M.Pharm.Semester-I to IV (Quality Assurance)

Prospectus No. 20161431

संत गाडगे बाबा अमरावती विद्यापीठ

SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा

(FACULTY OF MEDICINE)

अभ्यासक्रमिका

औषधिनिर्माण पदव्युत्तर परीक्षा

सत्र-१ व ३, हिवाळी-२०१५ व सत्र-२ व ४, उन्हाळी -२०१६

PROSPECTUS

OF

MASTER OF PHARMACY (QUALITY ASSURANCE) EXAMINATIONS

SEMESTER-I & III, WINTER-2015

SEMESTER-II & IV, SUMMER-2016

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M.Pharm. (Quality Assurance)
Semester-I & IV
(Prospectus No.20161431)

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. 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 BABA AMRAVATI 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 ñExaminations Leading to the Degree of **भेषजी पारंगत** (Master of Pharmacy) (Two year - four Semester Degree Course) (Credit Grade Based System), Direction, 2013ò.
2. 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.
3. In this Direction unless the context otherwise requires the expression ñDepartmentò shall mean the Department of Pharmaceutical Sciences and ñCollegeò shall mean affiliated college approved for conducting M.Pharm. course.
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.ò

   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.

9. 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 ñProject and the Seminarsò 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 ñProject report and seminar,ò 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 ñAn 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.18ò 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.
   ii) 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)

Semester	Paper code	Title of paper	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	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 shall be based on the communication, representation and skill in oral presentation										
Semester-II	MPH-201	Novel Drug Delivery Systems	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPH-202	Biopharmaceutics & Pharmacokinetics	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPH-203	Industrial Pharmacy	04(04)	--	30	--	03	70	--	--	50	--	100
	MPH-204	Advanced Pharmaceutics & Cosmetology	04 (04)	--	30	--	03	70	--		50	--	100
	MPH-205	Selected Topics in Pharmaceutics	04(04)	--	30	--	03	70	--		50	--	100
	MPH-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MPH-207	Seminar (2 per each subject)*	04 (04)								25		50
			*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-III	MPH-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MPH-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
		Total			**100**			**150**					
Semester-IV	MPH-401	Dissertation	10 Credits		100	--		150	--		125		250
	MPH-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MPH-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													2000

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	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	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 shall be based on the communication, representation and skill in oral presentation										
Semester-II	MPL-201	Advanced Pharmacology and toxicology	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPL-202	Advanced Clinical Pharmacokinetics	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPL-203	Topics in Pharmacology	04(04)	--	30	--	03	70	--	--	50	--	100
	MPL-204	Biological evaluation Techniques	04 (04)	--	30	--	03	70	--		50	--	100
	MPL-205	Receptor in Pharmacology	04(04)	--	30	--	03	70	--		50	--	100
	MPL-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MPL-207	Seminar (2 per each subject)*	04 (04)								25		50
			*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-III	MPL-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MPL-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
		Total			**100**			**150**					
Semester-IV	MPL-401	Dissertation	10 Credits		100	--		150	--		125		250
	MPL-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MPL-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													2000

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 code	Title of paper	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	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 shall be based on the communication, representation and skill in oral presentation										
Semester-II	MPC-201	Advanced Organic chemistry	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPC-202	Advanced Medicinal chemistry	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPC-203	Modern Analytical Techniques	04(04)	--	30	--	03	70	--	--	50	--	100
	MPC-204	Rational Drug Design	04 (04)	--	30	--	03	70	--		50	--	100
	MPC-205	Chemistry of Natural Product	04(04)	--	30	--	03	70	--		50	--	100
	MPC-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MPC-207	Seminar (2 per each subject)*	04 (04)								25		50
		Total	*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-III	MPC-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MPC-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
					100			**150**					
Semester-IV	MPC-401	Dissertation	10 Credits		100	--		150	--		125		250
	MPC-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MPC-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													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 code	Title of paper	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	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 shall be based on the communication, representation and skill in oral presentation											
Semester-II	MPG-201	Phytotherapeutic Materials	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPG-202	Herbal Drug Technology	04 (04)	--	30	--	03	70	--	--	50	--	100
	MPG-203	Cultivation of Medicinal Plants	04(04)	--	30	--	03	70	--	--	50	--	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	--	03	70	--		50	--	100
	MPG-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MPG-207	Seminar (2 per each subject)*	04 (04)								25		50
		*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation											
Semester-III	MPG-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MPG-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
		Total			**100**			**150**					
Semester-IV	MPG-401	Dissertation	10 Credits		100	--		150	--		125		250
	MPG-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MPG-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													2000

