SYLLABUS

Saurashtra University

DDU Kaushal Kendra

Curriculum for

MASTER of VOCATION

in

PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

(Under UGC – DDU Kaushal Kendra sanctioned to Shree Manibhai Virani & Smt. Navalben Virani Science College-Rajkot)

(Sanction Letter No. 3-43/2015(KAUSHAL) dated 14.08.2015)

M.Voc. Semester I & II

Credit Based Semester System (CBSS)

Effective from June 2015-16

Master of Vocation – Pharmaceutical Analysis & Quality Assurance

(2 years – Four Semester Full Time Course)

DEEN DAYAL UPADHYAY KAUSHAL KENDRAs

(XII plan guidelines for Deen Dayal Upadhyay Centres for knowledge acquisition and up gradation of skilled human abilities and livelihood (KAUSHAL) in universities and colleges - 2014 - 2017)

Introduction:

Education plays an important role in the overall development of a human being as well as the nation. It is a unique investment in the present and for the future. Every country develops its own system of education to express and promote its unique socio-cultural identity besides meeting the challenges of time to leverage the existing potential opportunities. India, at present, is recognized as one of the youngest nations of the world with over 50% of population under the age of 30 years. It is estimated that by 2025, India will have 25% of the world's total workforce. In order to harness the full demographic dividend, India needs high quality educational system which is affordable, flexible and relevant to the individuals, as well as to needs of the society as a whole. Today, the country faces a demand – supply mismatch as the economy needs more 'skilled' workforce as also the managers and entrepreneurs than produced annually. In fact, majority of the contemporary institutions of higher learning remain almost disconnected with the requirements of the workplace. The higher education system has to incorporate the requirements of various industries in its curriculum, in an innovative and flexible manner while producing well groomed graduates. UGC introduced two schemes known as – Community Colleges and B.Voc. Degree Program in universities and colleges during the XII Plan. However, there is a need for taking integrated initiatives towards knowledge acquisition and up-gradation of skilled human competencies in universities and colleges to address the emerging needs of the economy so as to ensure that the graduates have adequate knowledge and skills to get appropriately employed or become entrepreneurs and, thereby, meet the economic and industrial needs at the regional and national level. Government of India, taking note of the requirement for skill development among students developed National Vocational Education Qualification Framework (NVEQF) which was later on assimilated into National Skills Qualifications Framework (NSQF). Various Sector Skill Councils (SSCs) are developing Qualification Packs (QPs), National Occupational Standards (NOSs) and assessment mechanisms in their respective domains, in alignment with the needs of the industry.

In view of this, the UGC implemented the scheme of Community Colleges from 2013-14 in pilot mode on the initiative of the MHRD. However, realizing the importance and the necessity for developing skills among students, and creating work ready manpower on large scale, the Commission decided to implement the scheme of Community Colleges as one of its independent schemes from the year 2014-15. The Commission also launched another

scheme of B.Voc. Degree program to expand the scope of vocational education and also to provide vertical mobility to the students admitted into Community Colleges for Diploma programs to a degree program in the Universities and Colleges. While these two schemes are being implemented, it is also realized that there is a need to give further push to vocational education on a even larger scale. It is therefore proposed to establish as many as 100 'Deen Dayal Upadhyay Centres for Knowledge Acquisition and Up gradation of Skilled Human Abilities and Livelihood (KAUSHAL)' during the XII Plan period. These Centers would take-up the vocational education to new levels and offer courses beyond B.Voc. degree also. These Centres would also embed and follow the guiding principles of NSQF, QPs, and NOSs for their programs and would not focus on skilling alone but also develop entrepreneurship traits. The Centres may endeavor to maintain a pyramidical structure of student enrolment with respect to Diploma, Advanced Diploma, B.Voc. and further studies.

