



Indian Pharmacopoeia Commission

JP 130th Anniversary Symposium

Tokyo, Japan

15th Sept, 2016

Dr. G. N. Singh

Secretary-cum-Scientific Director,



Overview

- **Indian Pharmaceutical Industry**
- **Pharmacopoeia and NFI**
- **IP Reference Substances**
- **International Cooperation & Harmonization**
- **Skill Development Programmes**
- **Way Ahead 2020**



Indian Pharmaceutical Industry – A Profile

Type of Manufacturing Unit	Number of Units (Approx)
Formulations	4900
Active Pharmaceutical Ingredients	1500
Vaccines	30
Medical Devices	350
Miscellaneous (Surgical dressings, Blood banks, Disinfectants etc)	2850
Other Industry	
Cosmetics	2300
Ayurveda and Unani	4800
Homeopathy	1000
Whole sale and Retails	800,000



Indian Pharmaceutical Industry – A Profile

Size of the Industry	USD 32 Billion
Export	USD 17 Billion
Domestic market	USD 15 Billion
Average Growth Rate	9- 10 %
Imports	USD 3.5 Billion
Exported to	205 countries / economies
Volume of Production	3rd Largest in the world
Value of production	10th in the world
USFDA Approved sites (Formulations + API)	605
EU GMP compliance sites	631
COPP holding sites	1400 (approx)



