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# PHARMACEUTICS – I

## UNIT 1

TOPIC :

- **Historical background and development of profession of pharmacy :** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.



# History of Pharmacy Profession and Pharmacopoeia

- Pharmacy refers to the health care profession that deals with both fields of health science as well as chemistry
- It is defined as the profession of the art, science, and economics of discovery and preparation from natural and synthetic sources, drugs and non-drug material needed for the prevention, management and treatment of diseases in man and animals
- The word Pharmacy was coined from Greek word
- **Pharmakon** meaning **medicine** or **drug**

## History of pharmacy

1. History of pharmacy with respect to Pharmacy education
2. History of pharmacy with respect to Pharmaceutics Industries

## Education Regulation by

- **PCI** : Pharmacy council of India
- **AICTE** : All India council of Technical Education

## History of pharmacy with respect to Pharmacy education

- **1860** : 1<sup>st</sup> Pharmacy course started in Madras medical college
- **1937** : 1<sup>st</sup> Degree level course in pharmacy started at Banaras Hindu University (BHU) ( 3 year degree course )
- **1940** : 1 year Master course ( M Pharma ) started at Banaras Hindu University (BHU)
- **1990** : B.V. Patel PERD Center (Pharmaceutics Education & Research Development Centre ) established at Ahmedabad & The director was H.L Bhalla

- **1991** : National Institute of pharmaceutical Education and Research (NIPER) was established at Mohali With Dr. C.L. Kaul as the first Director

## Courses

- ◆ D – Pharm ( Diploma in pharmacy )
- ◆ B – Pharm ( Bachelor of Pharmacy )
- ◆ M. Pharm ( Master of Pharmacy )
- ◆ MS Pharm ( Master of Science in Pharmacy )
- ◆ M – Tech ( Master of Technology in Pharmacy )
- ◆ Pharm. D ( Doctor of Pharmacy )
- ◆ PhD (Doctor of Philosophy in Pharmacy )

## History of pharmacy with respect to Pharmaceutics Industries

- 19<sup>th</sup> Century Britishers used to import Alopathic Medicines from Germany & U.K
- 1901 Establish BCPW ( Bengal Chemical and Pharmaceutical Works ) in Calcutta by Acharya P.C Roy
- 1904 – 07 Establish four Research institues
  - Haffkins Institue
  - King Institue
  - Central research Institue
  - Paster Institue
- 1930 First time BCPW started Producing Tetanus Antitoxin
- 1939 - 13% Medical requirement met by India rest by imports
- During Independence { 1947 } Production of Galenicals , Simple Formulation & Few vaccines
- Post Independence { 1948 } Govt. of india lanuched a five year plan
- 1954 Establish “ Hindustan Antibiotic LTD “

## Act in Pharmacy

- ⦿ Patent Act
- ⦿ DPCO Act ( Drug price control act )
- ⦿ FERA Act ( Foreign establish Regulation act )

### Amendments in Patent Act

1. 1995 1<sup>st</sup> Amendments in Patent Act
2. 1999 2<sup>nd</sup> Amendments in Patent Act
3. 2004 3<sup>rd</sup> Amendments in Patent Act
4. 2015 4<sup>th</sup> Amendments in Patent Act

### Amendments in DPCO ( Drug Price Control Act )

1. 1955 1<sup>st</sup> Amendments in DPCO Act
2. 2013 2<sup>nd</sup> Amendments in DPCO Act

### Amendments in FERA Act ( Foreign Establish Regulation ACT )

1. 1993 1<sup>st</sup> Amendments in FERA Act
2. 1999 Abolish / Closed
3. 2004 FEMA (Foreign Established Management Act ) is Established

## Pharmacy as a Career

### Pharmacist

- Hospital Pharmacist
- Community Pharmacist
- Clinical Pharmacist

### Industries Production

- Quality Control
- Quality Assurance
- Research & Development
- Marketing Representative (MR)

## Hospital

- Medical Writer
- Medical Coder
- Medical Adviser
- Medical Claim Association

## Academic Lectures

- Assent Professor
- Associated Professor
- Professor

## Other

- ◆ Bioinformatics
- ◆ Clinical research coordinator
- ◆ Pharmacovigilance

## Pharmacopoeia

The term pharmacopoeia comes from Greek Word

**Pharmakon** means **Drug**

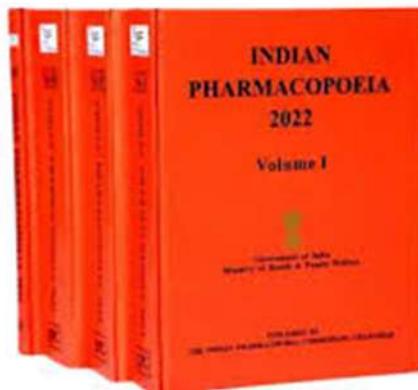
**Poiein** means **Make**

- It can be defined as any recipe or formula that standard required for making or preparing a drug
- It is also known as Compendia

## Indian Pharmacopoeia (I.P.)

- Indian Pharmacopoeia is an official document meant for overall quality control and assurance of pharmaceutical product marketed in India by way of contributing to their safety & affordability.
- The Indian Pharmacopoeia is published by the Indian Pharmacopoeia Commission (IPC) on the behalf of the Ministry of Health and Family Welfare, Government of India.