Objectives of the Scheme:

The main objectives of these centres are to:

a) create skilled manpower for industry requirements at various levels. The scheme provides for vertical mobility from short term certificate courses to full-fledged post graduate degree program, and further research in specialized areas. The courses would be planned/ designed to have provision of multiple entry and exit at various levels culminating up-to a research degree level. These shall also include courses which are offered under the Community College Scheme and B.Voc. degree program of UGC.

b) Formulate courses at postgraduate level keeping in mind the need of i) Industry in specialized areas; ii) Instructional design, curriculum design and contents in the areas of Skills Development; iii) Pedagogy, assessment for skills development education and training; iv) trained faculty in the areas of skill development; and v) Entrepreneurship; etc.

c) work for coordination between the higher education system and industry to become a Centre of Excellence for skill development in specialized areas.

d) network with other such centers and universities and colleges imparting vocational education under the scheme of Community Colleges and B.Voc degree program in their region and coordinate with them for targeted development of skill oriented education.

e) undertake R&D in the areas related to skill education & development, entrepreneurship, employability, labour market trends etc. at the post-graduate and research level.

f) act as finishing school by providing supplementary modular training programs so that a learner, irrespective of his/her training background, is made job ready with necessary work skills (soft, communication, ICT skills etc) and fill the gaps in the domain skills measured against QPs/NOSs.

g) provide for Recognition of Prior Learning (RPL) framework for job roles at NSQF Level 4 onwards by conducting assessment and certification with respective Sector Skill Councils (SSCs) / Directorate General of Employment and Training (DGET).

h) Maintain 'Labour Market Information' for respective regions in coordination with other government agencies and industry associations.

i) develop and aggregate curriculum, content and learning materials for skills development in different sectors.

Basic Principles for Curriculum Design:

While formulating the curriculum under the scheme, the Centers may:

a) follow credit based semester system;

b) provide for provision for credit transfer across courses;

c) ensure alignment of skill component with the QPs/NOSs of the relevant job roles based on the exit profiles of the students. The focus of skill development components should be to equip students with appropriate knowledge, practice and attitude, so as to make them work ready. The skill development components should be relevant to the industries as per their requirements;

d) provide credits for practical work, apprenticeship, on the job training, and project work;

e) provide multiple exit and entry points with provision for vertical and horizontal mobility;

f) assess and certify the skill competence for the selected job roles through the respective SSCs / DGET;

g) provide credits for general education component and skill component broadly in the ratio of 40 : 60. The general education will also include credits in communication skills, ICT skills, soft skills, critical thinking, problem solving, environmental studies and value education.

h) review the courses periodically in accordance with the changing requirements of the industry and regional / national economic priorities.

i) follow UGC guidelines for skill development courses at different levels specified under Community Colleges, B.Voc. degree program and as may be prescribed from time to time.

Programs and Curricula: (UGC guidelines for curricular aspects, assessment criteria and credit system in skill based vocational courses under national skills qualification framework (NSQF))

In order to make education relevant and to create 'industry fit' skilled workforce, the institutions recognized under Community Colleges / B.Voc Degree program, and Deen Dayal

Upadhyay KAUSHAL Kendras offering skill based courses will have to be in constant dialogue with the industry and respective Sector Skill Council(s) so that they remain updated on the requirements of the workforce for the local economy. There will be credit-based modular programs, wherein banking of credits for skill and general education components shall be permitted so as to enable multiple exit and entry. This would enable the learner to seek employment after any level of Award and join back as and when feasible to upgrade her / his qualification / skill competency either to move higher in her / his job or in the higher educational system. This will also provide the learner an opportunity for vertical mobility to second year of B.Voc degree program after one year diploma and to third year of B.Voc degree program after a two year advanced diploma. The students may further move to masters and research degree programs (NSQF Level 8 – 10)

Degree of Master of Vocation in
Pharmaceutical Analysis & Quality Assurance
(M.Voc. – Pharm. Analysis & QA) Degree Course

O.S. M.Voc.- Pharm. Analysis & QA – 1 :

Admission Eligibility: There may be three types of learners getting admission to first semester of skill based courses under NSQF:

Category – 1 : students already acquired NSQF certification Level 7 in a particular industry sector and opted admission in the skill based courses under NSQF in the institutions recognized under Community Colleges / B.Voc Degree program / DDU KAUSHAL Kendras in same trade with job role for which he / she was previously certified.

Category – 2 : students who have acquired NSQF certification Level 7 but may like to change their trade and may enter into skill based courses in a different trade(candidate has to take up Skill Bridge course during semester I/II).

Category – 3 : students passed B.Sc. - Chemistry / Ind. Chemistry/ Applied chemistry / B. E. - Chemical Engineering / B. Pharm. examination with at least second class from recognized University.

