M.Pharm.Semester-I to IV (Pharmacology)

Prospectus No. 20161432

संत गांडगे बाबा अमरावती विद्यापीठ SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा (FACULTY OF MEDICINE)

अभ्यासक्रमिका औषधिनिर्माण पदव्युत्तर परीक्षा

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PROSPECTUS

OF

MASTER OF PHARMACY (PHARMACOLOGY)
EXAMINATIONS
SEMESTER-I & III, WINTER-2015
SEMESTER-II & IV, SUMMER-2016



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(Prospectus No.20161432)

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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

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Ordinance No. 18/2001: An Ordinance to provide grace marks for

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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. 6/2008 : For improvement of Division/Grade.

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.

Registrar Sant Gadge Baba Amravati University

SANT GADGE BABAAMRAVATI UNIVERSITY DIRECTION

NO. 12 / 2013 Dated: 14/06/2013

Subject: Examinations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year - Four Semester Degree Course) (Credit Grade Based System), Direction, 2013.

Whereas, Direction No.22 of 2010 in respect of Examinations Leading to the भेषजी पारंगत (Master of Pharmacy) (Two year - Four Semester Degree Course), Direction 2010 is in existence in the University.

AND

Whereas, the above Direction was corrected vide Direction Nos.9/2011, 5/2012, 26/2012.

AND

Whereas, the aforesaid Directions are related to semester pattern and credit grade system. The credit grade system is provided in above directions on the base of the marking system.

AND

Whereas, all above Directions are still to be converted into respective Ordinance.

AND

Whereas, the B.O.S. in Pharmaceutical Sciences in its meeting held on 27.8.2012, reviewed the above Directions and recommended the fresh revised draft schemes of teaching and examinations along with other details, and credit system on teaching hours basis with some necessary additions/deletions in the provisions of above direction.

AND

Whereas, while considering the revised schemes and provisions, the B.O.S. recommended that the paper titles and syllabus be kept as it is.

AND

Whereas, the faculty of Medicine in its meeting held on 2.3.2013 has accepted the above recommendations of the B.O.S. and recommended to the Academic Council with some corrections.

AND

Whereas, the Academic Council in its meeting held on 18.4.2013 vide item No.24 3) A) R-3 accepted the recommendations of the faculty of Medicine to be implemented for Summer-2013 examinations of regular students of M.Pharm. Semester-II & IV, and from Academic Session 2013-

14 & onwards for all semesters of M.Pharm. and resolved to refer the Draft Schemes of teaching and examinations alongwith other related provisins, and Draft Ordinance to the Ordinance Committee for framing Ordinance/Regulation for placing it directly before Management Council.

AND

Whereas, the Summer-2013 examinations are already in process and the Academic Session 2013-14 is commencing from June, 2013.

AND

Whereas, the above revised schemes and provisions are to be implemented instead of the provisions of Direction Nos. 22 of 2010, 9/2011, 5/2012 & 26/2012.

AND

Whereas, the above revised schemes and provisions are to be regulated by framing the Ordinance.

AND

Whereas, making of Ordinance is a time consuming process.

Now, therefore, I, Dr.Mohan K.Khedkar, Vice-Chancellor, Sant Gadge Baba Amravati University, Amravati 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 õExaminations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year four Semester Degree Course) (Credit Grade Based System), Direction, 2013ö.
- This Direction shall come into force from
 - i) Summer-2013 Examination for M.Pharm. Semester-II & IV.
 - ii) Academic Session 2013-14 & onwards for M.Pharm. Semester-I to IV.
- 4. The several courses leading to the Degree of भेषजी पारंगत (Master of Pharmacy) shall be as follows:
 - 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 four examinations leading to the Degree of भेषजी पारंगत (Master of Pharmacy) namely the first semester examination at the end of first semester, second semester examination at the end of second semester, third semester examination at the end of third semester and Final semester examination at the end of fourth semester in each of the courses specified in paragraph 4 above. The duration of the course shall be of two Academic years (consisting of two semesters in each year). The supplementary examination shall be held for all semesters of M.Pharm. examinations for FF grade examinees.
- 6. The duration of each semester shall be of six months.
- 7. The Master of Pharmacy First, Third Semester Examination shall be held in winter, and the Second and Fourth semester examination in summer at such places and on such dates as may be fixed by the Borad of Examinations. Subject to the compliance with the provisions of this Direction and of other ordinances in force from time to time, an applicant for admission to -
 - A) Semester-I of First M.Pharm. 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 study in the department/college as prescribed in this Direction.
 - Provided that, the first Semester examinee shall have passed the final B.Pharm. examination by securing not less than 45% marks or its equivalent grade point in C.G.P.A. for SC/ST category and 50% marks or its equivalent grade point in C.G.P.A. for others.ö
 - B) The Final M.Pharm. (Semester-III & IV) Examinee shall have satisfactorily completed Ist and IInd Semester i.e. 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 Direction. An applicant for the examination to the Final M.Pharm. (Semester-III & IV) shall not be allowed to take the examination if he/she fails to submit his/her dissertation on or before the 20th December or 31st May of the calendar year in which he/she has to take the examination.
- 8. A) Without prejudice to the other provisions 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 (Semester-I & II), may be allowed to carry out his research work for dissertation for Final M.Pharm. (Semester-III & IV) Examination and be permitted to appear for the Semester-IV of

- M.Pharm. Examination. But his/her result of Semester-IV shall not be declared till he/she clears all lower semester examinations.
- The fee for each examination shall be as prescribed by the University from time to time.
- 10. The scheme of teaching and credits to be given with maximum marks allotted to each subject and the sessionals, papers, practicals, dissertation, and viva-voce, and seminars if any, in which a candidate is to be examined, and the minimum marks which an examinee must obtain in order to pass the examination and computation of S.G.P.A. and C.G.P.A., shall be as indicated in the Annexures-I to IX appended with this Direction.
- 11. (i) The scope of the subject shall be as indicated in the syllabus.
 - (ii) The medium of instructions and examinations shall be in English.
- 12. An examinee passing in a subject or a part thereof, shall be exempted from appearing in that subject at all subsequent examinations.
- 13. An applicant for admission to an examination shall satisfy the Head of the Department /Principal in the Terminal and other Tests conducted during the academic year regarding his suitability to take the examination.
- 14. The Head/ Principal shall maintain in his office a complete record of marks obtained by the candidate in the sessionals. He shall send it to the Controller of Examinations in a sealed cover the final marks in sessional examination obtained by every applicant.
- 15. In order to pass an examination, an examinee shall obtain not less than 50% of the total marks allotted to each written paper/practical and its respective sessional examination taken together as shown concerned annexures.
- 16. If a student fails in an examination his/her marks of Internal/Sessional Assessment of Theory of the examination shall be carried over for the next examination. However, he can give a declaration to the effect that his Internal/Sessional Assessment marks of the Theory should not be counted and his/her marks in the Theory shall be only on the basis of external examination.
- 17. Improvement of Internal Assessment:
 - If a Ex-student desires for improvement of internal assessment
 of theory/practical, he may reappear for an examination and fresh
 marks for internal assessment will be considered. There is only
 one chance to appear for improvement of internal assessment
 examination for internal theory/practical subject after fail in the
 regular examination only.

- Examination of the subject head õProject and the Seminarsö will be conducted by the institute. The criteria for marks distribution is specified in the scheme of examination. The institute must submit the marks awarded in the Project report and in Seminar to the Controller of Examination along with the periodic test marks (i.e. internal assessment marks). Once the candidate has passed in the subject head õProject report and seminar,ö the candidate will not be allowed to reappear for examination in this subject head.
- 18. i) An examinee for the Third and fourth semester of final year M.Pharm. examination shall carry out research for not less than six months under regular faculty 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 his dissertation 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. The Principal of concerned college shall submit the copies of dissertation within 15 days to the University.
 - iii) a) The examination based on the dissertation shall be carried out by
 - i) The Guide as Internal Examiner and
 - ii) One External Examiner out of University area
 - b) The examiners may after conducting the seminar, dissertation work and viva-voce examination shall award the marks, out of the marks prescribed for dissertation. 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 dissertation is not found upto the mark & if the candidate fails in the dissertation, the External examiner shall give his suggestions / recommendations for re-submission / modification in the dissertation to the Principal along with a copy to the Controller of Examination of University for information.

- iv) An examinee who fails to submit his/her dissertation within the prescribed date or whose dissertation has not been accepted or fails to present himself for Viva-voce, may subject to other provisions of this Direction be readmitted to the examination at any subsequent examination provided that,
 - a) he/she pay the fees as prescribed 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 dissertation on the same subject two weeks prior to the examination date. Examinee whose dissertation 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 dissertation on a fresh subject shall be required to join the department/college as a regular student.
- 19. As soon as possible after examinations the Board of Examinations shall publish result of the examinees and the branchwise merit list shall be notified as provided in Ordinance No.6.
- 20. Examinees who have passed in all the subjects prescribed for the first Year (semester I and semester II) and final M. Pharm. (Semester III and Semester IV) examinations shall be eligible for the award of degree of Master of Pharmacy.
- 21. Provision of Ordinance no. 18 of 2001 relating to õAn 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.18ö shall apply to the examinations under this Direction.
- 22. 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 Direction at the first semester examination, if there is equivalence in the syllabus. However he/she is required to appear for the Semester-II, III & IV of respective specialization.
 - i) An examinee passing the examination under subparagraph (i) shall not be eligible for inclusion of his name in Merit List.