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	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	100
	MC -106	Laboratory course -I	--	08 (04)		40			12	60	--	50	100
	MC -107	Seminar (2 per each subject)*	04 (04)								25		50
			*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-II	MIP-201	Advanced Industrial Pharmacy-I	04 (04)	--	30	--	03	70	--	--	50	--	100
	MIP-202	Advanced Industrial Pharmacy-II	04 (04)	--	30	--	03	70	--	--	50	--	100
	MIP-203	Pharmaceutical Process Validations and Product Management	04(04)	--	30	--	03	70	--	--	50	--	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)	--	30	--	03	70	--		50	--	100
	MIP-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MIP-207	Seminar (2 per each subject)*	04 (04)								25		50
			*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-III	MIP-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MIP-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
		Total			**100**			**150**					
Semester-IV	MIP-401	Dissertation	10 Credits		100	--		150	--		125		250
	MIP-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MIP-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													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	Scheme of Teaching in Hrs. per Week and Credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lecture (Credits)	Practical (Credits)	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
							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)	--	30	--	03	70	--	--	50	--	100
	MC -103	Quality Control of Pharmaceutical Products	04(04)	--	30	--	03	70	--	--	50	--	100
	MC -104	Drug Regulatory Affairs	04 (04)	--	30	--	03	70	--		50	--	100
	MC-105	Product Development and Formulation	04(04)	--	30	--	03	70	--		50	--	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 shall be based on the communication, representation and skill in oral presentation										
Semester-II	MQA-201	Quality Assurance Technique	04 (04)	--	30	--	03	70	--	--	50	--	100
	MQA-202	Biological evaluation and standardization	04 (04)	--	30	--	03	70	--	--	50	--	100
	MQA-203	Advanced Analytical Technique	04(04)	--	30	--	03	70	--	--	50	--	100
	MQA-204	Packaging technology	04 (04)	--	30	--	03	70	--		50	--	100
	MQA-205	Selected topics in Quality assurance	04(04)	--	30	--	03	70	--		50	--	100
	MQA-206	Laboratory Course -2	--	08 (04)		40			12	60	--	50	100
	MQA-207	Seminar (2 per each subject)*	04 (04)								25		50
			*Evaluation of seminar shall be based on the communication, representation and skill in oral presentation										
Semester-III	MQA-301	Seminar on Research envisaged for dissertation	04 Credits		40	--		60	--		50		100
	MQA-302	Seminar on recent trends in Pharmaceutical sciences	04 Credits		60	--		90	--		75		150
		Total			**100**			**150**					
Semester-IV	MQA-401	Dissertation	10 Credits		100	--		150	--		125		250
	MQA-402	Seminar (on dissertation)	02 Credits		40	--		60	--		50		100
	MQA-403	Viva-voce			--			100	--		50		100
		Total			**140**			**310**					
GRAND TOTAL													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

Contents	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

Contents	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**

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

SEMESTER - IV

A. Dissertation Work

Contents	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

Contents	Marks
1. Representation	50
2. Skill in oral presentation	50
Total	**100**

C. Viva-Voce

Contents	Marks
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) Masterôs 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.
6) Two credit courses of practicals will consist of 4 hours of laboratory exercise for 12 weeks.
7) 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 = 08 credit
   Total = 56 credits

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

    Third Semester ï 1) Seminar on Research Envisaged for Dissertation 08 Credits
    2) Seminar on Recent Trends in Pharmaceutical Sciences

    Fourth Semester - 1) Dissertation 12 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	BB
6 - 6.99	BC
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.

$$SGPA = \frac{U1xM1 + U2xM2 + \acute{e}\ UnMn}{U1+U2+\acute{e}\ \acute{e}\ Un}$$

Where U1, U2,é é é é are subject credit of the respective course and M1, M2,é é .. 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 (Semester I, and III)	:	As per University academic calendar
Vacation	:	As per University academic calendar
Beginning of Second Term (Semester II, and IV)	:	As per University academic calendar

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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 ñCorrigendum 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.ò.