Candidate who have passed an equivalent examination from any other University or examining body and is seeking admission to the Master of Vocation – Pharm. Analysis & QA (M.Voc.- Pharm. Analysis & QA) course will be required to provide necessary eligibility certificate.

O.S. M.Voc.- Pharm. Analysis & QA – 2 :

The duration of the course will be of two full time academic years. No candidate will be allowed to join any other course or service simultaneously. The examination for the Master of Vocation – Pharm. Analysis & QA (M.Voc.- Pharm. Analysis & QA) course will be divided into four semesters.

Multi-level Exit :
Candidate will be eligible to receive PG Diploma(NSQF Level 8) after first 2 semesters according to guidelines of UGC.

O.S. M.Voc.- Pharm. Analysis & QA – 3 :
Subject to the provisions laid down in Ordinance **O.S. M.Voc.- Pharm. Analysis & QA – 2**, a candidate who has passed the M. Voc. semester I & II of this University and if there is a break in the studies for any reason and if there is a change in the courses from semester system to annual part Examination system, the candidate will be admitted to M. Voc. Part II and the marks/ credits obtained by the candidate in his previous examination of this University in M. Voc. semester I and II will be carried forward and the result of the M. Voc. Final Examination will be declared accordingly.

O.S. M.Voc.- Pharm. Analysis & QA – 4 :
To pass the whole M. Voc. Examination, student should clear M. Voc. Semesters I to IV and examinations within a period of five years from the date of his/her registration. Failing to

this He /She will be required to register himself as a fresh candidate and keep the attendance and appear and pass all semester examinations afresh from first onwards in order to obtain the Degree of Master of Vocation.

O.S. M.Voc.- Pharm. Analysis & QA – 5 :

No candidate will be admitted to any semester examination for Master of Vocation – Pharm. Analysis & QA (M.Voc.- Pharm. Analysis & QA) unless a student has put on at least 80% of the total lecture periods and practical periods in each subject in each semester.

O.S. M.Voc.- Pharm. Analysis & QA – 6 :

No candidate will be permitted to reappear at any semester examination, which he has already passed. The marks of successfully completed paper will be carrying forwarded for the award of class.

O.S. M.Voc.- Pharm. Analysis & QA – 7 :

There shall be an examination at the end of each semester to be known as Pre PG Diploma (first semester) examination, PG Diploma (second semester-NSQF Level-8) examination, Pre M.Voc. Degree (third semester) examination and M.Voc. Degree (fourth semester-NSQF Level-9) examination. At which a student shall appear in that portion of theory papers, practical and viva – voice if any, for which he has kept the semester in accordance with the regulations in this behalf.

A candidate whose term is not granted for what so ever reason shall be required to keep attendance for that semester or term when the relevant papers are actually taken at the college.

R.S.M.Voc.- Pharm. Analysis & QA-1:

The M. Voc. Degree may be taken by written examination and practical (if any) or partly by papers including practical (if any) and Training / dissertation.

R.S.M.Voc.- Pharm. Analysis & QA-2:

There will be theory and practical examinations at the end of each semester. The viva voce examination will be conducted at the end of each semester.

A candidate failing in more than two theory papers at the end of Semester-I and II will not be allowed to keep term. The candidate must have at least 80% presence in theory as well as practical. In any circumstances if candidate fails in fulfilling the required presence, the term will not be granted for appearing in the examination.

R.S.M.Voc.- Pharm. Analysis & QA-3:

Standard of Passing

The standard of passing for Master of Vocation – Pharm. Analysis & QA (M.Voc.- Pharm. Analysis & QA) degree examination will be as under :

1) To pass any semester examination of the Master of Vocation – Pharm. Analysis & QA (M.Voc.- Pharm. Analysis & QA) degree, a candidate must obtain at least 40% marks in the University examination separately in each course of theory and practical.
2) Total marks of each theory paper are 100 (External examination 70 marks + Internal examination 30 marks)
3) No internal examination marks in practical and project-viva papers.
4) Total marks of Entrepreneurship Development & Soft skill Training is 100. This subject will be evaluated either orally &/or practically on the basis of Project report submitted by the student.

