SANDIP FOUNDATION''s
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# Course Module

## Pre-formulation Studies

| Unit | Content | Allotted Hours |
|---|---|---|
| **Unit I** | **The Scope of Pre-formulation Studies**<br>Introduction, Pre-formulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization<br>Transport Across Biological Membranes | 5 |
| **Unit II** | **Dissociation, Partitioning, and Solubility**<br>Introduction, The Ionization Principle, Quantitative Structure –Activity Relationships, Partitioning, Measurement Strategies | 5 |
| **Unit III** | **Release, Dissolution, and Permeation**<br>Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems | 5 |
| **Unit IV** | **Solid-State Properties**<br>Introduction, Crystal Morphology, Polymorphism, High-Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms, Hygroscopicity,<br>Solubility, Study Methods | 5 |
| **Unit V** | **Dosage Form Considerations in Reformulation**<br>Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze-Dried Formulations, Suspensions, Topical, Pulmonary Delivery, General Compatibility | 5 |

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| **Unit VI** | **Chemical Drug Substance Characterization**<br>Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice | 5 |
| **Unit VII** | **Characterization of Biopharmaceutical Drugs**<br>Introduction, preformulating Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Designof Preformulation Studies | 5 |

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| IQAC In charge | Dr. Marina Dsouza |
| Signature |  |


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