- 23. The Ordinance No.6 of 2008 regarding Improvement of Division / Grade shall be applicable to the examinees under this Direction.
- 24. Notwithstanding anything to the contrary in this Direction, no person shall be admitted to an examination under this Direction if he has already passed the same examination in the course or an equivalent examination of any other statutory University.
- 25. The Degree in the prescribed form shall be signed by the Vice-Chancellor.
- 26. The provisions and schemes provided under the Direction Nos. 22/2010, 9/2011, 5/2012 & 26/2012 shall stand cancelled after enforcement of this Direction.

Dated: 13/6/2013

Sd/(Dr.M.K.Khedkar)
Vice-Chancellor,
Sant Gadge Baba Amravati University,
Amravati

Annexure-I Sant Gadge Baba Amravati University

Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in PHARMACEUTICS (MPH)

| Paper code | Title of paper | Hrs. per | Week and | | of Internal | Schem | e of Extern | al Examin | ation | | | Total Marks |
|---------------|---|--|---|-----------------|--|--------------------------------------|---|--|--|---|-------------|--|
| | | | | Theory | Practical | Theory | , | Practica | 1 | Minimum Marks | for Passing | |
| | | (Credits) | (Credits) | | | Hrs. | Marks | Hrs | Marks | Theory | Practical | |
| MC-101 | Research Methodology & Biostatistics | 04 (04) | | 30 | ** | 03 | 70 | | *** | 50 | (===) | 100 |
| MC -102 | Biotechnology and Bioinformatics | 04 (04) | | 30 | | 03 | 70 | | | 50 | | 100 |
| MC -103 | Quality Control of Pharmaceutical Products | 04(04) | | 30 | (TE) | 03 | 70 | | : - | 50 | 1000 | 100 |
| MC -104 | Drug Regulatory Affairs | 04 (04) | | 30 | | 03 | 70 | | | 50 | | 100 |
| MC-105 | Product Development and Formulation | 04(04) | 1000 | 30 | | 03 | 70 | | | 50 | | 100 |
| MC -106 | Laboratory course -1 | 1.00 | 08 (04) | | 40 | | | 12 | 60 | ##S | 50 | 100 |
| MC -107 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | | *Evaluation | of seminar sh | all be based on | the communication | i, represe | ntation and | skill in o | ral presenta | ation | | |
| MPH-201 | Novel Drug Delivery Systems | 04 (04) | 122 | 30 | 1925 | 03 | 70 | 122 | 11225 | 50 | - | 100 |
| MPH-202 | Biopharmaceutics & Pharmacokinetics | 04 (04) | | 30 | 122 | 03 | 70 | | 122 | 50 | | 100 |
| MPH-203 | Industrial Pharmacy | 04(04) | | 30 | 1990 | 03 | 70 | 0.000 | | 50 | | 100 |
| MPH-204 | Advanced Pharmaceutics & Cosmetology | 04 (04) | | 30 | S | 03 | 70 | | | 50 | | 100 |
| MPH-205 | Selected Topics in Pharmaceutics | 04(04) | 1920 | 30 | 122 | 03 | 170 | 1.02 | | 50 | TREE: | 100 |
| MPH-206 | Laboratory Course -2 | 14 | 08 (04) | | 40 | | | 12 | 60 | (1) (1) (1) (1) (1) (1) (1) (1) (1) (1) | 50 | 100 |
| MPH-207 | Seminar (2 per each subject)* | | | | | | | | | | 25 | -50 |
| | | | of seminar sh | all be based on | the communication | i, represe | | l skill in o | ral presenta | | | |
| MPH-301 | Seminar on Research envisaged for dissertation | 04 Credits | | 40 | 122 | | 60 | 1922 | | 50 | | 100 |
| MPH-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | | 60 | 1 3 <u>20</u> 2 | | 90 | (C) | | 75 | | 150 |
| | Total | | | 100 | | | 150 | | | | | |
| MPH-401 | Dissertation | 10 Credits | | 100 | | | 150 | | | 125 | | 250 |
| MPH-402 | Seminar (on dissertation) | 02 Credits | | 40 | 142 | | 60 | | | 50 | | 100 |
| MPH-403 | Viva-voce | | | 1932 | | | 100 | 722 | | 50 | | 100 |
| | Total | | | 140 | | | 310 | | RAND TO | | | 2000 |
| | MC-101 MC -102 MC -103 MC -104 MC-105 MC -106 MC -107 MPH-201 MPH-202 MPH-203 MPH-204 MPH-205 MPH-207 MPH-301 MPH-302 MPH-401 MPH-401 | mC-101 Research Methodology & Biostatistics MC-102 Biotechnology and Bioinformatics MC-103 Quality Control of Pharmaceutical Products MC-104 Drug Regulatory Affairs MC-105 Product Development and Formulation MC-106 Laboratory course -1 MC-107 Seminar (2 per each subject)* MPH-201 Novel Drug Delivery Systems MPH-202 Biopharmaceutics & Pharmaceutics & Pharmacekinetics MPH-203 Industrial Pharmacy MPH-204 Advanced Pharmaceutics & Cosmetology MPH-205 Selected Topics in Pharmaceutics MPH-206 Laboratory Course -2 MPH-207 Seminar (2 per each subject)* MPH-301 Seminar on Research envisaged for dissertation MPH-302 Seminar on recent trends in Pharmaceutical sciences Total MPH-401 Dissertation MPH-402 Seminar (on dissertation) MPH-403 Viva-voce | MC-101 Research Methodology & D4 (04) | Code | IIrs. per Week and Credit system Lecture Practical (Credits) | IIrs. per Week and Examination | IIrs. per Week and Credit system Lecture Practical Theory Practical Theory Hrs. | IIrs. per Week and Credit system Lecture Practical (Credit system Lecture Practical (Credits) (Credits) (Credits) (Theory Practical Hirs. Marks Mark | Hirs. per Week and Credit system Practical (Credits) Practic | Code | Code | Credit system Leverur Practical Theory Theory |

MPH – M.Pharm. in Pharmaceutics MC- M.Pharm. Common Paper

Annexure-II Sant Gadge Baba Amravati University Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in PHARMACOLOGY (MPL)

| Semester | Paper code | Title of paper | | Teaching in Week and em | Scheme Examination | of Internal | Schem | ne of Extern | al Examin | ation | | | Total Marks |
|--------------|---------------|--|-------------|-------------------------------|-----------------------|----------------------|------------|--------------|---------------|--------------|---------------|-------------|-------------|
| | | | Lecture | Practical | Theory | Practical | Theory | y | Practica | 1 | Minimum Marks | for Passing | |
| | | | (Credits) | (Credits) | | | Hrs | Marks | Hrs | Marks | Theory | Practical | |
| Semester-I | MC-101 | Research Methodology & Biostatistics | 04 (04) | | 30 | | 03 | 70 | | | 50 | | 100 |
| | MC -102 | Biotechnology and Bioinformatics | 04 (04) | 220 | 30 | 220 | 03 | 70 | 22.0 | 944 | 50 | | 100 |
| | MC -103 | Quality Control of Pharmaceutical Products | 04(04) | | 30 | | 03 | 70 | | | 50 | | 100 |
| | MC -104 | Drug Regulatory Affairs | 04 (04) | 1 220 II | 30 | 440 | 03 | 70 | III 1940 | | 50 | 1 12 1 | 100 |
| | MC-105 | Product Development and Formulation | 04(04) | | 30 | ma)) | 03 | 70 | | | 50 | (944) | 100 |
| | MC -106 | Laboratory course -1 | | 08 (04) | | 40 | | | 12 | 60 | | 50 | 100 |
| | MC -107 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | | - | *Evaluation | of seminar sh | nall be based or | n the communication | 1, represe | entation and | d skill in or | ral presenta | ition | | |
| Semester-II | MPL-201 | Advanced Pharmacology and toxicology | 04 (04) | (40) | 30 | | 03 | 70 | | | 50 | | 100 |
| | MPL-202 | Advanced Clinical Pharmacokinetics | 04 (04) | 960 | 30 | 4. (2) | 03 | 70 | 440 | : A4 | 50 | (mm); | 100 |
| | MPL-203 | Topics in Pharmacology | 04(04) | 11 1443 | 30 | 11.1443 | 03 | 70 | | | 50 | I need / | 100 |
| | MPL-204 | Biological evaluation Techniques | 04 (04) | II 423 II | 30 | II <u>22</u> 3 II | 03 | 70 | 11220 | | 50 | 11.122.14 | 100 |
| | MPL-205 | Receptor in Pharmaeology | 04(04) | (4) | 30 | (() () | 03 | 70 | | | 50 | - | 100 |
| | MPL-206 | Laboratory Course -2 | CPM. | 08 (04) | | 40 | | | 12 | 60 | · ***. | 50 | 100 |
| | MPL-207 | Seminar (2 per each subject)* | 04 (04) | | | | П | | | | | 25 | 50 |
| | | | | ı of seminar sh | | n the communication | i, represe | | d skill in or | ral presenta | | | II. |
| Semester-III | MPL-301 | Seminar on Research envisaged for dissertation | 04 Credits | | 40 | -22* | in . | 60 | 11 227 | | 50 | | 100 |
| | MPL-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | | 60 | 100 | | 90 | llan: | | 75 | | 150 |
| | | Total | | | 100 | | | 150 | | | | | |
| Semester-IV | MPL-401 | Dissertation | 10 Credits | ıl I | 100 | 11 223 | | 150 | 111220 | | 125 | | 250 |
| | MPL-402 | Seminar (on dissertation) | 02 Credits | | 40 | 1 200 | | 60 | 1 | | 50 | | 100 |
| | MPL-403 | Viva-voce | | | | | | 100 | | | 50 | | 100 |
| | | Total | | | 140 | | | 310 | | | | | |