R.S.M.Voc.- Pharm. Analysis & QA-4:

The passing standard in theory, practical and viva voce examination will be 40% in each head of passing. The final class will be awarded as under:

1) The candidate securing greater than equal to 70% aggregate marks obtained in all semesters together (Sem. I –IV) will be awarded a distinction class.
2) The candidate securing below 70% but less than equal to 60% aggregate marks obtained in all semesters together (Sem. I –IV) will be awarded first class.
3) The candidate securing the aggregate percentage from 48 to less than 60% aggregate marks obtained in all semesters together (Sem. I –IV) will be awarded a second class.

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M.Voc. Pharmaceutical Analysis & Quality Assurance

Name of the Program(s) (Diploma, Adv. Diploma, Degree)	Semesters	No. of Credits **30 Cr./Sem**	Job Roles and **NSQF**-Levels
B. Voc. (Hons.) **OR** PG Diploma in **Pharm. Analysis**	1	60 Credits	**NSQF Level 8** Hons / PG Dip
	2		
M.Voc. in **Pharm. Analysis & Quality Assurance**	3	60 Credits	**NSQF Level 9** M.Voc. Master
	4		

Note: A student has to earn additional 1 credit per year for Universal Human Value Education Course.

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M. Voc. Pharm. Analysis & Quality Assurance

Semester-I

S.N.	Paper No.	Subject	Credit	Marks
1	MPAQA-101	Stereo chemistry & Organic reaction Mechanism	3	100
2	MPAQA-102	Separation Techniques	3	100
3	MPAQA-103	Electro-analytical Methods	3	100
4	MPAQA-104	Modern Analytical Techniques	3	100
5	MPAQA-105	Practicals-1,2,3 & 4 & Viva voce	18	250+50
		Total Credit Semester-I	**30**	**700**

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M. Voc. Pharm. Analysis & Quality Assurance

Semester-II

S.N.	Paper No.	Subject	Credit	Marks
1	MPAQA-201	Pharmaceutical Technology	3	100
2	MPAQA-202	Pharm. Formulation Development	3	100
3	MPAQA-203	Stability of Drugs and Drug Products	3	100
4	MPAQA-204	Advanced Pharmaceutical Analysis	3	100
5	MPAQA-205	Instrumentation Training (Report and viva)	2	100
6	MPAQA-206	Practicals-1, 2, 3 & 4 & Viva voce	16	250+50
		Total Credit Semester -II	**30**	**800**

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M. Voc. Pharm. Analysis & Quality Assurance

Semester-III

S.N.	Paper No.	Subject	Credit	Marks
1	MPAQA-301	Medicinal Chemistry	3	100
2	MPAQA-302	Phyto-Pharmaceutical Analysis	3	100
3	MPAQA-303	Analytical Method Development, Validation & Stability Studies	3	100
4	MPAQA-304	Regulatory Affairs and Intellectual Property Rights	3	100
5	MPAQA-305	Practicals-1, 2 & 3 & Viva voce	18	250+50
		Total Credit Semester -III	**30**	**700**

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M. Voc. Pharm. Analysis & Quality Assurance

Semester-IV

S.N.	Paper No.	Subject	Credit	Marks
1	MPAQA-401	GLP & GMP	3	100
2	MPAQA-402	Entrepreneurship Development & Soft Skill Training	3	100
3	MPAQA-403	Dissertation Work - Presentation & Viva	24	200+50+50
		Total Credit Semester -IV	**30**	**500**

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M.Voc. Pharmaceutical Analysis & Quality Assurance

Semester – I

Pharmaceutical Analysis & Quality Assurance

Paper No.	Subject	Marks
MPAQA-101	Stereochemistry and Organic Reaction Mechanism	100
MPAQA-102	Separation Techniques	100
MPAQA-103	Electro-analytical methods	100
MPAQA-104	Modern Analytical Techniques	100
MPAQA-105	Practical -101,102,103 & 104 + viva voce	250+50
	Total	**700**

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M. Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