Indian Pharmacopoeia Commission



Sector-23, Raj Nagar,
Ghaziabad - 201002, Uttar Pradesh

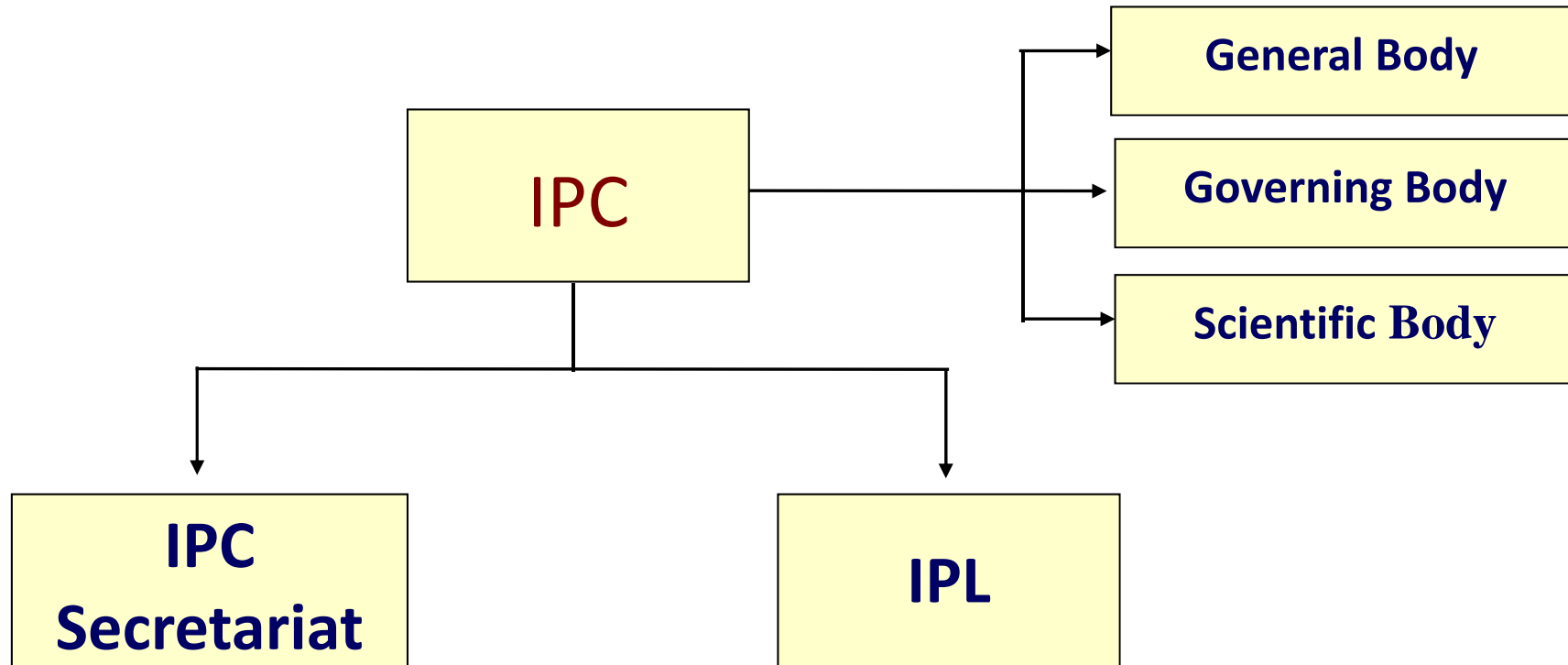


Introduction

- The Commission has become operational from 1st Jan., 2009 as an Autonomous Institution, under administrative control of the Ministry of Health & Family Welfare, Government of India.
- The Indian Pharmacopoeia commission has a three-tier policy formulation and execution setup comprising of the **General Body**, **Governing body** and **Scientific Body** with experts drawn from various Science & Technology areas.
- The Secretary-cum-Scientific Director is the **Chief Scientific and Chief Executive Officer**



Composition of Commission





Vision

To promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacturing and analysis.

Mission

To promote public health and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.



Mandate

- To publish new edition and addendums of the Indian Pharmacopoeia.
- To publish the National Formulary of India.
- Certification and distribution of IP Reference Substances.
- National Coordination Centre (NCC) for running Pharmacovigilance Programme of India (PvPI)
- To establish working relations with other similarly placed institutions at National and International level.
- To organize educational programs, skill development and research activities.



Publication of Indian Pharmacopoeia

(By IP Committee)

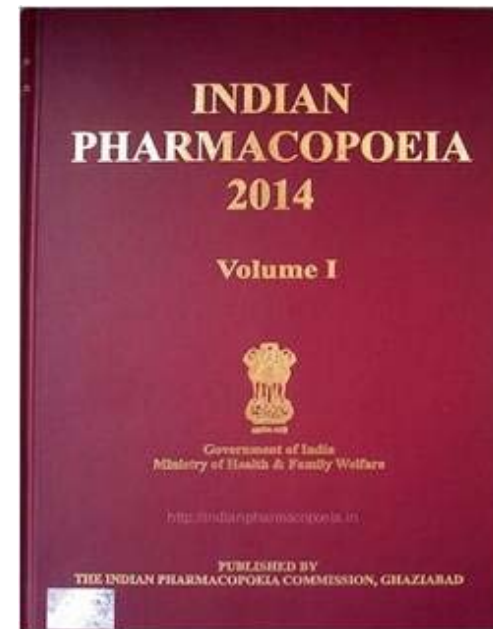
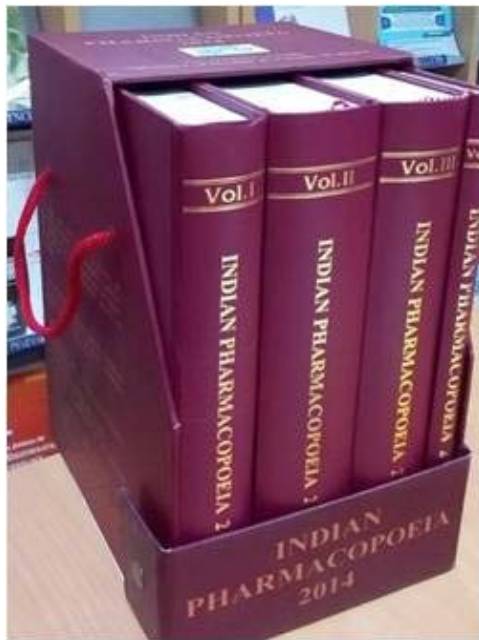
<u>Edition</u>	<u>Year</u>
I	1955
Supplement	1960
II	1966
Supplement	1975
III	1985
Addendum	1989 & 1991
IV	1996
Addendum	2000
Vet Supplement	2000
Addendum	2002

(By IP Commission)