MPL – M.Pharm. in Pharmacology MC- M.Pharm. Common Paper

Annexure-III Sant Gadge Baba Amravati University Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in PHARMACEUTICAL CHEMISTRY (MPC)

| Semester | Paper | Title of paper | | Teaching in Week and | Scheme Examination | of Internal | Schem | e of Extern | al Examin | ation | | | Total Marks |
|--------------|---------|---|---|-------------------------|-----------------------|---------------------------------------|------------|--------------|-------------------|------------|---------------|----------------|-------------|
| | | 1 | Lecture | Practical | Theory | Practical | Theory | y: | Practica | 1 | Minimum Marks | for Passing | 1 |
| | | | (Credits) | (Credits) | | | Hrs. | Marks | Hrs | Marks | Theory | Practical | |
| Semester-I | MC-101 | Research Methodology & Biostatistics | 04 (04) | | 30 | | 03 | 70 | ***) | | 50 | | 100 |
| | MC -102 | Biotechnology and Bioinformatics | 04 (04) | read I | 30 | | 03 | 70 | | | 50 | | 100 |
| | MC -103 | Quality Control of Pharmaceutical Products | 04(04) | 1880 | 30 | ** | 03 | 70 | HELL | ** | 50 | | 100 |
| | MC -104 | Drug Regulatory Affairs | 04 (04) | S03 | 30 | :rn: | 03 | 70 | | | 50 | · | 100 |
| | MC-105 | Product Development and Formulation | 04(04) | () | 30 | D 0 | 03 | 70 | | | 50 | [3 | 100 |
| | MC -106 | Laboratory course -1 | ·** | 08 (04) | | 40 | | | 12 | 60 | | 50 | 100 |
| | MC -107 | Seminar (2 per each subject)* | 04 (04) | | 11 | | | | | | 25 | <u>'</u> | 50 |
| | | | *Evaluation of seminar shall be based on the communication, representation and skill in oral presentation | | | | | | | | | | |
| Semester-II | MPC-201 | Advanced Organic chemistry | 04 (04) | 1220 | 30 | 1 m | 03 | 70 | 220 | H1597 | 50 | 10.22 | 100 |
| | MPC-202 | Advanced Medicinal chemistry | 04 (04) | (144) | 30 | - | 03 | 70 | 200 /3 | | 50 | (| 100 |
| | MPC-203 | Modern Analytical Techniques | 04(04) | i merci | 30 | PM I | 03 | 70 | 650 | | 50 | unn . | 100 |
| | MPC-204 | Rational Drug Design | 04 (04) | C **** C | 30 | | 03 | 70 | 1000 | | 50 | | 100 |
| | MPC-205 | Chemistry of Natural Product | 04(04) | F-225 | 30 | i i i i i i i i i i i i i i i i i i i | 03 | 70 | April . | | 50 | 1.02 | 100 |
| | MPC-206 | Laboratory Course -2 | ire <u>ns</u> | 08 (04) | 11 | 40 | | | 12 | 60 | 1102 | -50 | 100 |
| | MPC-207 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | | Total | *Evaluation | of seminar sh | all be based on | the communication | i, represe | entation and | skill in or | al present | ation | | 111 |
| Semester-III | MPC-301 | Seminar on Research envisaged for dissertation | 04 Credits | | 40 | er ••• te | | 60 | | | 50 | | 100 |
| | MPC-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | | 60 | 10. <u>00</u> 7.0 | | 90 | 11227 | li . | 75 | | 150 |
| | | | | | 100 | | | 150 | | | | | |
| Semester-IV | MPC-401 | Dissertation | 10 Credits | | 100 | i ma i | | 150 | Tww/S | | 125 | | 250 |
| | MPC-402 | Seminar (on dissertation) | 02 Credits | | 40 | i dia i | | 60 | 220 | | 50 | | 100 |
| | MPC-403 | Viva-voce | | | 1820 | | | 100 | -227 | | 50 | | 100 |
| | | Total | | | 140 | | | 310 | | | | | |
| | | | | | | | | | G | RAND TO | TAL | | 2000 |

MPC – M.Pharm. in Pharmaceutical Chemistry MC- M.Pharm. Common Paper

Annexure-IV
Sant Gadge Baba Amravati University
Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in PHARMACOGNOSY & PHYTOCHEMISTRY (MPG)

| Semester. | Paper | Title of paper | | Teaching in Week and | Scheme Examination | of Internal | Schem | ne of Extern | al Examin | ation | | | Total Marks |
|--------------|---------|--|-------------|-------------------------|-----------------------|---|------------|--------------|--------------|---|---------------|---------------|-------------|
| | | | Lecture | Practical | Theory | Practical | Theory | V° | Practica | ıl | Minimum Marks | s for Passing | |
| | | | (Credits) | (Credits) | | 1011 | Hrs. | Marks | Hrs | Marks | Theory | Practical | |
| Semester-I | MC-101 | Research Methodology & Biostatistics | 04 (04) | | 30 | **: | 03 | 70 | ne. | | 50 | ** | 100 |
| | MC -102 | Biotechnology and Bioinformatics | 04 (04) | I lees | 30 | III aak | 03 | 70 | 441 | Commercial | 50 | The S | 100 |
| | MC -103 | Quality Control of Pharmaccutical Products | 04(04) | | 30 | I i i i i i i i i i i i i i i i i i i i | 03 | 70 | 1 | 1000 | 50 | | 100 |
| | MC -104 | Drug Regulatory Affairs | 04 (04) | | 30 | | 03 | 70 | | | 50 | ** 6 | 100 |
| | MC-105 | Product Development and Formulation | 04(04) | 11222 | 30 | 11 (22) | 03 | 70 | 1000 | | 50 | 11.224 | 100 |
| | MC -106 | Laboratory course -1 | : | 08 (04) | | 40 | | | 12 | 60 | | 50 | 100 |
| | MC -107 | Seminar (2 per each subject)* | 04 (04) | III | | IIII I | | | | | 25 | <u>'</u> | 50 |
| | | | *Evaluation | of seminar sh | all be based o | n the communication | , represe | entation and | skill in o | ral presenta | ntion | | |
| Semester-II | MPG-201 | Phytotherapeutic Materials | 04 (04) | I I | 30 | The second | 03 | 70 | | - | 50 | news: | 100 |
| | MPG-202 | Herbal Drug Technology | 04 (04) | History | 30 | HT220 | 03 | 70 | 1000 | 10.22 | 50 | 11.122% | 100 |
| | MPG-203 | Cultivation of Medicinal Plants | 04(04) | 11227 | 30 | 111227 | 03 | 70 | 122 | 1000 | 50 | 10-221 | 100 |
| | MPG-204 | Biogenesis and Chemistry of Natural Products | 04 (04) | | 30 | - | 03 | 70 | *** | | 50 | : | 100 |
| | MPG-205 | Selected Topics in Pharmacognosy | 04(04) | | 30 | 11122 | 03 | 70 | | 10 | 50 | II need o | 100 |
| | MPG-206 | Laboratory Course -2 | F-20 | 08 (04) | | 40 | | | 12 | 60 | Ing | 50 | 100 |
| | MPG-207 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | 25 | ' | 50 |
| | | | *Evaluation | of seminar sl | iall be based o | n the communication | i, represe | entation and | l skill in o | ral presenta | ation | | |
| Semester-III | MPG-301 | Seminar on Research envisaged for dissertation | 04 Credits | 11 | 40 | 1122 | | 60 | 122 | 10 | 50 | | 100 |
| | MPG-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | 111 | 60 | 11 (22) | | 90 | 11020 | | 75 | | 150 |
| | | Total | | | 100 | | | 150 | | | | | |
| Semester-IV | MPG-401 | Dissertation | 10 Credits | III | 100 | III we: | | 150 | 1440 | | 125 | | 250 |
| | MPG-402 | Seminar (on dissertation) | 02 Credits | HII | 40 | 111220 | | 60 | 221 | | 50 | | 100 |
| | MPG-403 | Viva-voce | | | | | | 100 | | | 50 | | 100 |
| | | Total | | | 140 | | | 310 | | | | | |