SEMESTER I

MPAQA-101: Stereochemistry and Organic Reaction Mechanism

1. **Fundamental of Stereochemistry:** Introduction, elements of symmetry, Chirality, stereoisomerism, Configurational isomerism, stereocentre, Three-dimensional formulas and interconversition with one & two stereocenter, R, S- system, Geometrical isomerism, Cis/Trans, E-Z isomerism, Oximes, Stereoisomerism without a stereogenic carbon, Stereoaxis (biphenyl & allenes), stereoplane (Ansa compound), Helicity, Conventions for D, L and, Threo & Erythro, Epimers, Anomers and Epimerization.
2. **Racemic mixtures & Asymmetric Synthesis:** Introduction, Racemization, Resolution of racemic mixtures, Optical purity & Enantiomeric excess, Stereoselective and stereospecific reactions, Prochirality, Homotopic & Heterotopic ligands and faces, Enantiotopic ligands & faces, Asymmetric synthesis**.**
3. **Conformational Analysis & Reactivity:** Conformational Isomerism, confirmations of ethane & butane, Conformations and chemical reactivity of acyclic system, Cycloalkane ring other than cyclohexane, Conformations of substituted cyclohexane, Effect of confirmations on reactivity-cyclic system.
4. **Stereochemistry of Aliphatic Nucleophilic Substitution Reactions**: Introduction, Stereochemistry of S_N1 & S_N2 reaction mechanism, The S_Ni mechanism, Mixed S_N1 & S_N2 reaction, ambient nucleophile, Regioselectivity, Neighbouring group participation.
5. **Stereochemistry of Elimination Reactions:** Introduction, Mechanism E1, E2 and E1cB, Stereochemistry of E2-anti-ellimination reaction, E2-syn-elimination, Orientation of the double bond, Pyrolytic elimination.

Reference Books

1. Organic chemistry - I. L. Finar
2. Stereochemistry -Conformation and mechanism-P. S. Kalsi.
3. Stereochemistry - D. Nasipuri
4. Organic Chemistry-J. Clayden
5. Stereochemistry-Eliel
6. Stereochemistry of organic compounds - P.S. Kalsi.
7. Stereo selective synthesis : A practical approach, - M. Nogradi, VCH

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

Semester 1

MPAQA-102: Separation Techniques

Introduction

1. Significance, Requirement and Role of Separation Techniques
2. Introduction and Classification of Chromatographic techniques (Adsorption Partition & Ion exchange phenomena)

Principle, Basic theory, Instrumentation, Operation & Applications-Case Study* of

1. Paper chromatography: AC, DC, CC, 2D-AC
2. TLC, 2D-TLC & HP-TLC
3. Column Chromatography
4. Flash chromatography
5. Ion Exchange chromatography
6. GC, HSGC & Hyphenated Technique GC-MS
7. HPLC & Hyphenated Technique LC-MS, SFC
8. Electrophoresis & Electro chromatography
9. Band broadening & Column efficiency: Definition of terms, Factors affecting, Plate theory & Rate theory of chromatography, Limitations of theory

*Interpretation/Analysis of results with or without regulatory standards

Reference Books

1. Thin layer chromatography, E. Stahl.
2. Chromatography, Heptman.
3. HPTLC, Dr. P. D. Sethi.
4. High Performance liquid chromatography, Dr. P. D. Sethi
5. Principles of Instrumental Analysis, D.A. Skoog and J.L. Loary, W.B. Saunders.
6. Fundamentals of Analytical Chemistry, D.A. Skoog, D.M. West and F.J. Holler, W.B. Saunders.
7. Principles of Instrumental analysis, D.A. Skoog and W.B. Saunders.
8. Instrumental Methods of Chemical Analysis, Dr. B. K. Sharma

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

Semester 1

MPAQA-103: Electro-Analytical Methods

1. **Mol. Luminescence: Fluorimetry & Phosphorimetry**
   Introduction, theory, instrumentation, application and comparison of fluorimetry & phosphorimentry
2. **Nephelometry & Turbidimetry:**
   Introduction, Theory, instrumentation, application & comparision of Nephelometry & Turbidimetry
3. **Polarography & Amperometric titration**
   Polarography: Introduction, Theory, apparatus, application
   Amperometric titration: Introduction, Theory, apparatus, technique, titration with two indicator electrode, advantages, disadvantages and application of amperometric titration
4. **Electro/ Thermo Gravimetric analysis**
   Introduction, theory, instrumentation, factor affecting curves and application of TG & DTA
5. **Polarimetry and spectropolarimetry**
   Polarimetry: Introduction, plane polarized light, optically active compound, Instrumentation, application
   Spectropolarimetry: Introduction, instrumentation and application of ORD & CD.

