

## Outline Syllabus for written test for the post of Drugs Inspector & Technical Officer

Basic understanding of the objectives of various drugs & cosmetics related legislations, which includes;

- Drugs & Cosmetics Act, 1940 and Rules 1945;
- Drugs and Magic Remedies (Objectionable Advertisements), Act, 1954 and Rules 1955;
- Drugs Price Control Order 2013;
- Narcotics and Psychotropic Substances Act, 1985 and Rules 1987;

Understanding of the basic principles involved in the manufacture and testing of drugs as well as those involved in the selling of drugs as regulated in the above drugs legislations, including the knowledge of various Schedules appended to these legislations;

Understanding of the basic concepts and principles involved in the categorization of drugs / cosmetics to the extent of various prohibitions envisaged in these legislations and the penal provisions attached to it;

Understanding of the basic principles attached to the drugs process qualification, process validation, real time / accelerated stability studies, / packaging of pharma products / labeling of drugs, both for domestic & exports markets / validation / calibration / functional principles of essential analytical sophisticated equipment / instruments used in the testing of drugs;

Understanding of the principles involved in the Pharmaco-vigilance Program of India relating to the drugs inter-action / adverse drugs reaction, etc; concepts envisaged under the law relating to clinical trials of drugs;

Understanding the basic principles involved in the self-audit compliance / training calendar / importance of the technology usage in the maintenance of drugs manufacturing & selling documents / SOP's / drugs master files / product approval / data integrity / quality-by-design;

Understanding of the principles involved in the drugs distribution / importance of drugs storage / supply chain monitoring /and product re-calls concepts;

Understanding of the principles involved in the advertisement of drugs as well as those in the pricing of drugs and its monitoring mechanism;

Understanding of the principles involved in the regulation relating to control over medicinal narcotics drugs, its labeling, storage, distribution and selling concepts to counter the misuse / abuse of drugs or self medication;