MPG – M.Pharm. in Pharmacognosy MC- M.Pharm. Common Paper

Annexure-V Sant Gadge Baba Amravati University

Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in Industrial Pharmacy (MIP)

| Semester | Paper code | Title of paper | Hrs. per | Teaching in Week and | Scheme Examination | of Internal | Schem | e of Extern | al Examin | ation | | | Total Marks |
|--------------|---------------|---|----------------------|-------------------------|-----------------------|-------------------|------------|--------------|---------------|----------------|---------------|----------------|-------------|
| | | | Credit syste | m Practical | Theory | Practical | Theory | | Practica | 1 | Minimum Marks | for Dogging | |
| | 1 | | Lecture (Credits) | (Credits) | Ineory | Practical | Hrs. | Marks | Hrs | Marks | Theory | Practical | - |
| Semester-I | MC-101 | Research Methodology & Biostatistics | 04 (04) | (Credits) | 30 | | 03 | 70 | | | 50 | | 100 |
| | MC -102 | Biotechnology and Bioinformatics | 04 (04) | | 30 | | 03 | 70 | 122 | | 50 | | 100 |
| | MC -103 | Quality Control of Pharmaceutical Products | 04(04) | 10221 | 30 | nee' | 03 | 70 | II 6152K | 11:228 | 50 | 1821 | 100 |
| | MC -104 | Drug Regulatory Affairs | 04 (04) | | 30 | | 03 | 70 | - | | 50 | - | 100 |
| | MC-105 | Product Development and Formulation | 04(04) | li 😅 | 30 | | 03 | 70 | i w | II II | 50 | | 100 |
| | MC -106 | Laboratory course -1 | 1 <u>56</u> 6 | 08 (04) | | 40 | | | 12 | 60 | <u>-20</u> 7a | 50 | 100 |
| | MC -107 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | | | *Evaluation | of seminar sh | all be based on | the communication | i, represe | entation and | skill in or | ral presenta | ntion | | |
| Semester-II | MIP-201 | Advanced Industrial Pharmacy-I | 04 (04) | 11.00 | 30 | | 03 | 70 | | 1.44 | 50 | 1 3443 | 100 |
| | MIP-202 | Advanced Industrial Pharmacy-II | 04 (04) | | 30 | 1000 | 03 | 70 | 1044 | 122 | 50 | 122 | 100 |
| | MIP-203 | Pharmaceutical Process Validations and Product Management | 04(04) | 10 <u>14.4</u> 0 | 30 | 0.44 | 03 | 70 | liñ <u>aŭ</u> | 10 <u>54</u> 8 | 50 | (2 <u>8-</u> 2 | 100 |
| | MIP-204 | Selected Topics in Industrial Pharmacy-I | 04 (04) | | 30 | | 03 | 70 | :: | | 50 | | 100 |
| | MIP-205 | Selected Topics in Industrial Pharmacy-II | 04(04) | 1.22 | 30 | | 03 | 70 | licas/ | | 50 | | 100 |
| | MIP-206 | Laboratory Course -2 | 1.2 | 08 (04) | | 40 | | | 12 | 60 | 220 | 50 | 100 |
| | MIP-207 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| 1 | | | *Evaluation | of seminar sh | all be based on | the communication | , represe | entation and | skill in o | ral presenta | ntion | | |
| Semester-III | MIP-301 | Seminar on Research envisaged for dissertation | 04 Credits | | 40 | | | 60 | 1022 | | 50 | | 100 |
| | MIP-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | | 60 | | | 90 | II COL | ll II | 75 | | 150 |
| | | Total | | | 100 | | | 150 | | | | | |
| Semester-IV | MIP-401 | Dissertation | 10 Credits | | 100 | | | 150 | i new | 11 | 125 | | 250 |
| | MIP-402 | Seminar (on dissertation) | 02 Credits | | 40 | | | 60 | Table 1 | | 50 | | 100 |
| 1 | MIP-403 | Viva-voce | | | 7922 | | | 100 | 1122 | | 50 | | 100 |
| | | Total | | | 140 | | | 310 | | | TAL | | 2000 |

MIP – M.Pharm. in Industrial Pharmacy

MC- M.Pharm. Common Paper

Annexure-VI Sant Gadge Baba Amravati University Scheme of Teaching and Examination as per Semester Pattern for M.PHARM in Quality Assurance (MQA)

| Semester | Paper code | Title of paper | | Teaching in Week and | Scheme Examination | of Internal | Schem | e of Extern | al Examin | ation | | | Total Marks |
|--------------|---------------|--|--|-------------------------|-----------------------|-------------------|-----------|--------------|----------------|--------------|--------------|---------------|-------------|
| | 11 | | Lecture | Practical | Theory | Practical | Theory | Ÿ | Practica | 1 | Minimum Mark | s for Passing | |
| | | | (Credits) | (Credits) | | | Hrs. | Marks | Hrs | Marks | Theory | Practical | |
| Semester-I | MC-101 | Research Methodology & Biostatistics | 04 (04) | | 30 | | 03 | 70 | | *** | 50 | l leex | 100 |
| | MC -102 | Biotechnology and Bioinformatics | 04 (04) | | 30 | | 03 | 70 | | 440 | -50 | 11 1443 | 100 |
| | MC -103 | Quality Control of Pharmaceutical Products | 04(04) | *** | 30 | | 03 | 70 | | 723 | 50 | | 100 |
| | MC -104 | Drug Regulatory Affairs | 04 (04) | | 30 | | 03 | 70 | | | 50 | 111 | 100 |
| | MC-105 | Product Development and Formulation | 04(04) | = | 30 | | 03 | 70 | II- <u></u> : | | 50 | 011212 | 100 |
| | MC -106 | Laboratory course -1 | in the state of th | 08 (04) | 1 | 40 | | | 12 | 60 | | 50 | 100 |
| | MC -107 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | | | *Evaluation | of seminar sh | nall be based on | the communication | , represe | entation and | skill in or | ral presenta | ation | | |
| Semester-II | MQA-201 | Quality Assurance Technique | 04 (04) | 520 | 30 | 11.22 | 03 | 70 | 122 | 220 | -50 | 111628 | 100 |
| | MQA-202 | Biological evaluation and standardization | 04 (04) | | 30 | 185 | 03 | 70 | +- | | 50 | 11 (45) | 100 |
| | MQA-203 | Advanced Analytical Technique | 04(04) | | 30 | J | 03 | 70 | | *** | 50 | eex | 100 |
| | MQA-204 | Packaging technology | 04 (04) | *** | 30 | - | 03 | 70 | | | 50 | I Description | 100 |
| | MQA-205 | Selected topics in Quality assurance | 04(04) | 220 | 30 | 1 220 | 03 | 70 | 1021 | | 50 | 111220 | 100 |
| | MQA-206 | Laboratory Course -2 | - | 08 (04) | | 40 | | | 12 | 60 | | 50 | 100 |
| | MQA-207 | Seminar (2 per each subject)* | 04 (04) | | | | | | | | | 25 | 50 |
| | 11 | | | of seminar sh | | the communication | , represe | | l skill in oi | ral presenta | | | |
| Semester-III | MQA-301 | Seminar on Research envisaged for dissertation | 04 Credits | | 40 | 1.02 | | 60 | | | 50 | | 100 |
| | MQA-302 | Seminar on recent trends in Pharmaceutical sciences | 04 Credits | | 60 | 11.722 | | 90 | 11/2/26 | | 75 | | 150 |
| | | Total | | | 100 | | | 150 | | | | | |
| Semester-IV | MQA-401 | Dissertation | 10 Credits | | 100 | | | 150 | | | 125 | 101 | 250 |
| | MQA-402 | Seminar (on dissertation) | 02 Credits | | 40 | 1 220 | | 60 | 1125 | | 50 | H | 100 |
| | MQA-403 | Viva-voce | | | 1122 | | | 100 | 15 <u>30</u> 4 | | 50 | H | 100 |
| | | Total | | | 140 | | | 310 | | RAND TO | | | 2000 |

MQA – M.Pharm. in Quality Assurance MC- M.Pharm. Common Paper

Annexure-VII

DISTRIBUTION OF TOTAL CREDITS SEMESTER WISE:

| Year | Semester | Total Credits |
|-------------|---------------|---------------|
| First year | Semester-I | 28 |
| | Semester-II | 28 |
| Second year | Semester-III | 08 |
| | Semester-IV | 12 |
| | Total Credits | Credits= 76 |

Annexure-VIII

SCHEME FOR MARK DISTRIBUTION OF SEMESTER III & IV SEMISTER-III

The topic for the **research envisage for dissertation** and **seminar on recent trends in Pharmaceutical science** shall be assigned to him/her by the Guide within one month from the date of the commencement of the third semester.

A. SEMINAR ON RESEARCH ENVISAGED FOR DISSERTATION

| Content | ts | Marks |
|---------|---|-------|
| 1. | Selection of research topic and their applicability | 25 |
| 2. | Introduction and information retrieval systems | 25 |
| 3. | Reading research papers | 25 |
| 4. | Skill in oral presentation | 25 |
| Total | | 100 |

B. SEMINAR ON RECENT TRENDS IN PHARMACEUTICAL SCIENCES

| Conten | ts | Marks |
|---------|--|-------|
| 1. | Introduction and information retrieval systems | 25 |
| 2. | Organization of material and references | 25 |
| 3. | Representation | 25 |
| 4. | Skill in oral presentation | 25 |
| 5. | Questioning and defending | 25 |
| 6. | Report | 25 |
| Total | | 150 |
| direct. | . 1 111 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | OF T |

^{*}The report shall be submitted to the respective guide/Head of Department/ Library/University.

