

Advanced Analytical Techniques (AAT): Basic Principles and Application for Quality Assessment of Drugs and Pharmaceuticals

Course contents in ITEC-AAT

The Theme

Analysis is an integral part of drug discovery and development process. The identified potential new chemical/molecular entity (NCE/NME) goes through an elaborate path of pre-clinical development (including safety, efficacy and quality aspects; pharmaceutical development) and clinical development.

Each stage of this path includes analysis of drug molecule that is being developed, using several analytical techniques.

The analysis of bulk drugs/intermediates (active pharmaceutical ingredient, API), drug product formulations, impurities and degradation products, biological samples containing drugs and their metabolites, plays an important role in pharmaceutical development research. Further the regulators worldwide demand increasingly high quality and safety standards of drugs and pharmaceuticals from the pharmaceutical industry. For meeting these standards, reliable analytical techniques and methods are constantly required and being developed by analytical scientists. Thus, pharmaceutical analyses play a vital role in advancing the concepts and theories of analytical science as well as provide an important information on practical aspects of drug design and development, quality control/quality assurance of drug manufacturing. Traditional analytical methods are commonly applied to chemical analysis of drugs and pharmaceuticals. However, in the recent past modern pharmaceutical analysis has been evolved significantly and led to development of combination (hyphenation) techniques, chemometrics, high throughput technologies, miniaturization and nanotechnology. Recently futuristic analytical techniques namely process analytical tools (PAT) are being developed.

In pharmacopoeial monographs assay methods for drugs including spectroscopy, chromatography, titrimetry, capillary electrophoresis and other electroanalytical methods are mentioned. The more advanced hyphenated analytical methods such as GC-MS, LC-MS, LC-MS-NMR, CE-MS etc. are finding applications in drug analysis.

Course Content - SCIENTIFIC TOPICS to be deliberated

- Fundamental principles and applications of spectroscopic techniques, UV, IR, NMR, X-Ray Diffraction, Spectrofluorometry and Mass Spectrometry including MALDI, in analysis of drugs and pharmaceuticals and biopharmaceuticals

- Modern Analytical Techniques such as HPTLC, HPLC, UPLC, hyphenated techniques such as LC-MS, Capillary electrophoresis (CE) and CE-MS and their applications in analysis of drugs and biopharmaceuticals
- Analytical Method Validation
- GPC and other spectroscopic tools for analysis of biopharmaceuticals
- Standardization and quality control of herbal drugs and formulation
- Stability testing and Impurity profiling of APIs and formulations: Challenges and Issues
- Good Laboratory Practices (Quality Control) and Significance of QA and QC in Pharma Industry
- Pharmacopoeial testing of drugs
- Analysis of Nanoparticles and Nano-formulations
- Solid state Pharmaceuticals
- Hands-on training sessions on above mentioned spectroscopic, chromatographic and hyphenated analytical techniques
- Non-Destruction Analytical Techniques/Process Analytical Tools (PAT)
- Visits to 2-3 pharmaceutical industries