CHAPTER 1

Introduction

Every government of a country in the World takes care of health of it's Citizens. This is a reflection from the constitution framed for the country. Health of the citizens is monitored by the Health ministry of the country. The ministry comprises of several departments. Relating to drugs for cure of a disease, the drug control departments takes the responsibilities. In India, initially ayurveda system of medicine prevailed and to meet the demands, cultivation was initiated. Slowly, the allopathic system of medicine entered into India and it prevailed due to its faster cure of disease. Drugs were imported into India but several quality issues raised. With this the Drugs and Cosmetics Act, 1940 and Rules 1945 came into existence. The objective of the Act is to ensure drug products that enter into Indian market are safe, efficacious, reliable and are of quality. In order to ensure that, the Act provided a provision of establishment of Drug Technical Advisor Boards (DTAB), Drug Consultative Committees (DCC). In addition to this, Central Drug Laboratories (CDL) were established to establish and test quality of drug products assigned. Several authorities such as inspector, analyst and directors for central drug laboratories were appointed. The qualification, powers and responsibilities of the boards, committees, laboratory and the authority were well defined.

Relating to import, manufacture, distribution and sale of drugs and cosmetics that are relating to Allopathy, Ayurveda, Homeopathy, Siddha, and Tibb systems of medicines the application forms for obtaining licence, the requirements to be fulfilled, the inspection procedures, fee and approval/renewal process are well defined in the Act. The Act also indicates the roads, railways, airports, sea by which the drug products can be imported. Especially relating to personal use of medicines, a limited amount of doses can be carried by the person returning. If more than permitted doses, under such circumstances prior permission is necessary.

Relating to schedules of the Act, Schedule M, N, T mainly speaks about the basic requirements for manufacture, distribution and sale of drugs and cosmetics including medical devices.

The First schedule of the Act mainly speaks about the list of books relating to Ayurveda, Siddha, Unani and Tibb system of medicine from which the

formulations can be planned for approval and market in India. In several circumstances, the patent and proprietary medicines, the labelling and contents are critical and the constituents have to be ensured for safety and efficacy. Unlike patented drug products are prior ensured for safety and efficacy and approved as a part of drug discovery and approval process, proprietary medicines reflecting to first schedule, especially for parenteral use have to be specially conducted for pre-clinical/clinical studies and ensure for their safety and efficacy and finally approved by authority to release into the market.

Coming to the current context of the book, reflecting to the Act, the word standard of quality reflects to set standard of drug product. This mainly reflects to standard books of reference for quality test procedures and quality limits set. Second schedule of the Act clearly indicates

the role of Central Drug Laboratories developing qualitative and quantitative analytical methods for quality test of drug products either it is organic, in-organic, vaccines, biological products, herbals, blood products including medical devices etc. The Second schedule indicates procedures and standard set with to respect not only Indian but also with other country Pharmacopoeias. This indicates for any system of medicine.

Pharmacopoeias are books of drug standards. Every country has its own pharmacopoeia and the drug products have to comply so as to release the product in the market. WHO and ICH Q4 clearly indicates harmonization of pharmacopoeia across countries. This harmonization helps to minimize procedures and make available the drug product in several countries across the World, but the drug product has to be approved in every country of interest.

With respect to Indian Pharmacopoeia, the very first edition was released in 1955. It is observed that over the years, Indian Pharmacopoeia was upgraded from one single volume to two to three to currently five volumes. All the general methods of analysis were included in the last of the book but with time, the general methods were dedicated in volume one of every pharmacopoeia edition. The remaining volumes comprises of drug, drug products in alphabetical order as monographs. For biological, herbal and veterinary products the monographs of drugs and drug products are separate.

As per Drugs and Cosmetics Act, 1940 a drug is defined as all medicines, substances, components, devices for internal or external use of human beings or animals intended to be used for or in diagnosis, treatment, mitigation or prevention of any disease or disorder including empty gelatin capsules, destruction of vermin, mosquito repellents.

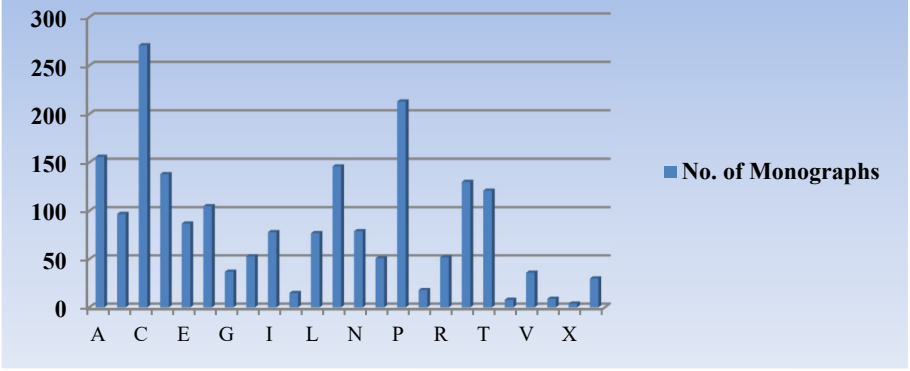
Hence the definition clearly indicates Active Pharmaceutical Ingredients (APIs), formulations, pharmaceutical aids, blood products, biologicals, vaccines, herbals, in-organic drugs etc. Hence purified water, water for injection, sterile water for injection are components of a formulation and hence

called as drugs and separate monographs are available in the Indian Pharmacopoeia.