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, ñSemester-II & IVò be substituted by the words ñSemester-I & IIò.

ii) In Semester-I & II of M.Pharm. Examination (All Specializations) under Annexures-I to VI, against the Title of Paper óSeminarô,

(a) the hours, credits ó04(04)ô shown under Scheme of Teaching óLecture (Credits)ô be deleted and the hours, credits **'08(04)'** be inserted in the column of óPractical (Credits)ô.

(b) the marks ó50ô be added in the column of Scheme of Internal Examination-Practical.

(c) the marks ó25ô 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 óSeminar on Research Envisaged for Dissertationô and óSeminar on Recent Trends in Pharmaceutical Sciencesô -

(a) the figure & word ó04 Creditsô shown in the column of Scheme of Teaching-Lecture (Credits) be shifted in the column of Practical (Credits).

(b) the marks ó40 & 60ô 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 ó60 & 90ô 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 ó50 & 75ô shown 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 Teaching in Hrs.per week and credit system		Scheme of Internal Examination		Scheme of External Examination						Total Marks
			Lect. Credits	Pra. Credits	Th.	Pr.	Theory		Practical		Minimum marks for passing		
							Hrs.	Marks	Hrs.	Marks	Theory	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

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SYLLABUS PRESCRIBED FOR MASTER OF PHARMACY IN
Quality Assurance
(Implemented from the Session 2010-11)

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

1. Pharmaceutics
2. 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.
2. 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 ï John W. Best Jems V. Kahn
(2) Research methodology ï C. R. Kothari
(3) Methodology and techniques of social research ï Willkinson and Bhandarkar
(4) Presentation skills ï Michel Halton ï Indian society for institute education
(5) Practical introduction to copyrights ï Gavin Mofariane
(6) Thesis projects in sciences and engineering ï Richard M. Devis
(7) Scientist in legal system ï Ann Labor Science
(8) Thesis and assessment writing ï Janolthon Anderson
(9) Writing a technical paper ï Donald Manzel
(10) Effective business report writing ï Lel and Brown
(11) Protection of industrial property rights ï Purshottam Das and Gokul Das
(12) Spelling for millions ï Edna Furmess
(13) Preparation for publications ï King Edwards hospital foundation for London
(14) Information technology ï The hindu speeks
(15) Documentation ï genesis and development ï 3792.
(16) Ayurveda and modern medicine ï R. D. Lele
(17) How to write and publish a scientific paper ï 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
5. **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).
3. Nelson, D.L, and Coy M.M. Lehningerôs Principles of Biochemistryô Worth publishers, NewYork
4. Gene therapy: principle and Application by Thomas Blankenste in Biòðhausef 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 semi-solid 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

6. **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 ï J. F. Despautz, Marcel and Dekker
2) Validation of aseptic pharmaceutical processing ï F. J. Carleton and J. P. Agalloco, Marcel and Dekker
3) Pharmaceutical process validation ï J. R. Berry and R. A. Nash, Marcel and Dekker
4) Good Manufacturing Practices for pharmaceuticals ï S. H. Will and J. R. Stoker, Marcel and Dekker
5) Design of Experiments for process improvement and quality Assurance ï R. F. Brewer
6) Encyclopedia of pharmaceutical technology, Marcel and Dekker
7) Achieving sterility in medical and pharmaceutical products ï 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 Analysisï Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
13) Pharmaceutical Analysis Modern Methods-Part A and Part B ï J. W. Munson, Marcel and Dekker
14) Indian Pharmacopoeia-2007
15) Martindale: The complete Drug Reference ï 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.
   · Industrial Development and Regulation Act 1951.
   · 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
   - Human health and patent laws latent lethality
   - 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, C^{13} NMR spectra and Mass Spectroscopy of some chemicals and drugs. (Minimum three combined spectra).