- The Indian Pharmacopoeia is being produced to fulfil the requirement in the Drug & Cosmetics Rules, 1945 of standard of drugs produced in India



### Editions of Indian Pharmacopoeia

S.No.of Edition	Year of Publication	Year of Addendum Released
First	1955	1960
Second	1966	1975
Third	1985	1989,1991
Fourth	1996	2000,2002,2005
Fifth	2007	2008
Sixth	2010	2012
Seventh	2014	2015
Eighth	2018	2019

### Sailent Features of I.P. 6<sup>th</sup> Edition

- It contains 3 volumes which are hard bound.
- It contains a total of 1918 monographs out of which 287 were newly added.
- Categorisation, dosage, and available strength of dose for the drug were also added.
- Traditional tests were replaced with more specific tests, such as IR and UV spectrophotometry.
- Application of chromatography is done extensively.
- Monographs related to herbal drugs are also added.

- It also contains many monographs which are not present in any other major Pharmacopoeias globally.
- It also contains a certificate to prove its authenticity.
- The format is quite simple and easy to understand.

### Sailent Features of I.P. 7<sup>th</sup> Edition

- A total of 2548 monographs were added.
- This edition also contains 577 new monographs.
- 19 monographs and one general chapter were added related to radiopharmaceuticals.
- The edition comprises of 4 volumes which are in hard bound, along with a DVD.
- Monographs related to veterinary are considered to be vital portion of this edition.
- Use of chromatographic methods is extensively mentioned.
- Traditional tests were replaced with more specific tests, such as IR and UV spectrophotometry.
- Monographs which were irrelevant were eliminated.
- Many monographs related to herbs were added.
- It also contains a certificate to prove its authenticity.
- The format is quite easy and simple to understand.

### Sailent Features of I.P. 8<sup>th</sup> Edition

- IP-2018, comprises of 4 Volumes, having 220 new monographs that are as follows
- 170 chemical monographs
- 15 herbal monographs
- 10 blood and blood related products
- 02 vaccines and immunosera for human monographs use
- 03 radiopharmaceutical monographs:

- 06 biotechnology derived therapeutic products
- 14 veterinary monographs
- It also contains 366 revised monographs and 7 omissions.

## British pharmacopoeia ( B.P. )

- ★ The british pharmacopoeia is published annually & comprises of the standard required for maintaining the quality of medical substance of United Kingdom ( U.K )
- ★ In 1864, the 1<sup>st</sup> Edition of B.P. was Published



<b>Edition</b>	<b>Year</b>	<b>Edition</b>	<b>Year</b>
1 <sup>st</sup>	1864	11 <sup>th</sup>	1980
2 <sup>nd</sup>	1874	12 <sup>th</sup>	1993
3 <sup>rd</sup>	1885	13 <sup>th</sup>	2007
4 <sup>th</sup>	1898	14 <sup>th</sup>	2008
5 <sup>th</sup>	1914	15 <sup>th</sup>	2010
6 <sup>th</sup>	1932	16 <sup>th</sup>	2013
7 <sup>th</sup>	1948	17 <sup>th</sup>	2014
8 <sup>th</sup>	1953	18 <sup>th</sup>	2016
9 <sup>th</sup>	1958	19 <sup>th</sup>	2018
10 <sup>th</sup>	1963	20 <sup>th</sup>	2020
		21 <sup>st</sup>	2021

## United State Pharmacopoeia ( U.S.P )

- ♦ The united state pharmacopoeia is a pharmacopoeia for the united states published annually by the United States Pharmacopoeial Convention.

<b>Edition</b>	<b>Year</b>
1 <sup>st</sup>	1820
9 <sup>th</sup>	1905
22 <sup>nd</sup>	1990
USP 37 NF 32	2013-2014
USP 39 NF 34	2016
USP 43 NF 38	2020



## Extra Pharmacopoeia [ Martindale ]

- A Pharmacist, William Martindale in 1883 edited, compiled, and published the extra pharmacopoeia to provide updated information regarding drugs as well as galenicals to pharmacist & physicians.
- Pharmacopoeia [ I.P , B.P , etc] does not contain & explanatory notes but only large amount of information .
- One should be aware of journal notices & appendices Maintain in pharmacopoeia.
- The extra Pharmacopoeia was included in B.P & four edition of martindale published in 3 years it has been 37 times & contain almost all the updated information about drugs & medicines

Edition	Year
1 st	1933
23rd	1955
24th	1958
25th	1967
26th	1972
40th	2011