SEMESTER - IV

A. Dissertation Work

| Conten | ts | Marks |
|--------|--|-------|
| 1. | Introduction, information retrieval systems | 25 |
| 2. | Experimental Work | 100 |
| 3. | Scientific Contents | 25 |
| 4. | Result/ Conclusion | 50 |
| 5. | Organization of scientific material, thesis, dissertation and references | 50 |
| Total | | 250 |

B. Seminar

| Conten | ts | Marks |
|--------|----------------------------|-------|
| 1. | Representation | 50 |
| 2. | Skill in oral presentation | 50 |
| Total | | 100 |

C. Viva-Voce

| | 1 1 0 C C | | | |
|----------|--|-----|--|--|
| Contents | | | | |
| 1. | Reading research papers and depth of knowledge on work topic | 25 | | |
| 2. | Discussion | 50 | | |
| 3. | Report | 25 | | |
| Total | | 100 | | |

Annexure-IX

Sant Gadge Baba Amravati University, Amravati M. Pharm Syllabus

Credit-grade based performance and assessment system (CGPA)) FEATURES OF THE CREDIT SYSTEM

- 1) Masterøs degree would be of 76 credits each.
- 2) One credit course of theory will be of one clock hour per week running for 12 weeks.
- 3) Two credit course of theory will be of two clock hours per week running for 12 weeks.
- 4) Four-credit course of theory will be of four clock hours per week running for 12 weeks.
- 5) One credit course of practicals will consist of 4 hours of laboratory exercise for 6 weeks.
- Two credit courses of practicals will consist of 4 hours of laboratory exercise for 12 weeks.
- Four credit course of practical will consist of 8 hours of laboratory exercise for 12 weeks.
- 8) Every student shall have to complete minimum 57 credits (75%) in first two semester.
- 9) First year may divide into two semesters (Semester-I & II) and shall have 10 theory courses, 2 practical course and 2 seminar

5 Theory courses x 4 credits = 40 credits 1 Laboratory courses x 4 credits = 08 credits 20 Seminar = 56 credits = 56 credits

10) Second year may divide into two semesters (Semester-III & IV) i.e.-

Third Semester ó 1) Seminar on Research Envisaged

for Dissertation

2) Seminar on Recent Trends in Pharmaceutical Sciences

Fourth Semester - 1) Dissertation

12 Credits

08 Credits

- 2) Seminar on Dissertation
- 11) **Scheme of Syllabus and Credit System**: The syllabus for the first semester is common to all M. Pharm. Specialization Courses which consist of total five theory paper and one laboratory course and seminar (2 per each subject).
- 12) Four credits shall be given for conducting the seminars for 04 hrs. in week.

- 13) Academic calendar showing dates of commencement and end of teaching, internal assessment tests and term end examination shall be duly notified before commencement of each semester every year by the affiliated colleges.
- 14) The term end examination, however, shall be conducted by the Sant Gadge Baba Amravati University in the allotted centers.
- 15) The research project shall be compulsory.
- 16) A student who passes the internal tests but fails in Term End Examination of a course shall be given FF grade.
- 17) Student with FF grade in a course would be granted credit for that course but not the grade for that course and shall have to clear the concerned course.
- 18) Grades-Marks for each course would be converted to grades as shown in following Table 1.

Table 1: Grade point for Theory/ Practical/Laboratory course /Seminar

| Grade | Range of Marks obtained out of 100 or equivalent fraction | Grade point | | | |
|-------|---|-------------|--|--|--|
| AA | 90-100 | 10 | | | |
| AB | 80-89 | 9 | | | |
| BB | 70-79 | 8 | | | |
| BC | 60-69 | 7 | | | |
| CC | 55-59 | 6 | | | |
| CD | 50-54 | 5 | | | |
| FF | Below 50 | 0 | | | |
| ZZ | Absent in Examination | | | | |

19) Equivalence of the conventional division/class with the CGPA in final semester is in accordance with the following Table-2, Grade Points for SGPA and CGPA of M.Pharm. shall be as per Table-3.

Table-2: Equivalence of class/Division to CGPA

| Sr. No. | CGPA | Class/Division |
|---------|---|------------------------------|
| 1. | 7.5 or more than 7.5 | First Class with Distinction |
| 2. | 6.00 or more but less than or equal to 7.49 | First Class |
| 3. | 5.50 or more but less than or equal to 5.99 | Higher Second Class |
| 4. | 5.00 or more but less than or equal to 5.49 | Second Class |

Table-3: Grade Points for SGPA and CGPA of M.Pharm.

| Grade Point | Final Grade |
|-----------------------|-------------|
| 9 - 10 | AA |
| 8 - 8.99 | AB |
| 7 - 7.99 | ВВ |
| 6 - 6.99 | ВС |
| 5.5 - 5.99 | CC |
| 5 - 5.49 | CD |
| 0 - 4.99 | FF |
| Absent in Examination | ZZ |

20) Based on the grade points obtained in each subject, Semester Grade Point Average (SGPA) and then Cumulative Grade Point Average (CGPA) are computed as follows.

Computation of SGPA and CGPA

Every student is awarded point out of maximum out of 10 point in each subject. (Based on 10 point scale). Based on the Grade point obtained in subject the Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) are computed. The computation of SGPA and CGPA is as under.

Semester Grade Point Average (SGPA) is the weightage average of point obtained by a student in a semester and computed as follows.

$$U1xM1 + U2xM2 + i \quad UnMn$$

$$SGPA = \hat{o} \quad \hat$$

Where U1, U2, i i i are subject credit of the respective course and M1, M2, i i .. are the grade point obtained in the respective subject (out of 10).

The Semester Grade Point Average (SGPA) for all the four semester is also mentioned at the end of every semester.

The Cumulative Grade Point Average (CGPA) is used to describe the overall performance of a student in the course and is computed as under. CGPA shall be calculated on final semester of the course (i.e from Semester I-IV).

$$CGPA = \frac{\sum_{n=1}^{n=4} SGPA(n)C(n)}{\sum_{n=1}^{n=4} C(n)}$$

Where SGPA (n) is the nth semester SGPA of the student and C_n is the nth semester total credit. The SGPA and CGPA are rounded off to the second place of decimal.

ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the college affiliated to Sant Gadge Baba Amravati University under CGPA shall be as per the dates given below, only the years shall be changed i.e. the dates shall remain same as given below irrespective of the year.

Beginning of First Term : As per University academic calendar

(Semester I, and III)

Vacation : As per University academic calendar Beginning of Second Term : As per University academic calendar

(Semester II, and IV)

SANT GADGE BABA AMRAVATI UNIVERSITY DIRECTION

NO. 5 / 2014 Dated: 03/03/2014

Subject: Corrigendum to Direction No.12/2013 in respect of Examinations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year - four Semester Degree Course) (Credit Grade Based System).

Whereas, Direction No.12 of 2013 in respect of Examinations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year - Four Semester Degree Course) (Credit Grade Based System), Direction, 2013 is in existence in the University.

AND

Whereas, the Academic Council in its meeting held on 17.2.2014 vide item No.22 4) A) R-3 II) accepted the recommendations of the Faculty of Medicine to be implemented from Academic Session 2013-14 & onwards and resolved to refer the matter to Ordinance Committee.

AND

Whereas, the above corrections are to be regulated by framing the Ordinance.

AND

Whereas, making of Ordinance is a time consuming process.

Now, therefore, I, Dr.J.A.Tidke, Vice-Chancellor, Sant Gadge Baba Amravati University, Amravati 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 õCorrigendum to Direction No.12/2013 in respect of Examinations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year Four Semester Degree Course) (Credit Grade Based System), Direction, 2014.ö.
- 2) This Direction shall come into force from the Academic Session 2013-14 & onwards for M.Pharm.

- 3) Following corrections shall be made in Direction No.12/2013 in respect of Examinations Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year Four Semester Degree Course) (Credit Grade Based System), Direction 2013:
 - i) In para 2. i), the words, õSemester-II & IVö be substituted by the words õSemester-I & IIö.
 - ii) In Semester-I & II of M.Pharm. Examination (All Specializations) under Annexures-I to VI, against the Title of Paper -Seminarø,
 - (a) the hours, credits $\div 04(04) \emptyset$ shown under Scheme of Teaching $\div L$ ecture (Credits) \emptyset be deleted and the hours, credits $\div 08(04)$ ° be inserted in the column of $\div P$ ractical (Credits) \emptyset
 - (b) the marks ÷50ø be added in the column of Scheme of Internal Examination-Practical.
 - (c) the marks -25ø be read in the column of Scheme of External Examination-Minimum Marks for Passing-Practical.
 - iii) In Semester-III of M.Pharm. Examination (All Specializations) under Annexures-I to VI, against the Title of Papers :Seminar on Research Envisaged for Dissertationø and :Seminar on Recent Trends in Pharmaceutical Sciencesø-
 - (a) the figure & word ÷04 Creditsøshown in the column of Scheme of Teaching-Lecture (Credits) be shifted in the column of Practical (Credits).
 - (b) the marks :40 & 60ø shown in the column of Scheme of Internal Examination-Theory be shifted in the column of Scheme of Internal Examination-Practical respectively.
 - (c) the marks ÷60 & 90ø shown in the column of Scheme of External Examination-Theory-Marks be shifted in the column of Scheme of External Examination-Practical-Marks respectively.
 - (d) the marks ÷50 & 75øshown in the column of Scheme of External Examination-Minimum Marks for Passing-Theory be shifted in the column of Scheme of External Examination-Minimum Marks for Passing-Practical respectively.