Reference Books

(1) Pharmaceutical Analysis ï Modern methods ï Part A and Part B ï J. W. Munson, Marcel ï Dekker

(2) Quantitative Analysis of Drugs in Pharmaceutical formulations ï P. D. Sethi, VBS Publishers, Delhi

(3) Pharmacopoeia of India.

(4) Practical Pharmaceutical Chemistry, Part I and Part II ï A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi

(5) Colorimetric Methods of Analysis ï F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.

(6) Chemical Applications of Infrared spectroscopy ï C. N. R. Rao, Academic Press N. Y.

(7) Applications of Absorption Spectroscopy of Organic Compound ï J. R. Dyer, Prentice Hall Englewood.

M. Pharm. (Quality Assurance)

Semester – II

Subject code: MQA -201

Subject : QUALITY ASSURANCE TECHNIQUES

THEORY : 60 Hours (4 hrs. /week)

SECTION- A

1. Concept of total quality management [TQM], Different quality management systems, ISO 9001: 2000, ISO 14000: their philosophy, awards and accredation. Quality Audit of process, systems, facility and vendor.
2. Documentation requirements in pharmaceutical industry for GMP compliance. Product developments in stage documentation, Site master file, manufacturing documents such as master formula record, Batch records, retention samples and records, Quality control documentation, batch release documents, distribution and recall records, complaints files and log books.
3. Steps involved in Pharmaceutical Manufacturing Documentation, preparation, issue and use of documents, storage, retrieval and disposal of documents.

SECTION- B

4. Regulatory basis for process validation, validation of medical devices, solid dosage form, biotechnology processes, transdermal system, lyophilization, inhalation aerosol, pharmaceutical ingredients, water and air handling system, integrated packaging and sterilization. Validation of aseptic process, raw material and cleaning processes. Validation in contract manufacturing.
5. Statistical methods for uniformity and dissolution testing change control, SUPAC and PAT.
6. Method development protocols with special reference to U.V., HPLC, and FTIR.

Books and References Recommended

1. Wiling S.H., Tuckerman M.M and Hitchings W.S.; ñGood manufacturing practices for pharmaceuticalsò Drugs and Pharm.Sci. Series, Marcel Dekker Inc., N.Y.
2. Lofts, B.T. and Nash, R.A.; ñPharmaceutical process validationò, Drug and pharm.Sci. Series, Marcel Dekker.
3. Swarbrick and Boylan; Encyclopedia of pharmaceutical technology, Marcel Dekker Inc., N.Y.
4. Carlton, F.J. and Agalloco J.P.; validation of aseptic pharmaceutical processes, Marcel Dekker Inc., N.Y.
5. Despautz,J.F; ñautomation and validation of information in pharmaceutical processing, Marcel Dekker Inc., N.Y.

6. Rothary B.; ISO 14000 and ISO 9000; gower.
7. Barry D.A.; Statistical design and analysis in pharmaceutical sciences,; Marcel Dekker Inc. N.Y.
8. Bergman, S.W. and Gittins J.C.; Statistical methos for pharmaceutical research and planning, Marcel Dekker Inc, N.Y.
9. Willard, ñInstrumental method of analysisò.
10. http://www.who.int/en
11. www.fda.gov.

Subject code: MQA -202

Subject : Drug Evaluation and Standardization

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. **Preclinical evaluation** of following categories of drugs.
   1. Neuropharmacological screening: Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, noortropics, antiparkinsonian agents, anticonvulsants, local anesthetics, CNS stimulations
   2. Analgesic, anti-inflammatory, antipyretic agents, antithypertensives, Antiulcer agents, Diuretics, Immunomodulators, Hypoglycemics, Cholesterol lowering agents, antifertility agents, Dermatological agents, Antitumor agents.
   3. **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.

SECTION- B

4. General method for microbial counts and bioburden determination.
5. Microbiological assays of antibiotics and vitamins.

6. Clinical trials for drugs and dosage forms.
7. Standardization of cosmetic products and Herbal formulations.
8. Thermal analysis of drug and excipients.

