

**SYLLABUS FOR THE POST OF SENIOR SCIENTIFIC ASSISTANT
(MICROBIOLOGY) IN DRUGS TESTING LABORATORY, GNCTD
UNDER DRUGS CONTROL DEPARTMENT, GNCTD**

1 -General Microbiology:

- a) History and scope of microbiology, Overview of microorganisms, Classification of bacteria, Microbial diversity, Microbial culture collections.
- b) Morphology and structure of bacteria, Cultivation of bacteria - culture media and methods, Aerobic and Anaerobic culture methods, Staining reactions, Culture preservation techniques, Microscopy, Growth and nutrition, Reproduction in Bacteria
- c) Fungi- Introduction, general characteristics, morphology.
- d) Sterilisation–
 - i) Concept and classification, principle and methods of sterilization.
 - ii) Construction working & applications of moist heat & dry heat sterilizer, gamma radiation sterilizer, filtration sterilizer. Indicators of sterilization, microbial death, kinetic terms-D value, z value.

2- Maintenance, Identification, Preservation and disposal of Micro-organisms as per Indian Pharmacopeia, Sterility Testing & Bacterial Endotoxin Test and Effectiveness of Anti-microbial preservatives as per Indian Pharmacopeia (IP 2022).

3- Microbial Assay:

Importance, general methods of Microbial assay of antibiotics (Cup & plate method, turbidometry, dilution method), microbial assay of Vitamin B12 & Calcium Pantothenate as per Indian Pharmacopeia (IP 2022).

4- Standard for Disinfectant fluids as per Schedule O of Drugs and Cosmetic Act 1940 /IS 1061: 1997(RW Coefficient).

5- Microbial Testing of Cosmetics as per Cosmetics Rules 2020 & IS 14648: 2011.

6- Clean area classification, Principle, construction & working.

7- Microbial Contamination in Non-Sterile Products (Microbial Limit Test) as per IP.

8- Instrumentation:

Principles, Apparatus/Instrumentation & Applications of Disintegration, Dissolution, UV-Visible Spectroscopy, Infra Red (IR) Spectroscopy, Microscope, Autoclave, Biosafety Cabinet and Laminar Flow Bench.

9- Knowledge of basic tests as per IP 2022:

Disintegration Test, Dissolution Test, Uniformity of Weight Single-Dose Preparations, Uniformity of Content of Single-Dose Preparations and Uniformity of Dosage Units.

10- Regulatory Affairs:

Basic knowledge of General Requirement for competence of testing and Calibration Laboratories as per ISO 17025:2017, NABL, Basic knowledge of Schedules in Drugs and Cosmetics ACT 1940 and Drugs Rules 1945.