

**SNDT Women's University**  
**C. U. Shah College of Pharmacy**  
**Name of Programme: M. Pharm.**

**SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE**

<b>Program Outcomes</b>		
<ol style="list-style-type: none"> <li>1. To emphasis on modern analytical techniques like spectrofluometry, infrared spectrophotometry, NMR, Spectrometry HPLC, X-ray diffraction analysis and spectral analysis and understand the packaging and product development designed to teach current trends in formulation of pharmaceuticals and newer drug delivery systems.</li> <li>2. To thrust on good manufacturing practices, quality audits, documentation and validation, Regulatory affairs, New Drug Application and Patenting procedures with a view to create total quality consciousness.</li> <li>3. To develop professionally competent and motivated individuals who can contribute effectively and ethically in academia, pharmaceutical industry and can also pursue higher education</li> </ol>		
<b>Program Specific Outcomes</b>		
<p>After successful completion of the program, the learner will be able to</p> <ol style="list-style-type: none"> <li>1. Sustain in the field of academia, pharmaceutical industry and also opt for higher education in pharmacy.</li> <li>2. Apply the principles of analytical techniques for qualitative and quantitative estimation of drug from formulation and plant extract along with their purity.</li> <li>3. Acquire knowledge about role of regulatory authority and about patenting of drug molecule in patent office.</li> <li>4. Apply the knowledge of QSAR for drug development.</li> <li>5. Analyze, criticize, organize, improvise and manage documentation related to Product development and evaluation.</li> </ol>		
<b>Course Outcomes</b>		
<b>Semester-I</b>		
<b>Course Code</b>	<b>Course Name</b>	<b>Course Outcomes</b>
1101	Analytical Techniques I	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the principles and applications of various analytical techniques such as UV, IR spectrophotometry, spectrofluometry, Atomic Absorption spectroscopy, Thermal methods of analysis, X Ray diffraction in determining purity of compounds, quantitative and qualitative evaluation of drugs.</li> <li>2. Use the knowledge of these instrumental techniques confidently while working with R&amp;D and QC/QA departments of industry.</li> </ol>

1201	Modern Analytical Techniques - I Practical	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Use different analytical instruments used for qualitative and quantitative analysis of drugs and formulations as per pharmacopoeial requirements</li> <li>2. Identify structure of any given compounds by determination of functional groups, nature of given compound (amorphous, crystalline) as well as polymorphic forms by use of analytical instruments such FTIR, DSC, etc.</li> </ol>
1102	Quality Management I	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand basic principles of TQM and building quality in products using current guidelines of GLP and GMP, factors controlling four M's for quality variation in various pharmaceutical products and documentation according to revised Schedule M.</li> <li>2. Deal with regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and Clinical Trials approval, risks associated with different occupational hazards in pharmaceutical industries and safety procedures and waste disposal techniques to be followed in pharmaceutical industries</li> </ol>
1103	Product Development- I	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the applications of preformulation, chemical kinetics and stability testing in pharmaceutical product development.</li> <li>2. Apply principles and techniques of coating technology to solid dosage forms and select various biodegradable &amp; non-biodegradable polymers, stimuli sensitive polymers, mucoadhesive polymers etc in product development.</li> <li>3. Understand the principles of dissolution and diffusion and pharmacokinetics in product development</li> </ol>
1104	Biological Evaluation (Theory)	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the importance and applications of pre-clinical drug evaluation, various testing methods such as microbiological and animal models.</li> <li>2. Apply principles and techniques of radioimmunoassays for some drugs like insulin, <i>digitalis</i> etc. Fluoroimmunoassay, Fluorescent Labelling</li> </ol>
1204	Biological Evaluation (Practical)	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand and apply pre-clinical drug evaluation, various testing methods in animal models</li> <li>2. Perform microbiological evaluation, analyse and interpret the results</li> <li>3. Get hands on training on animal handling and study various dosing methods in animal models</li> </ol>

<b>Semester-II</b>		
2101	Analytical Techniques II	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the principles and use various analytical techniques such the basic principles, techniques and instrumentation of thin layer chromatography (TLC), HPLC, PC in determining purity of compounds, quantitative as well as qualitative evaluation of drugs</li> <li>2. Use the thorough knowledge of these instrumental techniques confidently while working with R &amp; D and Quality Control departments of industry</li> </ol>
2201	Analytical Techniques II (Practical)	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Develop various analytical methods for quantitative estimation of drugs from formulations using HPLC and other chromatographic methods</li> <li>2. Identify impurities in synthetic samples and/or plant extracts and implement pharmacopoeial requirements</li> </ol>
2102	Product Development-II	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the various aspects in formulation development of pharmaceutical dosage forms and novel drug delivery carriers.</li> <li>2. Encompass the development of formulations, selection of various excipients, selection of routes of administration and evaluation of novel pharmaceutical carrier systems</li> </ol>
2103	Quality Management-II	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the aspects in formulation development of pharmaceutical dosage forms and novel drug delivery carriers using guideline of GLP and GMP</li> <li>2. Apply the Regulatory aspects of pharmaceutical and bulk drug manufacture to build quality in products.</li> <li>3. Develop an understanding of quality review and quality audit in pharmaceutical industries.</li> </ol>
2104	Packaging Development	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the importance of packaging in pharmaceutical product development.</li> <li>2. Gain knowledge of protective function of commonly used packaging materials, their limitations and possible interactions with various drugs and help in choosing appropriate pharmaceutical packaging</li> </ol>
2204	Packaging and Product Development-II (Practical)	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Perform various quality control tests on packaging materials, analyze and interpret the results.</li> <li>2. Understand the importance of packaging in pharmaceutical product development and select appropriate packaging materials</li> </ol>
<b>Semester-III</b>		

3101	Computer & Statistics	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Use of computer systems to access and retrieve information and develop an understanding of various application softwares with respect to pharmaceutical sciences for drug discovery, drug design, formulation development, production and Quality Assurance, QSAR for drug modelling and simulation of data</li> <li>2. Understand concept of statistics as applied to pharmaceutical data, to analyze and interpret the data and factorial designs</li> </ol>
3102	Validation	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand the principles and methods of validation</li> <li>2. To apply validation to different processes for mixing, granulation, drying, compression, filtration, filling, etc.</li> </ol>
3103	Research Methodology	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>3. Understand problem identification, its implementation and evaluation and also introduce various research funding agencies for pharmacy.</li> <li>4. Introduce different methods of assessment and concepts of basic research and give a brief overview of formation of research problems.</li> <li>5. Apply concepts of mathematical and experimental modeling and types involved in processes of formulation of model based on simulation.</li> </ol>
3104	Research Seminar	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Collect and collate scientific data on recent topics in Pharmaceutics and prepare presentations</li> <li>2. Develop aptitude, attitude, communication, presentation and soft skills</li> </ol>
3105	Research Project	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Apply knowledge for development and evaluation of conventional, novel and modified drug delivery systems</li> <li>2. Present the research and develop aptitude, attitude, communication, presentation and soft skills</li> </ol>
3106	Industrial Training	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Gain knowledge during hands on training in the pharmaceutical industry for better understanding of career prospects and avenues available</li> <li>2. Understand the working of various departments of the pharmaceutical industry</li> </ol>
<b>Semester-IV</b>		
4101 and 4102	Research Project	<p>The learners will be able to:</p> <ol style="list-style-type: none"> <li>1. Apply knowledge for development and evaluation of conventional, novel and modified drug delivery systems</li> <li>2. Present the research and develop aptitude, attitude, communication, presentation and soft skills</li> </ol>