iv) The Scheme of Teaching, Credits & Examination prescribed for Semester-IV of M.Pharm. Examination (All Specializations) under Annexures-I to VI be substituted by the following scheme.

| Semester | Paper Code | Title of Paper | Scheme of Scheme of Teaching in Internal Hrs.pcr week and credit system | | mal | | | | | | | Total Marks | |
|-----------------|---------------|-----------------------------|---|-----------------|-----|-----|--------|-------|-----------|-----------|------------------------------|----------------|-----|
| | | | Lect. Credits | Pra. Credits | Th. | Pr. | Theory | | Practical | | Minimum marks for passing | | |
| | | | | | | | Hrs. | Marks | Hrs. | Mar ks | Theor y | Pract. | |
| Semester -IV | *- 401 | Dissertation & Viva-voce | | 10 Credits | | 100 | | | | 250 | | 175 | 350 |
| | *- 402 | Seminar (on dissertation) | | 02 Credits | | 40 | | | | 60 | | 50 | 100 |
| | | Total | | | | 140 | | | | 310 | | | |

^{* -} of respective specialization

Dated: 01/03/2014

Sd/(Dr.J.A.Tidke)
Vice-Chancellor,
Sant Gadge Baba Amravati University,
Amravati

SYLLABUS PRESCRIBED FOR MASTER OF PHARMACY IN Pharmacology

(Implemented from the Session 2010-11)

The several courses leading to the Master Degree of Pharmacy covers following subjects namely

- 1. Pharmaceutics
- Pharmacology
- 3. Pharmaceutical chemistry
- 4. Pharmacognosy
- 5. Quality assurance
- 6. Industrial Pharmacy
- 1. There are four semesters leading to Degree of Master in Pharmacy. The theory syllabus for first semester shall be compulsory to all above M. Pharm courses. Second semester syllabus covers in the field of above mention specialization.
- In third semester examination the research envisage for dissertation and one seminar on recent trends in Pharmaceutical science shall be assigned to him/her by the Guide within one month from the date of the commencement of the third semester.
- 3. In forth semester examination the dissertation work shall be perform by him/her and at the end student shall deliver the seminar on dissertation work and viva voce examination.

Seminar

Each candidate shall deliver 2 seminars per subject covering the current research interest as in journal in the field of pharmaceutical sciences. Evaluation of seminar shall be based on the communication, representation and skill in oral presentation

M.Pharm. Semester-I COMMON TO ALL M. PHARM COURSES Subject code: MC-101

Subject: RESEARCH METHODOLOGY & BIOSTATISTICS
THEORY 60 Hours (4 hrs./week)

SECTION-A

I. Research

1. Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research) objects of research

- 2. Literature survey:
 - Using library, book and journals, MEDLINE- internet getting patents and reprints of articles as sources for literature survey.
- 3. Selecting a problem and preparing a research proposal for different types of research sources of procurements of grants.
- 4. Documentation:
 - Importance of documentation in case of research record and GMP/GLC
 - Techniques of documentation in case of research record and GMP and GLC
 - Uses of computer packages in clinical trials
 - Documentation in clinical trails
- 5. Research report/paper writing/thesis writing / poster presentation: Different parts of research report or paper
 - Title-title of project with authors name
 - Abstract-statement of the problem, background list in brief, purpose and scope
 - Key words
 - Methodology-subject, apparatus/instrumentation and procedure
 - Results-tables, graphs, figures and statistical presentation
 - Discussion-support or non-support to hypothesis. Practical and theoretical implications
 - Acknowledgements
 - References
 - Errata
 - Importance of spell check
 - Use of foot notes

II. Methods and tools used in research:

- Research design (futures of good design, types of research designs, basic principles of experimental design).
- Qualitative studies, quantitative studies.
- Simple data organization, descriptive data organization.
- Limitations and sources of errors.
- Enquiries in forms of questionnaire, opinionnaire and interviews

III. Presentation:

- Importance, types, different skills
- Content of presentation format of model, introduction and endings.
- Posture, gesture, eye contact, facial expression, stage fright.
- Volume, pitch, speed, pauses and languages
- Visual aids and seating arrangements
- Question and answer session

SECTION-B

IV. Cost Analysis of Projects and Clinical Trials

V. Biostatistics

- Statistical analysis of data including variance, standard deviation, Parametric and Non-Parametric statistic test, corelation of data and its interpretation, computer data analysis, bio statistics for clinical trials.
- Scientific method in medicine
- Scientific equations of therapy

Reference Books

- (1) Research in education ó John W. Best Jems V. Kahn
- (2) Research methodology ó C. R. Kothari
- (3) Methodology and techniques of social research ó Willkinson and Bhandarkar
- (4) Presentation skills ó Michel Halton ó Indian society for institute education
- (5) Practical introduction to copyrights ó Gavin Mofariane
- (6) Thesis projects in sciences and engineering ó Richard M. Devis
- (7) Scientist in legal system ó Ann Labor Science
- (8) Thesis and assessment writing ó Janolthon Anderson
- (9) Writing a technical paper ó Donald Manzel
- (10) Effective business report writing ó Lel and Brown
- (11) Protection of industrial property rights ó Purshottam Das and Gokul Das
- (12) Spelling for millions ó Edna Furmess
- (13) Preparation for publications ó King Edwards hospital foundation for London
- (14) Information technology ó The hindu speeks
- (15) Documentation ó genesis and development ó 3792.
- (16) Ayurveda and modern medicine ó R. D. Lele
- (17) How to write and publish a scientific paper 6 Robert A. Day Cambridge University Press 4th edition 1994
- (18) Lecture notes on patent TIFAC: DOC: 022, TIFAC July 2002.
- (19) Introduction to Statistical Methods- C. B. Gupta
- (20) A first course in Mathematical Statistics- C. E. Weatherborn
- (21) Introduction to Biostatistics-Mahajan

COMMON TO ALL M. PHARM COURSES Subject code: MC-102

Subject: BIOTECHNOLOGY AND BIOINFORMATICS THEORY 60 Hours (4 hrs. /week)

SECTION-A

- 1. **Genetics:** Structure and function of DNA replication & repair, expression of genetic information, structure and function of RNA, transcription, genetic code, translation, post translational modification.
- 2. Recombinant DNA technology: Constructing recombinant DNA molecules, restriction enzymes, vectors, gene cloning, genomic libraries, polymerase chain reaction based DNA cloning, restriction mapping, blotting technique, DNA sequencing, pharmaceutical applications of recombinant DNA.
- **3. Gene therapy:** General introduction, potential target diseases for gene therapy, gene transfer methods, clinical studies, pharmaceutical production and regulation.
- **4. Immunology:** Basics of immunology, Monoclonal antibodies & Hybridoma technology and its applications
- Vaccines-conventional vaccines, modern vaccines technologies, genetically improved vaccines, genetically improved subunit vaccines, pharmaceutical considerations

SECTION-B

- 6. Quality control testing methods of Biotech products: Determining impurities/contamination (viral, bacterial endotoxins (in-vitro) rabbit Pyrogen, sterility, protein identification, finger prints by electrophoresis, isoelectric focusing immunogenicity, and partial sequential analysis.
- **7. Immobilization of enzyme:** different techniques, effect on production of enzymes, applications.
- **8. Plant Biotech products:** Substances produced by plant cell culture, Transgenic plants their application, Biotransformation with plant cell culture
- **9. Molecular biology of cancer:** Causes of cancer and genetics of cancer, New strategy for combating cancer
- **10. Introduction to Bioinformatics:** Biological databases, sequence analysis, protein structure, genetic and physical mapping, application of bioinformatics in pharmaceutical industries and in drug discovery.

Reference Books

- 1. Biotechnology-Applications and research-Paul N. Chermisinol (Technomic publishing co. Inc)
- 2. Molecular Biochemistry-Therapeutic applications and strategies (Salil D. Patel, John Wiley and sons).
- Nelson, D.L, and Coy M.M. Lehninger & Principles of Biochemistry & Worth publishers. New York
- 4. Gene therapy: principle and Application by Thomas Blankenste in Biöghausef Verlag Basel Boston . Berlin
- 5. *Immunogenicity of Biopharmaceuticals by* Marco van de Weert, Eva Horn Møller (Springer)
- 6. Recombinant DNA technology by Watson and Trooze
- 7. Molecular biology of cell by Watson
- 8. Molecular biology of cell by Albert B, Johnson A, Lewin J.
- 9. Fundamental of Immunology by Paul W.E
- 10. Molecular biotechnology By Glick B.R and Pasternak J.J (ASM press)
- 11. Molecular biology and biotechnology by Walker J.M
- 12. Essential of genetics by Klug W.S. Cummings M.R.
- 13. Bioinformatics by Baxevanis A.D, Frana, Duelette B.F.

COMMON TO ALL M. PHARM COURSES Subject code: MC-103

Subject: QUALITY CONTROL OF PHARMACEUTICAL PRODUCTS

THEORY

60 Hours (4 hrs. /week)

SECTION-A

- 1. Good manufacturing practices: GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. GMP for ayurvedic products, Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP)
- 2. **Validation:** Pharmaceutical process validation, equipment validation and sterile products validation.
- **3. Quality control of pharmaceutical dosage forms:** Solid and semisolid dosage forms, disperse systems and parenteral dosage forms.