Reference Books

Instrumental Methods of Chemical Analysis, Dr. B. K. Sharma
Instrumental Methods of Chemical Analysis, Gurdeep R. Chatwal, S. K. Anand

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

SEMESTER-1

MPAQA-104: Modern Analytical Techniques

1. **Fundamental Principal of Spectroscopy:** Introduction, classification and Overview of spectroscopic methods based on wave length regions of Electromagnetic radiation, Properties of Electromagnetic radiation.
2. **UV-VIZ Spectroscopy**: Absorbance Phenomena, Various types of Transitions and shifts observed in UV Spectroscopy, Auxochrome and Chromophore, Basic theory, Instrumentation, and Applications of UV Spectroscopy
3. **Infrared Spectroscopy:**Introduction to IR and FTIR, Principle &Theory of Infrared absorption spectrometry, Infrared sources and transducers, Sample handling, Instrumentation, Interpretation of IR spectra, Applications and limitations of IR spectroscopy.
4. **Atomic Absorption & Emission Spectroscopy:** Principle, Basic theory, Instrumentation, and Application, advantages and disadvantages of Atomic absorption and Atomic emission Spectroscopy. Introduction and Overview of ICPMS and MPAES
5. **Mass Spectrometry:** Introduction, Principle, Theory and components of mass spectrometers, Different ionization and detection techniques, recording and resolution of mass spectrometer, Types of ions produced in mass spectrometer, Interpretation of Mass spectra of selected compounds /API, Applications of Mass spectrometry, Introduction to ICP-MS.
6. **Nuclear Magnetic Resonance Spectroscopy:** Introduction to Nuclear Magnetic Resonance, NMR Spectrometer, Chemical shift, factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, Applications of Nuclear magnetic resonance spectroscopy, Introduction, Principle, Theory, Application and Problems of C^{13}– NMR, Introduction to 2D NMR.
7. **X-RAY Diffraction Methods**: Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

Reference Books

1. Practical NMR Spectroscopy, M.L. Martin, J.J. Delpeuch and G.J. Martin, Heyden.
2. Spectrometric identification of Organic Compounds, R. M. Silverstein, G. C. Bassler and T. C. Morrill, John Wiley.
3. Introduction to NMR Spectroscopy, R. J. Abraham, J. Fisher and P. Loftus, Wiley.
4. Application of Spectroscopy of Organic Compounds, J. R. Dyer, Prentice Hall.
5. Spectroscopy Methods in Organic Chemistry, D. H. Williams, I. Fleming, Tata McGraw-Hill.
6. Spectroscopy of Organic Compounds, P. S. Kalsi, New Age International Ltd.

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

SEMESTER-1

MPAQA-105: Laboratory course

Laboratory course of M.Voc- PHARMACEUTICAL ANALYSIS & QUALITY includes practical based on following subjects.

- Stereochemistry and Organic Reaction Mechanism
- Separation Techniques
- Electro-Analytical Methods
- Modern Analytical Techniques

Saurashtra University

M.Voc. Pharmaceutical Analysis & Quality Assurance

Semester – II

Pharmaceutical Analysis & Quality Assurance

Paper No.	Subject	Marks
MPAQA-201	Pharmaceutical Technology	100
MPAQA-202	Pharma. Formulation Development	100
MPAQA-203	Stability of Drug and Drug products	100
MPAQA-204	Advanced Pharmaceutical Analysis	100
MPAQA-205	Instrumentation Training (Report and viva)	100
MPAQA-206	Practical -201,202,203 & 204 + viva voce	250+50
	Total	**800**

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M. Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

SEMESTER II

MPAQA-201: Pharmaceutical Technology

1. Tablet

(a) Definition, Advantages and disadvantages, Introduction to types of tablets**,** formulation of different types of tablets; excipients, granulation techniques, machinery for large scale granulation and compression, physics of tablet making, In process controls, processing problems and remedies,

(b) Evaluation (Pharmacopoeial and non pharmacopoeial test) and equipment.

(C) Coating of Tablets: objectives, types of coating, film forming materials, formulations of coating solution, equipment for coating, coating process, evaluation of coated tablets, coating defects.

2. Capsules

Hard Capsules: Definitions, Advantages, disadvantages, Ideal requirements, Production of Hard capsules (Gelatin and nongelatin e.g. vegetable), Capsule storage, size of capsules, formulation and methods of capsule filling, problems and remedies, quality control.