<u>Edition</u>	<u>Year</u>
Addendum	2005
V	2007
Addendum	2008
VI	2010
Addendum	2012
VII (New Edition)	2014
Addendum	2015
Addendum	2016
VIII	2018
	(Under Preparation)

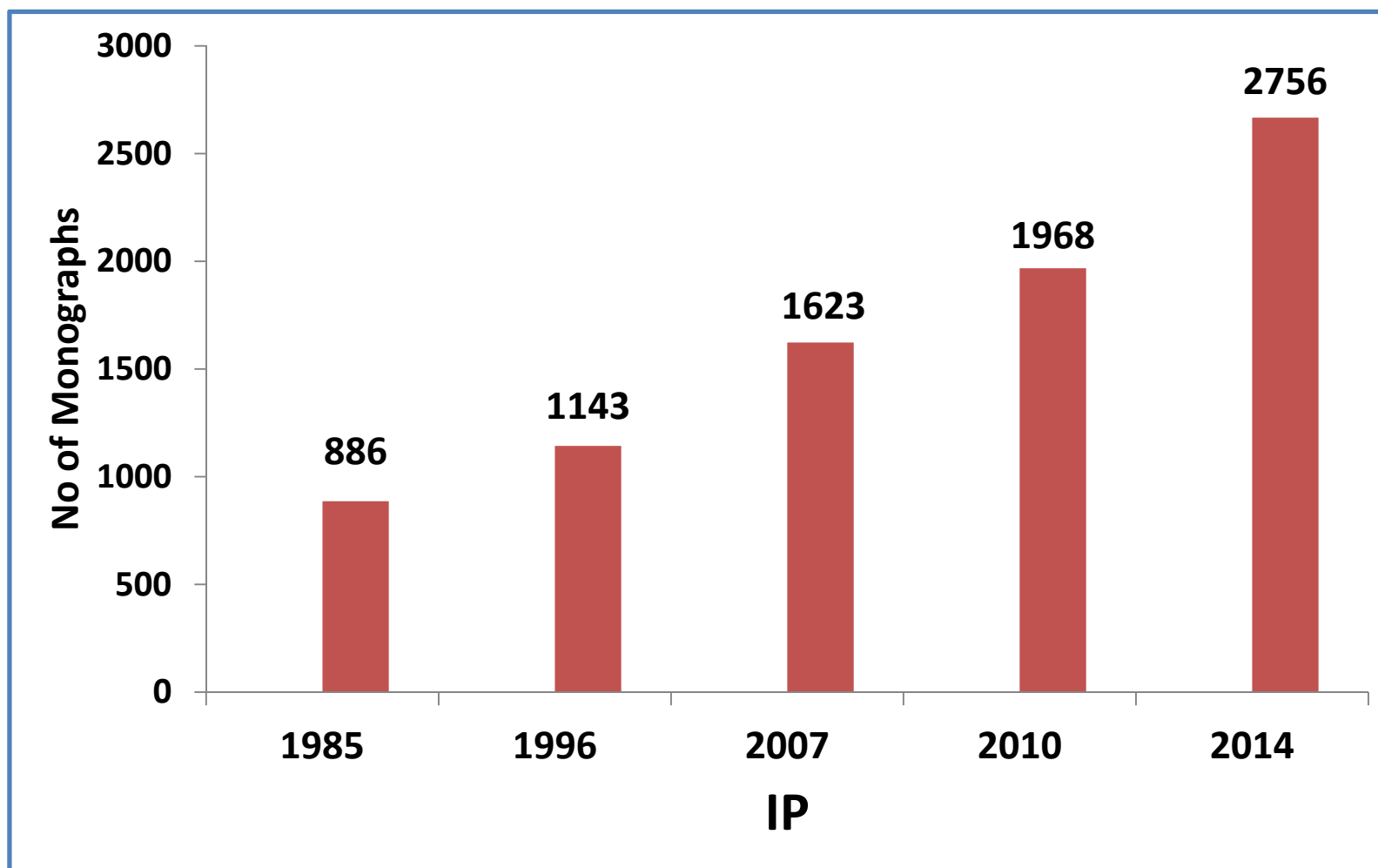


Latest Edition : IP 2014





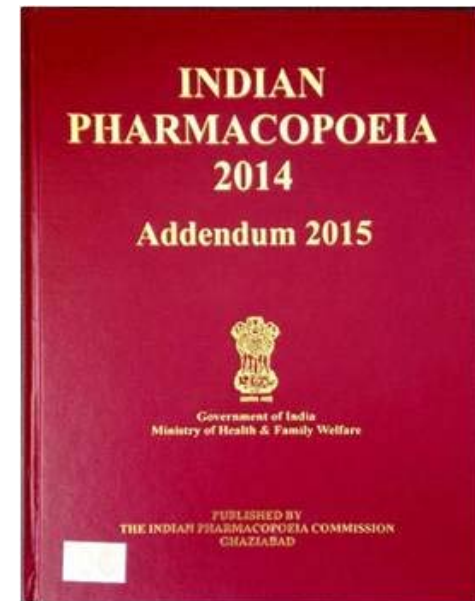
Monographs Developed





IP- Addendum-2015 to IP-2014

- 57 New Chemical monographs
- 13 New Herbal monographs
- 02 New Human Vaccines Monographs
- 10 Radiopharmaceutical Monographs