Book and References Recommended

1. Turner R.A., Screening methods in pharmacology.
2. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
3. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
4. Mutagenicity testing and related analytical techniques by R. W. Frei & U.A.Th.Brinkman
5. Quantittave methods in Pharmacology by H. De Jonge
6. Invitro toxicity testing by John M.Fraizer
7. OECD and EPA Guidelines
8. Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical,Newyork Chicago
9. General and Applied toxicology by Bryan Ballantyne , T. mars & PTurner
10. Safety evaluation of drugs and chemicals by W.Eugene Llyod
11. Ayurvedic formulary of India , Govt of India , 1962.
12. Indian herble pharmacopoeias, Vol-1998.
13. British herbal pharmacopoeias , 1996.
14. WHO publications.
15. Pharmacopoeias of various countries.

Subject code: MQA -203

Subject : ADVANCED ANALYTICAL TECHNIQUES

THEORY : 60 Hours (4 hrs. /week)

SECTION- A

1 **Spectroscopic methods:** Theory, Instrumentation, chemical applications and structural elucidation by UV, IR, FTIR, NMR, C^{13} NMR, Mass Spectrometry, ESR and Emission spectroscopy.

2 **Separation Techniques:** Fundamental principles, theory, instrumentation and applications of Gas-liquid chromatography, HPLC, Gel chromatography, GC-MS, HPTLC, normal and reverse phase chromatography, and Ion Pair Chromatography. **Counter-**current chromatography, droplet counter-current chromatography, solvent system, ion exchange affinity, size exclusion, cation/anion exchange, gel electrophoresis for protein and DNA

SECTION- B

3. **Thermal Analysis:** Theory, Instrumentation and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).

4. **Immunochemical Techniques:** Immunoelectrophoresis, Immunoprecipitation, ELISA, Radioimmunoassay.

References:

1) Theory and applications of ultraviolet spectroscopy ï M. Orchin and H. H. Jaffe, John Wiley and Sons, N. Y.
2) Spectrometric identification of organic compounds ï Silverstein, Basseler, Morril, John Wiley and Sons, N. Y.
3) Instrumental Methods of Analysisï Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
4) Applications of Absorption Spectroscopy of Organic Compounds ï J. R. Dyer, Prentice Hall, London
5) Chemical Applications of Infra-red spectroscopy ï C. N. R. Rao., Academic Press, N. Y.
6) Quality assurance of drugs in Pharmaceutical chromatography by P.D.Sethi.
7) Introduction to High Performance Liquid Chromatography ï R. J. Hamilton, Chapman and Hall, London
8) Pharmaceutical Analysis Modern Methods-Part A and Part B ï J. W. Munson, Marcel and Dekker
9) Indian Pharmacopoeia-2007
10) Martindale: The complete Drug Reference ï 2007
11) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
12) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja , Neil Jespessen
13) An introduction to thermogravimetry by keattch/Dollimore
14) Jenkins Quantitative Pharmaceutical chemistry,adelbert M.Khevel,Frans Diagangi
15) Thermal analysis: theory and application by R.T.Sane, Jagdish K. Gadge
16) Practical HPLC Method Development, 2nd Edition- Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch

Subject code: MQA -204

Subject : Packaging Technology

THEORY : 60 Hours (4 hrs. /week)

SECTION- A

1. Concept in Pharmaceutical packaging
2. The packaging function
3. Regulatory aspects of pharmaceutical packaging system

4. Package design research
5. Packaging materials with special reference of glass, plastics, metals and polymers.
6. Control of packaging materials.
7. Ancillary materials used in packaging
8. Types and testing of containers and closures, Pharmacopoeial tests and specifications closure system.

SECTION- B

9. Types of packaging with special reference to blister, strip, sachet, child resistant and tamper evident packaging.
10. Packaging of parentral, ophthalmic and aerosols.
11. Stability of packages and packaging materials
12. Sterilization of packaging materials
13. Printing and decoration of labels and packages
14. Package testing
15. Defects in packaging.