Soft Gelatin Capsules: Formulation of shell and capsule coat, quality control with special emphasis on current dissolution testing.

3. Sterile dosage forms:

Definitions, Advantages, Disadvantages, Ideal requirements and Formulation of sterile dosage forms, Water for injection-Preparation and quality control, Design and requirements for production area- Aseptic techniques, sources of contamination and methods of prevention, design of aseptic area, laminar flow benches, services and maintenance, containers and closures, methods of filling including form fill and seal technology. Evaluation of sterile dosage forms.

4. Cosmeticology and cosmetic preparations:

Fundamentals of cosmetic science, formulation, preparation and packaging of cosmetics for skin - Sunscreen, moisturizers, cold cream, and vanishing cream, hair - Shampoo and conditioners, dentifrice- powders, gels, paste and manicure preparations like- nail polish, lipsticks, eye lashes, brief introduction to cosmaceuticals, baby care products, shaving cream, hygienic products

5. Liquid dosage forms:

Introduction, advantages and disadvantages, types of additives used vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubilizers, colors, flavors, etc.

Reference Books

1. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J
2. Kanig. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
3. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
4. Pharmaceutics: The Science of Dosage Form Design by Michael E. Aulton

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

Semester II

MPAQA-202: Pharma. Formulation Development

1. Pre formulation studies:

(a) Physical, Chemical and Pharmaceutical factors influencing formulation

(b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties

(c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form

(d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Pre formulation study.

(e) Drug-excipient compatibility study

(f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).

(g) Pre formulation studies of biotechnological derived products and reference guidelines.

2. Controlled and sustained release dosage forms:

Design of oral sustained release systems: Biological factors, Physicochemical factors.

Diffusional systems: - Reservoir system, Lag time, Burst effect, Matrix system, Effect of porosity and tortuosity Dissolution controlled system, Cube route dissolution equation, Diffusion layer controlled dissolution. Bioerodible and Combination of diffusion and dissolution systems. Design, development and evaluation of oral and parenteral controlled release formulations.

3. Novel drug delivery system

(a) Modified drug delivery systems: Fundamentals, rational of modified release drug delivery, factors influencing the design and performance, pharmacokinetic and pharmacodynamic basis for modified drug delivery systems, estimation of loading and maintenance dose.

(b) Design and development of oral modified release dosage forms: Matrix tablets, microspheres, hydrogels, osmotic pressure controlled systems, gastro retentive systems, colon targeting.

(c) Fabrication of parenteral drug delivery systems: Parenteral emulsions & parenteral suspensions, microspheres, liposomes, niosomes, nanoparticles.

(d) Formulation and evaluation of Transdermal drug delivery systems.

(e) A brief study of site specific and targeted drug delivery systems, transmucosal and ocular drug delivery systems.

4. Recent Innovations in Conventional Dosage Forms – including site specific and time release modulation.

Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, Sublingual.
Capsules: Modified release, Semi-solids: Parenterals:
Powders: Particle coating, Taste-masking, Liquids:

5. Basic Techniques for development of NDDS:

Nanotechnology, Bioadhesive systems, Insitu gels, intelligent drug delivery, tailor made medicines, Strips, Disketts and film products. Liposomes/neosomes. Ionto and sonophoretic systems.

References Books:

1. Remingtons "Pharmaceutical Sciences" 19th edition.
2. Lachman "The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing by Banaker.
8. United States Pharmacopeia.
9. Drug stability (Principles and Practices) by Jens. T. Carstensen.

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M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

Semester II

MPAQA-203: Stability of Drug and Drug products

1. **Stability Study of pharmaceuticals**
   (a) Basic concept and objectives of stability study,
   (b) Order of reaction and their applications in predicting shelf life and half-life of pharmaceutical formulations, acid base catalysis, decomposition reactions and stabilization of pharmaceuticals. Real time stability.
   (c) Importance of accelerated stability study,
   (d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.
   (e) Regulatory requirements related to stability testing with emphasis on matrixing/bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,
   (f) Applications of microcalorimetry in stability study.
   (g) Current WHO, USFDA and stability testing as per ICH guidelines for pharmaceutical drug substances and drug products. c) Product stability: Requirements, shelf-life, overages, containers, closures. d) Overage calculations

2. **Biopharmaceutics: a)** Introduction to biopharmaceutics and its role in formulation development. **b)** Passage of drugs across biological barriers (passive diffusion, active transport, facilitated diffusion and pinocytosis. **c)** Factors influencing absorption, physiochemical, physiological and pharmaceutical. **d)** Drug distribution in the body, plasma protein binding and drug excretion.

