M.P.H 1.4 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS
THEORY 3 Hrs/Week

UNIT – I

1. W.H.O. certification scheme on the quality of pharmaceutical products.
2. Quality management in the drug industry: philosophy and essential elements.
3. Guidelines on the inspection of pharmaceutical manufacture and drug distribution channels.

UNIT – II

4. Drugs Prices Control Order, 1995.
5. New Drug Policy, 1994.
6. ISO 9000 and 9002 documentation: Introduction and Support package: Guidance on the terminology used in ISO 9001:2000 and ISO 9004:2000.

UNIT – III

7. General Principles of Intellectual Property: Copyright, Trademark
   Patents: need of patents, major types of patents, patent offices in India, US and Europe, International registration of patents, how patents are obtained for drugs and their impact on industry and patients, patent term and extension The Patents Act, 1970 – Salient features.
8. New Drug Application: Steps involved in the development of new drug. New drug applications as per WHO guidelines and abbreviated NDA. Requirement and guidelines on clinical trials.

UNIT – IV

9. Industrial safety: Industrial hazards due to fire, chemicals, pharmaceuticals, radiation and accidents - mechanical and electrical equipments. Monitoring and prevention systems, Industrial effluent testing.
10. Stability Studies: ICH guidelines and WHO guidelines and stability protocols for dosage forms.