Coming to Monographs in a Indian Pharmacopoeia, every monograph is specially meant for a drug and its specification. Usually a monograph starts with a title, common name, chemical structure, molecular formula, molecular weight, category, dose, description, solubility, standards, identification tests (including colour reactions, IR spectra), pH, physical tests like melting point, boiling point, optical rotation, semi-quantitative tests like chloride, sulphate, heavy metals, arsenic, lead, iron, quantitative tests like related substances, assay and storage. Depending the nature of drug, the qualitative and quantitative tests are observed.

For instance, analysis of the Indian Pharmacopoeia, 2014 is as indicated below:

Figure 1.1 Number of Monographs in Indian Pharmacopoeia 2014-Alphabet wise



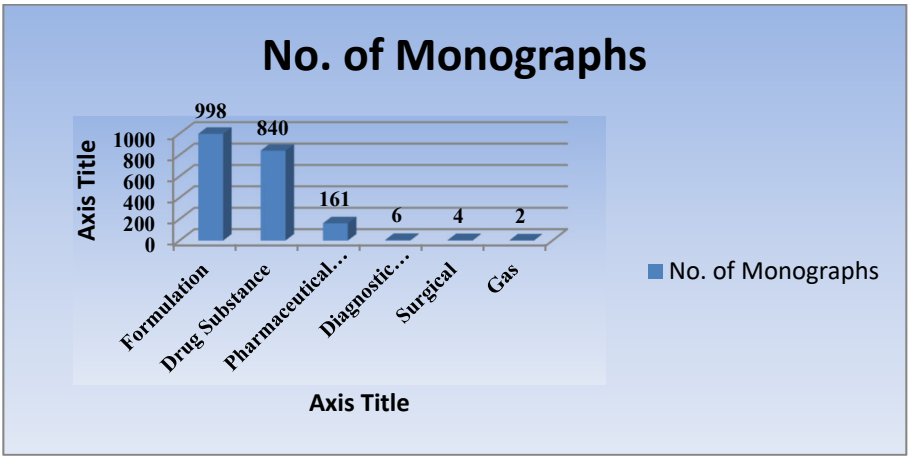


Table 1.1- Number of Monographs in Indian Pharmacopoeia, 2014-Analytical method wise.

S. No	Assay Method	Number of Monographs	% Contribution
1	HPLC	809	40.23
2	Non-Aqueous titration	302	15.02
3	UV spectroscopy	243	12.08
4	Acid-base titration	165	8.2
5	No assay mentioned	78	3.88
6	Others (Multi ingredients with corresponding analytical technique)	66	3.28
7	Oxidation-reduction titration	62	3.08
8	Antibiotic assay	57	2.83
9	Visible spectroscopy	45	2.24
10	Complexometric titration	40	1.99
11	Gas Chromatography	34	1.69
12	Argentometry titration	22	1.09
13	Gravimetry	21	1.04
14	Diazotization titration	14	0.7
15	Enzyme assay	10	0.5
16	Indicator extraction titration	10	0.5
17	Assay of Insulin	6	0.3
18	Optical rotation	5	0.25
19	Anti-factor Xa activity, and Xa to IIa ratio	3	0.15
20	Gasometry	3	0.15
21	Precipitation titration	3	0.15
22	Biological assay	2	0.1
23	Prevention of clotting time of sheep/goat/human plasma	2	0.1
24	Relative density	2	0.1
25	Atomic absorption spectrometry	1	0.05
26	Column chromatography and Visible spectroscopy	1	0.05
27	Egg albumin assay	1	0.05
28	Fluorescence spectroscopy	1	0.05
29	IR spectroscopy	1	0.05

Table Contd…

S. No	Assay Method	Number of Monographs	% Contribution
30	Mercurimetric titration	1	0.05
31	Specific gravity	1	0.05
	Grand Total	**2011**	**100**

Table 1.2- Number of Monographs in Indian Pharmacopoeia, 2014-Formulation wise.

S. No	Formulation type	Number of Monographs	% Contribution	S. No	Formulation type	Number of Monographs	% Contribution
1	Tablets	424	42.5	**14**	Ear Drops	3	0.3
2	Parenterals	264	26.5	**15**	Linctus	3	0.3
3	Capsules	85	8.5	**16**	Powder for Oral	3	0.3
4	Liquid orals	74	7.4	**17**	Suppositories	3	0.3
5	Solution	30	3	**18**	Emulsion	2	0.2
6	Eye Drops	26	2.6	**19**	Lotion	2	0.2
7	Cream	25	2.5	**20**	Nasal Spray	2	0.2
8	Ointment	25	2.5	**21**	Parenterals (Diagnostic aid)	2	0.2
9	Inhalation	7	0.7	**22**	Mouth Wash	1	0.1
10	Diagnostic aid	1	0.1	**23**	Paste	1	0.1
11	Powder for inhalation	5	0.5	**24**	Powder for topical	1	0.1
12	Gel	4	0.4	**25**	Tincture	1	0.1
13	Pessaries	4	0.4	**Grand Total**		998	100