3. **Drug Absorption** 08
   (a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.
   (b) Method of studying bioavailability and bioequivalence.
   (c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

4. **Pharmacokinetic parameters** 08
   (a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
   (b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

5. In-vitro In-vivo Correlation (IVIVC) :

(a) Methods of establishing IVIVC

(b) Factors affecting IVIVC

References Books:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.
2. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig.
3. Pharmaceutical Preformulation by Carstensen JT, Technomic Publishing Company, Inc., New Holland Avenue, Lancaster, Pennysylvania, USA.
4. Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton, Pennsylvania.
5. Pharmacokinetics by Milo Gibaldi and Donald Perrier.
6. Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K.
7. Stability Studies, Marcel Dekker.
8. Pharmaceutical dissolution testing by Umesh V. Banker, Marcel Dekker Inc

Saurashtra University

M.Voc. PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE
SEMESTER-II

MPAQA-204: Advanced Pharmaceutical Analysis

1. Application of instrumental methods in the development of medicines, concept of analytical method development.

2. Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC.

3. Ion Selective electrodes: Classification, instrumentation and applications in drug analysis.

4. Principles and procedures involved in quantitative determination of functional groups such as Hydroxyl, Aldehyde, Ketone, Ester & Amine.

5. A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of pharmaceutical dosage forms containing the different classes of drugs such as Sulphonamides Barbiturates, Steroids,Vitamins, Antibiotics, Alkaloids, Glycosides etc.

6. Elemental analysis: determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and iodine.

7. Principles and procedures involved in the use of the following reagents in pharmaceutical analysis: N_1-naphthyl ethylene diamine, *p*-Dimethylaminobenzaldehyde (PDAB), 2,6-Dichloro quinone chlorimide, 1,2-Naphthoquinone–4–sulphonate, 2,3,5-Triphenyl tetrazolium Salt, Ninhydrin, Folin–Ciocalteau reagent, *p*-Dimethylamino cinnamaldehyde, 3-Methyl-2-benzothiazoline hydrazine (MBTH), 2,4-Dinitrophyenyl hydrazine.

References Books:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.
2. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig.
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M. Voc. Pharmaceutical Analysis & QA

SEMESTER END UNIVERSITY EXAMINATION

THEORY QUESTION PAPER STYLE- Semester I & II

Time: 2:30 hrs **Theory- Total Marks-70**

Que.:1 Objective type Q & A - 14 Marks
Any **SEVEN** out of ten Questions - Each carrying **2 marks**- Total- 14 marks

Que.:2 Subjective type Q & A - 14 Marks
Any **TWO** out of three Questions - Each carrying **7 marks**- Total- 14 marks

Que.:3 Subjective type Q & A - 14 Marks
Any **TWO** out of three Questions - Each carrying **7 marks**- Total- 14 marks

Que.:4 Subjective type Q & A - 14 Marks
Any **TWO** out of three Questions - Each carrying **7 marks**- Total- 14 marks

Que.:5 Subjective type Q & A - 14 Marks
Any **TWO** out of three Questions - Each carrying **7 marks**- Total- 14 marks

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<table>
<tr><th>PRACTICAL - Semester I</th><th>PRACTICAL - Semester II</th></tr>
<tr><td>Days: 02
Time: 6 hrs/day</td><td>Days: 03
Time: 6 hrs/day</td></tr>
<tr><td rowspan="2">Practical - 250 Marks
Viva voce - 50 Marks</td><td>Practical - 250 Marks
Viva voce - 50 Marks</td></tr>
<tr><td>Training Report - 50 marks
Viva voce - 50 Marks</td></tr>
</table>

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M. Voc. Pharmaceutical Analysis & QA

INTERNAL EVALUATION - THEORY

Semester I & II

Marks per Paper 30 marks

SN	Detail	Marks
1	MCQ – Objective test	10
2	Attendance & Theoretical Assignment/ Seminar	10
3	Theoretical &/or Practical Assignment	10
	Total	**30 marks**

No Internal Evaluation for Practical & Project/Training Components