SECTION-B

- 4. ICH Stability Guidelines, Schedule M and Schedule Y
- **5. Spectroscopic methods:** Theory and applications of UV, IR, FTIR, NMR, Mass Spectrometry, ESR and Emission spectroscopy, XRD

 Separation techniques: Introduction and applications of Gas-liquid chromatography, HPLC, Gel chromatography, gel electrophoresis, GC-MS, HPTLC, Ion Pair Chromatography.

7. Safety into the laboratory

Designing safety into the laboratory: Laboratory accident and First aid for chemical burns and accident, egress, hazard zoning, emergency facilities, Hazards: slippery spill of Hazardous substances and their handling.

Laboratory design-safety aspect: storage of laboratory chemicals, laboratory design;

Principle of chemical storage; inventory control; segregation.

Reference Books

- 1) Automation and Validation of information in Pharmaceutical Processing ó J. F. Despautz, Marcel and Dekker
- 2) Validation of aseptic pharmaceutical processing ó F. J. Carleton and J. P. Agalloco, Marcel and Dekker
- 3) Pharmaceutical process validation ó J. R. Berry and R. A. Nash, Marcel and Dekker
- Good Manufacturing Practices for pharmaceuticals ó S. H. Will and J. R. Stoker, Marcel and Dekker
- 5) Design of Experiments for process improvement and quality Assurance ó R. F. Brewer
- 6) Encyclopedia of pharmaceutical technology, Marcel and Dekker
- Achieving sterility in medical and pharmaceutical products 6 N.A.Halls, Marcel and Dekker
- 8) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- 9) Official and standardized methods of analysis by Colins Watson
- 10) Handbook of Quality Assuarance for the analytical chemistry Laboratory by Jam Dux
- 11) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) Satinder Ahuja , Neil Jespessen
- 12) Instrumental Methods of Analysisó Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
- 13) Pharmaceutical Analysis Modern Methods-Part A and Part B ó J. W. Munson, Marcel and Dekker
- 14) Indian Pharmacopoeia-2007
- 15) Martindale: The complete Drug Reference ó 2007

COMMON TO ALL M. PHARM COURSES

Subject code: MC -104 Subject: DRUG REGULATORY AFFAIRS

THEORY

60 Hours (4 hrs./week)

SECTION-A

- 1. Aims, objects and salient features of following legislations affecting pharmaceutical industry.
 - É Industrial Development and Regulation Act 1951.
 - É Consumer Protection Act.
- 2. Australian TGA guidelines
- 3. US-FDA, CDER guidelines
- 4. New Drug Application
- 5. Pollution and Environmental Control Act

SECTION-B

- 6. Drug Master File
- 7. Intellectual Property Rights:
 - Protection of patients and trademarks and design and copy rights and patent system in India.
 - Present status of IPR future changes expected in Indian patents.
 - What may be patented
 - Who may apply for patent
 - Preparation of patent proposal
 - Registration of patent in India and foreign countries and vice versa
 - ICH guidelines for clinical trials, therapeutic drugs monitoring drugs and bioequivalence.
 - Exclusive marketing rights
 - Black box
 - IPR and IDMA views on patents
 - 1 Human health and patent laws latent lethality
 - 1 Indian patent act and copyright (Indian act)
- **8.** Drug and Cosmetics Act 1940
- **9.** Prevention of Food Adulteration Act 1954 (5 hrs)
- **10.** Preparation of DMF, Site Master File, Master Formula Record. Procedure for filing of Patent.

Reference:

- (1) Guidelines of various countries like MCA, TGA, ICH.
- (2) Drug and cosmetic act 1940 and rules their under
- (3) IPR Lecture notes
- (4) GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
- (5) GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
- (6) I.P., B.P., U.S.P. International Pharmacopoeia
- (7) Pharmacokinetics, Regulatory, Industrial, academic prospective by P. G. Willing and F.T.S. Tse.

COMMON TO ALL M. PHARM COURSES

Subject code: MC -105

Subject: PRODUCT DEVELOPMENT AND FORMULATION

THEORY 60 Hours (4 hrs. /week)

SECTION-A

1. 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.

2. PREFORMULATION STUDIES

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

3. PHYSICAL PROPERTIES

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

4. 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.

SECTION-B

5. 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:

6. LIQUID ORALS:

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

7. TOPICALS:

Antibiotic ointment, analgesic gels.

8. TABLETS:

Common cold, multivitamin, chewable antacid, soluble aspirin and dispersible/kid tablets.

9. 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.

COMMON TO ALL M. PHARM COURSES

Subject code: MC-106

Subject: Laboratory course -1

Practical 8 hrs. /week (Minimum 20 practicals should be conducted)

1. Combination Drug Analysis (any two)

Vitamins, Sulphas, Analysis of Antipyretics and Analgesics, Steroidal anti-inflammatory drugs, Antihistamins.

2. Illustrations of theoretical principles using assay of drugs form in various pharmacopoeias (any five).

This should cover titrimetric, gravimetric, spectro-photometric (including flame photometric) methods. HPLC etc. The titrimetric methods should include agrentometric, conductometric, and potentiometric end point determination. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

Validation of equipments: Autoclave, hot air oven, membrane filter (Minimum two practical).

Validation of an analytical method: Calibration of instruments as per official procedure (UV, FTIR, Conductivity meter, flourimeter, Digital pH meter, Digital balance, Potentiometer, HPLC, Gas chromatography) (Minimum two practical).

3. Interpretation of UV, IR, NMR, C¹³ NMR spectra and Mass Spectroscopy of some chemicals and drugs. (Minimum three combined spectra).

Reference Books

- (1) Pharmaceutical Analysis ó Modern methods ó Part A and Part B ó J. W. Munson, Marcel ó Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations ó P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II ó A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis ó F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy ó C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound ó J. R. Dyer, Prentice Hall Englewood.

M. Pharm. (Pharmacology)

Semester – II

Subject code: MPL-201

Subject: ADVANCED PHARMACOLOGY AND TOXICOLOGY

THEORY : 60 Hours (4 hrs. /week)

SECTION- A

- 1. Cellular and molecular mechanism for drug dependence, tolerance and resistance (illustrate with suitable examples).
 - Microbial resistance to drug and their testing methods. Hypersensitivity, allergy, adverse drug reaction, anaphylaxis, idiosyncrasy and detection methods.
- 2. Concept of gene therapy and recent development in the treatment of varioushereditary diseases. Human genome mapping and its potential in drug research. Antisence genes as a research tool.
- **3.** Endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

SECTION-B

- **4.** Endogenous bioactive molecules as TNF Interleukins, Process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.
- 5. Introduction to molecular biology (Bioinformatics) / Computational Biology Basics of DNA, RNA and protein, Structure of cell, cell reproduction, concept ofgene, control of protein synthesis. Introduction to Southern Blots, Northern Blots, Western Blots, Cloning and Sub-cloning.

6. Toxicology:

Preparation of protocol for safety assessment

Biochemical basis of acute, sub-acute, chronic, ocular, dermal and skin sensitization testing.

Biochemical basis of toxicokinetics, mutagenesis, carcinogenesis, reproductive genocity and teratogenicity

Knowledge of documentation and protocol preparation, knowledge of planning, performing, analyzing, reporting and monitoring of above toxicity.

Reference Books

- (1) Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London
- (2) Guyton LC, Text Book pf Medical Physiology, Saunders Co., London
- (3) Best CH and Taylor NB, The Physiological Basis of Medical Practice, The Williams and Wilkins Co., Baltimore
- $(4) \quad Carig\ C.\ R.\ and\ Stizel\ B.\ E.\ Modern\ Pharmacology\ (Little\ Brown\ \&\ Co.$

- Boston)
- (5) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- (6) Scientific basis of drug dependence by Hannah steingerg
- (7) Hypersensitivity to drugs vol-I by Samter & C.W parker
- (8) Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (9) Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
- (10) Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K.
- (11) Mutagenicity testing and related analytical techniques by R. W. Frei & U.A.Th.Brinkman
- (12) Invitro toxicity testing by John M. Fraizer
- (13) OECD and EPA Guidelines
- (14) Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, Newyork Chicago
- (15) General and Applied toxicology by Bryan Ballantyne, T. mars & PTurner
- (16) Safety evaluation of drugs and chemicals by W. Eugene Llyod
- (17) Review articles from published journals.

Subject code: MPL-202

Subject: ADVANCED CLINICAL PHARMACOKINETICS

THEORY: 60 Hours (4 hrs./week)

SECTION- A

- 1. Introduction, concentration time profile, plotting the data, different fluid compartment and blood flow rate compartment models
- 2. Protein and tissue binding, factors effecting protein binding, kinetics of protein binding determination of rate constants and different plots (direct, scatchard and reciprocal); significance of volume of distribution, implications and invitro methodologies
- 3. Drug disposition, renal clearance, mechanism of clearance, clearance ratio, determination of clearance, hepatic clearance, biological half life, area under curve %drug metabolized, relationship between blood flow, intrinsic clearance, protein binding, different volume of distribution and its significance.