- 06 Revised monographs
- 29 Revised tests





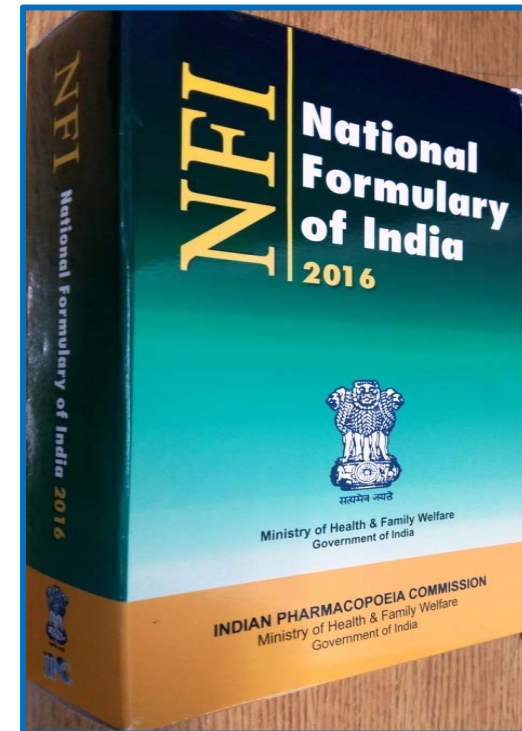
IP Addendum -2016

- 64 New Chemical Monographs
- 14 New Herbal Monographs
- 03 New Human Vaccines Monographs
- 03 Radiopharmaceutical Monographs
- 04 Biotechnology Products



National Formulary of India

- A guidance document to Medical Practitioners, Pharmacists, Nurses, Medical and Pharmacy Students, other Healthcare Professionals and stakeholders in healthcare System.



