs
- Drug–excipient and drug-drug interactions in solid dosage forms

8. Role of pharmaceutical analyst in bio-equivalence / bio-availability techniques and US FDA Guidelines.

9. Regulatory considerations registration requirements of quality for new drugs, generics and off-patent drugs, international harmonization.

REFERENCE BOOKS

1. Chromatographic science series Vol. 31.
2. Chromatographic science series Vol. 37.
3. Chromatographic Science Series : Vol. 74.
4. Chromatographic Science Series : Vol. 75.
5. Clarke's Isolation and Identification of Drugs.
6. Thermal Analysis: Theory and Application, R.T. Sane, J. K. Gadge.
7. An Introduction to Thermogravimetry, Keattch/Dollimore.
8. Chiral Separations by HPLC, A.M. Krstulovic.
9. Quality Assurance of Drugs in Pharmaceuticals, P.D. Sethi.
10. Stability Testing of Drug Products.
11. Latest editIon of IP, BP, USP, E.P. Homeopathic Pharmacopoeia, Ayurvedic Pharmacopoeia and Ayurvedic Formulary.
12. High Performance Liquid chromatography, P.D. Sethi.
13. Principals of Instrumental Analysis, Skoog, Holler.
14. Quantitative Analysis of Drugs, Garrett.
15. A practical Introduction to copyrights - Gavin M. C. Fariane
16. Commercial Exploitation of Intellectual Property Rights by Licensing - Charles D. Desforges ISBN 2005 - 1854182854.
17. Connors Chemical Stability of Pharmaceuticals 'A Handbook for Pharmacists Wiley Inter - sciences.
18. Gilber S. Banker and C.T. Rhodes, Modern Phrmaceutics Marcel Dekker Inc.
19. Intellectual Property Rights : The TRIPS Agreement and Policy Options - Carlos Maria Correa ISBN 2000 - 1856497372
20. SOP - Guidelines by D.H. Shah By Business Horizons Pharmaceutical Publisher - 1999 - New Delhi.
21. The Patents (Second Amendment) Bill, 1999 - An Analysis by Dr. N. S. Gopalkrishnan (Eastern Book Company)
22. Project Management & Plant Lay -out - Marcel Dekker.
23. United States Pharmacopoeia.

P-5 : PRACTICALS IN PHARMACEUTICS

1. To evaluate the stability of suspensions and emulsions by particle size and zeta potential measurement.
2. To study the thixotropic behaviour of semisolids.
3. To study the influence of air-entrapment on rheology of creams.
4. To study in-vitro release of medicaments from ointments.
5. To evaluate the antibiotic ointment by microbiological assay.
6. To evaluate the acid neutralizing capacity of marketed antacid preparations
7. To study the influence of time, temperature and pH on aspirin hydrolysis.
8. To perform bioequivalence testing on marketed analgesic tablets.
9. To study the influence of gastrointestinal pH on drug absorption.
10. To determine Ka, biological half-life, AUC and other pharmacokinetic parameters of rifampicin/nitrofurantion by urinary excretion method.
11. To determine P-D binding of drug by equilibrium dialysis method.
12. To determine the enzyme activity of liquid oral enzyme preparation.
13. To study uptake of drug by RBCs.
14. To determine the saliva concentration of paracetamol and its relation to blood and urinary drug concentration.
15. To study the influence of urinary pH on salicylate excretion.
16. To design and evaluate drug formulations belonging to following category –
    (a) Controlled release matrix tablet of diclofenac sodium.
    (b) Controlled release pellet formulation of diltiazem HCL.
    (c) Microemulsion oral formulation (drops) of water and oil soluble vitamins.
    (d) Antiinflammatory gel of NSAID.
    (e) Antiinfective cream
    (f) Taste masking formulation with use of ion-exchange resin or particle coating
    (g) Orally disintegrating tablets
17. Workshop Technology to acquaint the students with the working of grinders, vices, welding and jobs relating to them.

II. FINAL EXAMINATION

P-6 : DESSERTATION AND VIVA-VOCE

Every student for the degree of master of pharmacy shall be required to undertake a project involving Methodical Research under the supervision of an approved guide and submit three copies of the report on

the project, duly certified by the supervisor to the Head of the Department, Principal. The work shall be conducted in accordance with the provision of para 13 of the ordinance.

P-7 : SEMINAR

The candidate shall deliver seminars during the session, on selected topics of current research interest as in the journals in the field of his specialisation. Viva-voce examination shall consist of the candidate during such seminars and his overall proficiency in the principles and practice of pharmaceutical sciences.

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Syllabus for M.Pharm-I & II Examination (Pharmaceutics)
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