Compartment modeling and their limitation: one compartment open model and multiple compartment models kinetics of i.v infusion, bolus and multiple dose regimen (including the calculations and derivatization)

SECTION-B

Drug selection, dosage regimen design, dosage adjustment in elderly, children and obese patient. Evaluation of patient response,

mesurment of serum drug concentration, monitoring of dosage regimen.

- Nonlinear pharmacokinetics, direct, linear and orbit graph methods of dosing. Nonlinear pharmacokinetic due to drug protein binding
- Therapeutic drug monitoring: introduction, necessity of TDM, criteria for valid TDM, essential for effective TDM, organization of TDM service, Effectivness of TDM

REFERENCE BOOKS:

- Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
- Remington® Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
- Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
- Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
- Biopharmaceutics; By Swarbrick.
- Biopharmaceuties and Pharmacokinetics- A Treatise; By D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
- Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N. Tozer. Lea and Febiger, Philadelphia, 1995.
- Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.
- 10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
- 11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

Subject code: MPL-203

Subject: TOPICS IN PHARMACOLOGY

THEORY: 60 Hours (4 hrs./week)

SECTION-A

- 1. Immunotherapy: Immunostimulants, Immunodepressant, cytokines
- Autacoids and endocrine PharmacologyPharmacodynamic, pharmacokinetic, therapeutic of Histamine and bradykinin agonist and antagonist, drug acting through eicosanoids and platelet activating factors, thyroid and antithyroid agents, adenohypophysial hormones and related substance, insulin and oral hypoglycemic agents, endocrine pancreas, adrenocortical

hormones and their inhibitors of synthesis, agent affecting calcifications, estrogens and progesterone and their antagonist, androgens, oral contraceptive.

Pharmacology of Ca, Na, K, Cl channel modulators. 3.

SECTION-B

- Chemotherapy of parasitic and microbial infections: Biology of 4. tuberculosis, viral infection, malaria, amobiasis, leishmaniasis, filariasis, (Including target for drug development and mechanism of drug resistance).
- **Drug metabolism:** Biotransformation of drugs, enzyme responsible for biotransformations, microsomal and non-microsomal mechanism, factors influencing enzyme induction and inhibition. Model to study drug metabolism. Dose effect relationship.
- Clinical Trials: Clinical evaluation of new drug, phases of clinical trial, ethics and protocol. Preparation of clinical trial. New drug development process and drugs registration.

Reference Books

- Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London
- Guyton LC, Text Book pf Medical Physiology, Saunders Co., London (2)
- Best CH and Taylor NB, The Physiological Basis of Medical Practice, The Williams and Wilkins Co., Baltimore
- Vander A, Sherman JH and Luciano D. Human Physiology of The Mechanisms of Body Functions, Tata McGraw Hill Publishing Co., New Delhi.
- Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston) (6)
- Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
- Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (10) Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
- Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K. (11)
- (12) Scientific basis of drug dependence by Hannah steingerg
- (13) Discoveries in Pharmacology vol. I and II by Parnham & J. Bruibvels
- (14) Pharmacological methods, receptors & chemotherapy by Parnham & J.Bruibvels
- (15) Pharmacotherapy: A Pathophysiologic Approach- Joseph T. Dipiro et al, Appletone & Lange.

(16) Discoveries in Pharmacology vol. I and II by Parnham & J.Bruibvels

(17) Pathologic Basis of Disease-Robinson SL, WB Saunders Publications.

Subject code: MPL-204

 ${\bf Subject: BIOLOGICAL\,EVALUATION\,(PRICLINICAL\,}$

PHARMACOLOGY)

THEORY: 60 Hours (4 hrs. /week)

SECTION- A

1. Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA.

Proforma for performing experiments on animals. Alternatives to animal studies.

Correlation between various animal models and human situations

- 2. Organization of Preclinical screening programme (Blind screening)
- **3. Preclinical evaluation** of following categories of drugs.
 - Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, noortropics, antiparkinsonian agents, anticonvulsants, local anesthetics, CNS stimulations
 - 2. Analgesic, anti-inflammatory & antipyretic agents,
 - 3. Cardiac glycosides, antiarrhythmic, antithypertensives, antitatherosclerotics.
 - 4. Antiulcer agents, laxatives, bronchodilators, antitussives,
 - 5. Diuretics.
 - 6. Histamine antagonists. Immunomodulators,
 - 7. Hypoglycemics, Cholesterol lowering agents, antifertility agents, andrognes.
 - 8. Anti-thyroid agents, Dermatological agents, Antitumor agents.

SECTION-B

- Concept of transgenic animals, knockout animals, nude animals, receptor binding assays, principles of immunoassay, patch clamp techniques.
- **5. In vitro testing of drugs**. Animal cell lines and their uses. Limitation of in vitro testing of drugs.

Correlation between invitro- and in-vivo screening methods (emphasis based on cell base assay, biochemical assay, radioligand binding assay, High throughput screening etc.)

6. Toxicity testing of drugs/chemicals

Evaluation of acute, sub-acute, chronic, dermal, ocular and skin sensitization toxicity testing of drugs and chemicals.

Invitro toxicity testing and its applications to safety evaluation of drugs and chemical,

References recommended

- (1) Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York.
- (2) Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
- (3) Turner RA, Screening Methods in Pharmacology, Academic Press, London
- Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
- (5) Crossland J, Lewis@ Pharmacology, Churchill Livingstone, Edinburgh
- (6) Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- (7) Bacq ZM, Capek, Fundamentals of Biochemical Pharmacology
- (8) Laurence DR, Bennett PN, Borown MJ, Clinical Pharmacology, Churchill Livingstone, New York
- (9) Vogel HG, Drug Discovery and Evaluation, Springer, Germany
- (10) Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
- (11) Mutagenicity testing and related analytical techniques by R. W. Frei & U.A.Th.Brinkman
- (12) Quantittave methods in Pharmacology by H. De Jonge
- (13) Invitro toxicity testing by John M.Fraizer
- (14) OECD and EPA Guidelines
- (15) Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, Newyork Chicago
- (16) General and Applied toxicology by Bryan Ballantyne , T. mars & P Turner
- (17) Safety evaluation of drugs and chemicals by W.Eugene Llyod
- (18) Review articles from published journals.

Subject code: MPL-205

Subject: RECEPTOR IN PHARMACOLOGY

THEORY: 60 Hours (4 hrs. /week)

SECTION-A

- Molecular mechanism of drug action, Receptor binding and occupancy theory, rate theory, criteria for characterization of receptor, receptor structure, receptor transduction, receptor classification.
 Dose response relationship and different types of antagonisms Receptor down regulation and up regulation
- 2. Study of different classes and subclasses of receptor

Ion channels and their modulators

G-protein couple receptor-

Tyrosine kinase link receptor

Neurotransmitters receptors

Hormone receptors

Opiod receptor

Nicotinic receptor

Glutamate receptor

Orphan receptor

SECTION-B

- 3. Presynaptic receptor for catecholamines: Muscarinic receptor, GABA receptor, Dopaminergic receptor, adrenergic receptor, cholinergic receptor, Serotoninergic receptor
- **4. Second messenger receptors:** Phospholipase and phasphokinase, cyclic, Protein kinase. Signal transduction through protein tyrosine kinase, diacyl glycerol and Phosphotidyl inositol

Recommended references

- (1) Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York. (MacGraw Hill)
- (2) Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- (3) Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
- (4) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- (5) Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
- (6) Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (7) Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K.
- (8) Receptor óbased drug design by paul left
- (9) Drug receptor and their effectors edited by Nigel J.M.Birdsall
- (10) Text book of receptor pharmacology by John C.Foreman, Torben Johasen
- (11) Scientific basis of drug dependence by Hannah steingerg
- (12) Receptor binding in drug research by Robert A O Brien
- (13) Receptor binding techniques edited by Mary keen Humana press
- (14) Text book of receptor pharmacology edited by John Foreman and Torben Johansen
- (15) Drug receptor by H.P.Raug
- (16) Discoveries in Pharmacology vol.I and II by Parnham & J.Bruibvels
- (17) Pharmacological methods, receptors & chemotherapy by Parnham &

J.Bruibvels

(18) Review articles from published journals.

Subject code: MPL-206

Subject: Laboratory course-I

PRACTICLE (4 hrs. /week)(Minimum 20 practical should be conducted)

- 1. Calculations of pA2 and pD2 values using isolated tissue preparations: Suitable isolated animal tissue.
- 2. Bioassay of drugs: Acetylcholine, adrenaline, Histamine, Oxytocin
- 3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
- 4. Use of anesthetics and cannulation of veins, arteries and trachea.
- 5. Pharmacological screening for drug acting on GIT
- 6. Pharmacological screening of drugs for bactericidal, wormicidal, fungicidal and etc.
- 7. Pharmacological screening of drug acting on kidney for diuretic activity
- 8. Neuropharmacological screening test: CNS stimulant and CNS depressants, Anticonvulsants, Anticonvulsants, Antipsychotics, Anxiolytics.
- 9. LD50 determination as per OECD guideline
- 10. Evaluation for Pyrogen testing in Pharmaceutical product

Reference Books:

- 1. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
- 2. Ghosh MN, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta
- 3. Kulkarni SK, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi
- 4. Seth UK, Dadkar NK, and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay
- Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
- Turner RA, Screening Methods in Pharmacology, Academic Press, London
- 7. Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
- 8. Vogel HG, Drug Discovery and Evaluation, Springer, Germanyeview articles from published journals.