Books Recommended

1. Swarbric, J and Bolyln, J. C., Encyclopedia of Pharmaceutical Technology Vol. 1-3, Marcel Dekker, Inc., New York.
2. Dean, D. A. Evans, E. R. and Hall, j. H. ñPharmaceutical Packaging Technologyò,Taylor and Francis, London.
3. Banker, G. S. and Rodes, C. ñModern Pharmaceuticsò, Marcel Dekker, Inc. N. Y.
4. Aulton, M.E., Pharmaceutics ï The Science of dosage form design, Churchill Livgstone, U.K.
5. Lachman, L. Lieberman, H.A. and Kanig, J. L. Varghese Publishing House, Bombay
6. Gennaro, A. R. ñRemington ï The science and practice of Pharmacyò Lippincott Williams and Wilkins, Philadelphia

Subject code: MQA -205

Subject : Selected topics in Quality Assurance

THEORY : 60 Hours (4 hrs. /week)

SECTION- A

1. Fundamental of cosmetic product development

   Regulatory requirements for cosmetic products, consumer safety consideration with microbiological preservation of cosmetic, intellectual property issue: patents of trade secrets.

2. Quality management of cosmetics
   1. Preparation of facial cream-vanishing cream,cold and moisturizing cream,face powder
   2. Preparation for oral hygiene-Dentrifices,mouthwashes
   3. Preparation for hair-shampoos, Hair des and conditioners
   4. Body cosmetics- Antiperspirant and deodrant,talcum powder

3. Immunoassay

   Application of Immunoassays in Research Quality control, Pollution enzyme electrode, immunosensor

4. Design and Application of Prodrugs

   Prodrug Concept, Prodrugs of various functional groups like carbonyl, hydroxyl, amide, amines. Application of prodrug approach to: i) Improvement of bioavailability ii) Prevent first pass metabolism iii) Reduction of side effects iv) Prolong duration of action v) Site specific delivery.

SECTION- B

5. General principle of Toxicology

   Toxicological testing methods, special toxicity test like teratogenicity. Toxicity testing in cosmetics

6. **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.

7. Polymer science

   Introduction, Polymer-classification, Applications of Polymers in formulation of controlled drug delivery systems, Biodegradable and Nonbiodegradable polymers, Properties of following commonly used polymers- Starch, Gelatin, Chitosan, Albumin, Cellulose derivatives and Poloxamers.

8. Novel drug delivery system

   Introduction and design: Sustained and control release drug delivery system, transdermally, mucoadhesive, ocular, intrauterine, peptide and targeted drug delivery system.

Reference Books

1. Drug and cosmetic Act 1945 Rules (Govt. of India)
2. Remingtonôs Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
3. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
6. Butterworther: Progress in Medicinal Chemistry Series

7. Novel drug delivery system; By Y.M.Chien, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Libermann et.al, Marcel Dekker, Inc.
9. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
10. Preparation and evaluation by P.P. Sharma
11. Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, Newyork Chicago
12. General and Applied toxicology by Bryan Ballantyne , T. mars & P Turner
13. Safety evaluation of drugs and chemicals by W. Eugene Llyod

Subject code: MQA -206

Subject : Laboratory course II

PRACTICLES : 60 Hours (4 hrs. /week)

1. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
2. LD50 determination as per OECD guideline
3. Evaluation for Pyrogen testing in Pharmaceutical product
4. Development, evaluation and Standardization of dosage forms, including solids, semisolid, liquid and sterile dosage form.
5. Experiments on chromatography: TLC and paper Chromatography
6. Determination of water in sorbitol, sodium citrate and Ampicillin
7. Assay of some official formulations by official methods (minimum one for each analytical methods)
8. Testing container, closure, liners, glass, plastics, used for packaging
9. Test for packaging material, cartons, aluminum foils, strip packing, blister packing, ampoules, vials etc.

Reference Books

1. Turner RA, Screening Methods in Pharmacology, Academic Press, London
2. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
3. Pharmaceutical Analysis ï Modern methods ï Part A and Part B ï J. W. Munson, Marcel ï Dekker
4. IP, BP, USP
5. Quantitative Analysis of Drugs in Pharmaceutical formulations ï P. D. Sethi, VBS Publishers, Delhi
6. Practical Pharmaceutical Chemistry, Part I and Part II ï A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
7. All books mentioned as reference books for theory should be used.

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