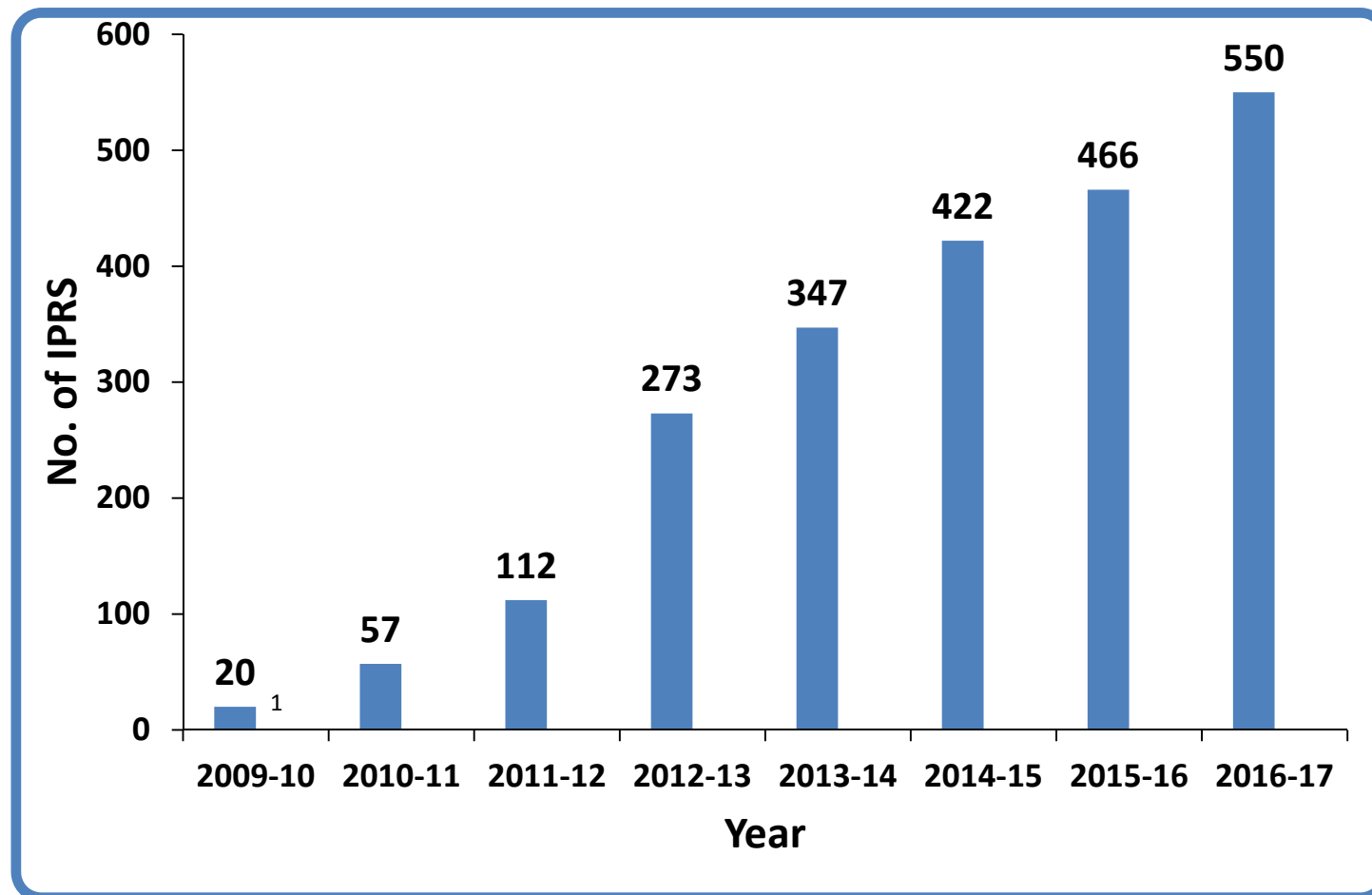


NFI- Special Features

- Total drug monographs 521
- Chapters 33
- Fixed dose combinations (FDCs) 33
- Immunological 20
- Vitamins 12
- Unique, highly informative and useful Appendices 22

