

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

**MFCP of Scientific Assistant (Instruments) to Sr. Scientific Assistant
(Instruments) at the Central Analytical Facility**

Syllabus for the written test

Physicochemical characterization of materials/devices and quality management system: Basic understanding of the principles of analysis of materials/devices under the quality management system, concept of quality and quality management systems, accreditation and its maintenance, ISO 17025:2017, and good laboratory practices. Chemical characterization of medical devices and biomaterials as per ISO 10993 parts 7, 18 and 19. Equivalence establishment for toxicological risk assessment.

Analytical measurements, method development and validation, accuracy, precision, specificity, selectivity and uncertainty of measurement, statistical analysis of test results, uncertainty evaluation methods, ensuring the validity of test results, interlaboratory comparisons and proficiency testing, error evaluation and mitigation, laboratory safety practices.

Spectroscopic evaluation of materials and devices: Electromagnetic radiation and its interaction with the materials, Theory and applications of various spectroscopic techniques: UV-Visible spectroscopy, FTIR spectroscopy, Raman spectroscopy and Raman chemical mapping, X-Ray spectroscopic techniques for biomedical evaluations, bulk and trace level elemental analysis, RoHS compliance testing, Role of spectroscopy in the chemical characterization of medical devices.

Chromatographic techniques for material analysis: Chromatography and its relevance in bio-analysis, Theory and applications of various chromatographic techniques: HPLC, GPC, Gas chromatography, and LCMS. Role of chromatography techniques in medical device evaluations, Extractable and leachables analysis: residual monomer, plasticiser, crosslinking agents, sterilizing agents, and degradation products.

Mechanical testing of materials and devices: Theory and operations of mechanical test systems such as Universal testing machines, Dynamic mechanical analyzers, and texture analyzers. ISO/ASTM/BIS standards for mechanical testing; modes of testing such as tension, compression and flexural; tests such as tear strength, puncture resistance, peeling force, muco and bio-adhesion analysis; and mechanical evaluation of small medical devices.

Thermal analyses of materials: Theory and applications of various thermal analytical techniques: Thermogravimetric analysis, Differential thermal analysis, Differential Scanning Calorimetry. ASTM methods, Standard and reference materials, modulated measurements, heat capacity, thermodynamic property estimation, Tacticity and crystallinity.

Other physicochemical techniques for analysis: Surface and interfacial tension, contact angle measurements, viscosity and viscoelastic properties, Rheological analysis, water vapour permeability, and extraction methods.


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