

Manuals under RTI Act, 2005

Manual 5- Rules, Regulations, Instructions, Manual and Records, for Discharging Functions.

List of rules, regulations, instructions, manual and records, held by public authority or under its control or used by its employees for discharging functions

The details of the documents are as follows:-

1.

Name/title of The document:	Type of document
Drugs & Cosmetics Act, 1940 Drugs & Cosmetics Rules, 1945	Central Act and Rules
Brief Write up on the Document:	An Act to regulate the import, Manufacture, distribution and Sale of drugs and cosmetics and Rules made theirunder.
From where one can get a copy of rules, Regulations, instructions, manual and Records:	Government of India publication, may be procured from any law bookstore.
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	Not applicable.

2.

Name/title of The document:	Type of document
IP and its Addenda	Book of standards
Brief Write up on the Document:	IP prescribes the standards for drugs manufactured and/or marketed in India and contributes to the control and assurance of quality of medicines.
From where one can get a copy of rules, Regulations, instructions, manual and Records:	The IP 2018 (in four volumes) alongwith DVD can be procured from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP). It can also be procured through our distribution network (available in our website www.ipc.gov.in)
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	IP can be procured by remitting the amount @ Rs.50,000/- + 5% GST to IPC, Ghaziabad.

3.

Name/title of The document:	Type of document
National Formulary of India (NFI)	Guidance document
Brief Write up on the Document:	NFI comprises of clinically oriented summaries and information related to different generic drugs, FDCs and other useful topics.
From where one can get a copy of rules, Regulations, instructions, manual and Records:	The NFI can be procured from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP) It can also be procured through our distribution network.
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	NFI-2016 can be procured by remitting the amount @Rs.600/+5%GST to IPC, Ghaziabad.

4.

Name/title of The document:	Type of document
Guidance Manual for Compliance of PvPI, IPC	(i) Guidance Documents for Spontaneous Adverse Drug Reaction Reporting (ii) Pharmacovigilance Guidance Document for Marketing Authorization holders of Pharmaceutical products
Brief Write up on the Document:	(i) This document is to help PvPI in specifying roles and responsibilities of stakeholders & to identify, analyse & minimize the risk associated with drugs. (ii) This document intends to be an aid to Marketing Authorization holders of Pharmaceutical products and other stakeholders in order to identify the risks associated with pharmaceutical products and establish a pharmacovigilance system in the Marketing Authorization holders to mitigate such risks.
From where one can get a copy of rules, Regulations, instructions, manual and Records:	Both the manual can be procured from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP). It can also be procured through our distribution network.
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	(i) This is given to the trainees of pharmacovigilance at free of cost. (ii) The Guidance Document can be procured by remitting the amount @Rs.500/- to IPC, Ghaziabad.

5.

Name/title of The document:	Type of document
Guidance Manual for Compliance	Guidance Document

of Indian Pharmacopoeia (IP)	
Brief Write up on the Document:	Guidance Manual for compliance of IP is a guidance book for stakeholder's to comply Indian Pharmacopoeia
From where one can get a copy of rules, Regulations, instructions, manual and Records:	The manual can be procured from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP) It can also be procured through our distribution network.
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	The Guidance Document can be procured by remitting the amount @Rs.300/- to IPC, Ghaziabad.

6.

Name/title of The document:	Type of document
Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs	Guidance Document
Brief Write up on the Document:	This Guidance Manual gives Standards Operating Procedures (SOPs) for development of monographs as well as botanical reference substances and phytopharmaceuticals and thus facilitates the concerned manufacturers and other stakeholders for understanding the process and development of Monographs of herbs, herbal products including Phytopharmaceutical Drugs.
From where one can get a copy of rules, Regulations, instructions, manual and Records:	The manual can be procured from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP) It can also be procured through our distribution network.
Fee charged by the department for a copy of rules, Regulations, instructions, manual and records (if any).	The Guidance Document can be procured by remitting the amount @Rs.250/- to IPC, Ghaziabad.