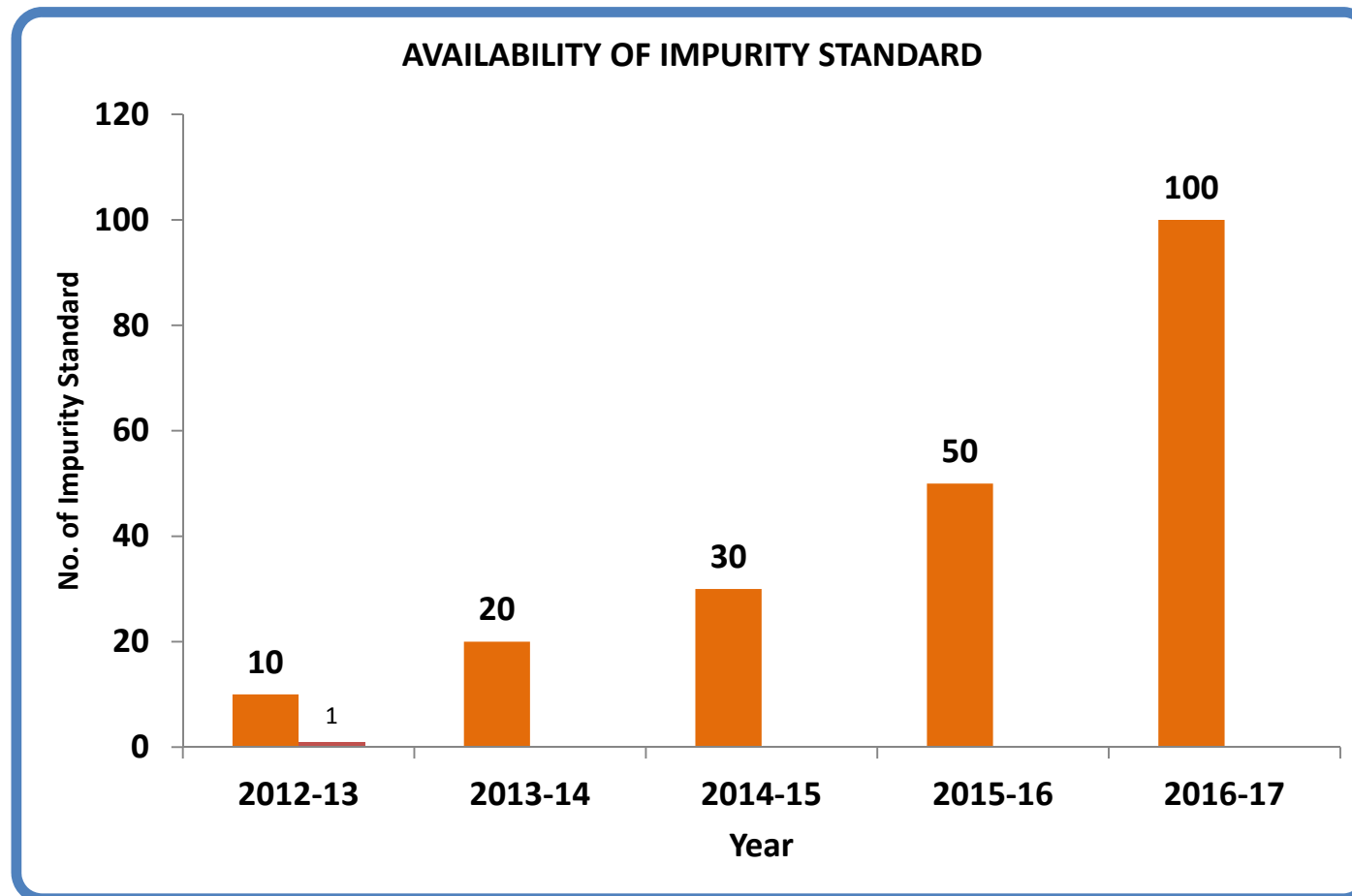


Availability of IP Reference Standards





Availability of Impurity Standards





Indian Pharmacopoeial Laboratory





Indian Pharmacopoeial Laboratory

- **ISO Guide 34 : 2009** for “Reference Material Producer”
- **WHO** Pre-qualified for Quality Control Laboratory
- **ISO/IEC 17025:2005** Accredited for Chemical and Biological Analysis.





International Cooperation

- World Health Organization (**WHO**)
- European Directorate for the Quality of Medicines (**EDQM**)
- Japanese Pharmacopoeia (**JP**)
- United States Pharmacopeia (**USP**)
- Chinese Pharmacopoeia (**ChP**)



International meeting of World Pharmacopoeias

- Active participation in World Pharmacopoeias Meetings for WHO Good Pharmacopoeia Practices (GPhP)
- Strengthening Global Pharmacopoeia Cooperation
- GPhP will enable transparency on development of Pharmacopoeial Standards



Second International Meeting of World Pharmacopoeias

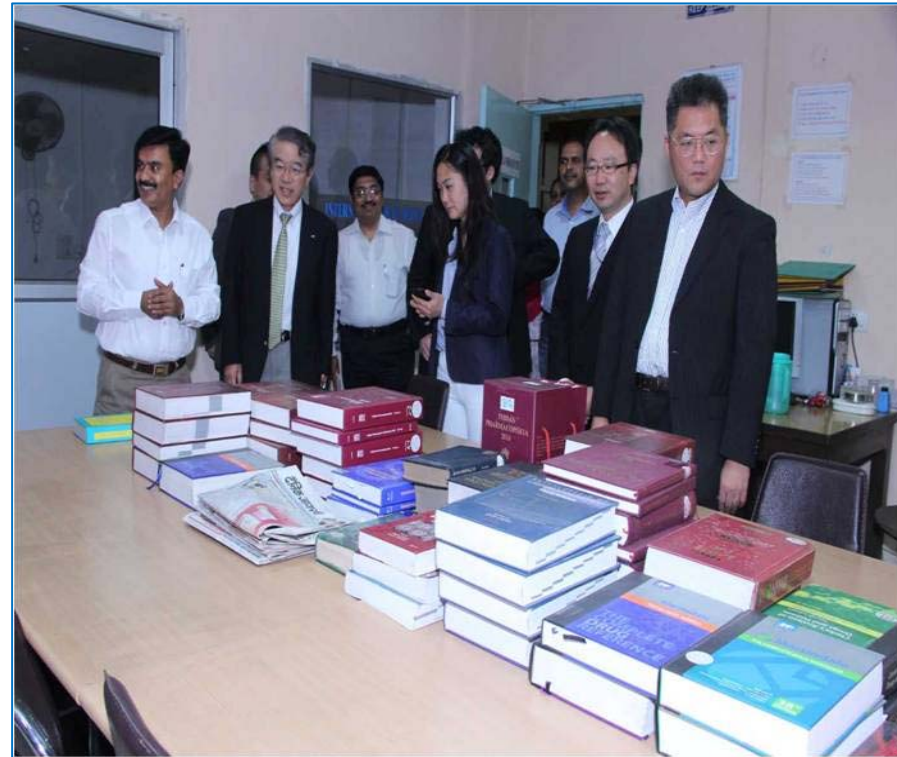


18-19 April 2013, New Delhi, India

- Co-hosted by the **Indian Pharmacopoeia Commission** and **WHO**
- Discussion of DRAFT Good Pharmacopoeial Practices

JP - IPC Meeting

- PMDA , JP team visited at IPC on 28th May 2015



PMDA - IPC Meeting



Group photo of IPC and PMDA team



International Cooperation

- Significant contribution in drafting Good Pharmacopoeial Practices, Chapters on Analytical Method Development, Validation & Herbal monographs



International Harmonization

IPC strengthen its efforts to work with

- Pharmacopeias,
- Industry,
- Academia,
- Regulators,
- Stakeholders

to develop harmonized global standards



International Harmonization

- Discussion with other pharmacopoeias
- Exploring scientists exchange programme
- International training programme
- Resolving regional issues
- Conferences / symposia



International Harmonization

- Focusing to Harmonize General Chapters of IP with other World Pharmacopoeias
- Updating the monographs with new Science and Technology inputs
- Coordinating and contributing with WHO for Good Pharmacopoeial Practices for Chemical and Herbal Monographs
- Active participation in development of International Chemical Reference Standards organised by EDQM and WHO



Skill Development

- IPC organizes skill development programs/ workshops for professional:
 - Analysts (Hands on training)
 - Drug Regulators
 - Research Students
 - Stakeholders
- Offers training for Analysts and Regulators from SAARC & ASEAN countries
- Offers support for Standards setting in Pharmaceuticals



Way Ahead: 2020

- Targeting for 800 IPRS.
- Targeting 300 Impurity Standards
- Enhancing the scope of **Green** Analytical Chemistry.
- Establishing the State-of-the-art laboratory as Referral Laboratory for Analytical investigations.

Way Ahead: 2020

- To make functioning the Advanced Level Research Center by 2017





Expectations form JP

- Mutual cooperation for developing the Pharmaceutical Standards.
- Bilateral cooperation on skill development of Professionals including training for the trainers.
- Knowledge sharing for mutual benefit and opening new areas of collaboration.



Expectations form JP

- IPC offers Indian Pharmacopoeia as a trustworthy Reference Pharmacopoeia to PMDA and expects it to be utilize for ensuring the Quality of Pharmaceuticals in Japan.



Thank you !!

ありがとうございました

Arigatou gozaimasu