INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health & Family Welfare, Government of India)
Sector 23, Raj Nagar, Ghaziabad 201002 (U.P.), India
E-mail: lab.ipc@gov.in; Website: www.ipc.gov.in

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Effective Use of Pharmacopoeia-Indian Model

RAJEEV SINGH RAGHUVANSHI
PhD
SECRETARY-cum-SCIENTIFIC DIRECTOR
INDIAN PHARMACOPOEIA COMMISSION

INTRODUCTION

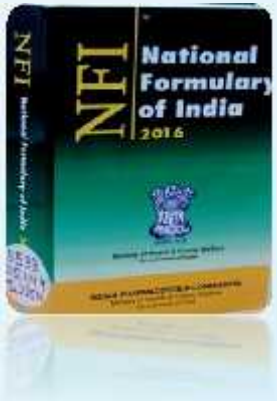
The Govt. of India has created a dedicated and autonomous institution - Indian Pharmacopoeia Commission (IPC) to be custodian of Indian Pharmacopoeia (IP), the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940. It came into existence on 1st January 2009 as an Autonomous Institute

Indian Pharmacopoeia (IP) specifies the Standards of Quality (identify, purity and strength) of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India.

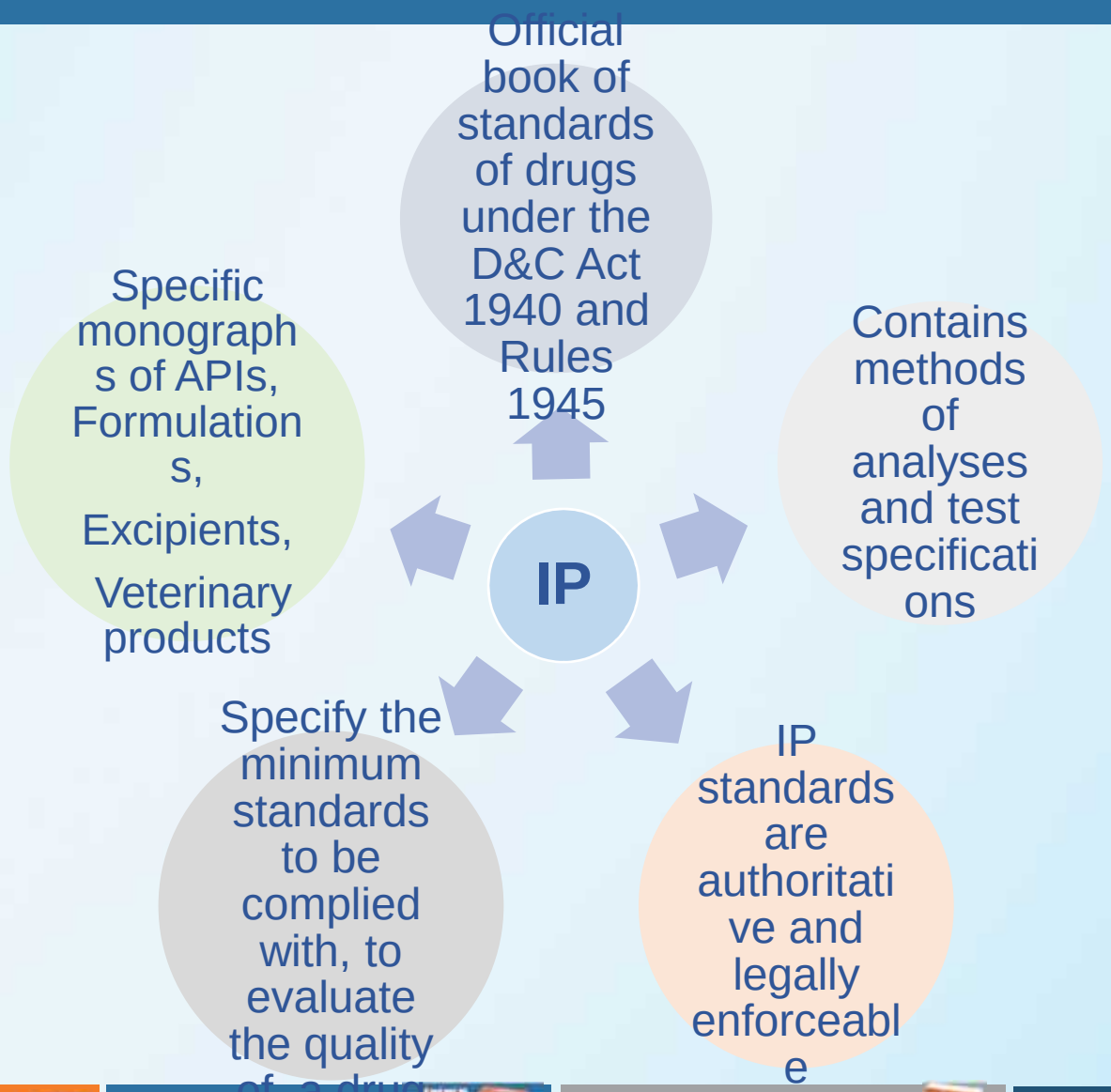
Mandates of Indian Pharmacopoeia Commission

Indian Pharmacopoeia Commission
Ghaziabad

- Indian Pharmacopoeia
- Reference Standards
- National Formulary of India
- Pharmacovigilance Programme of India

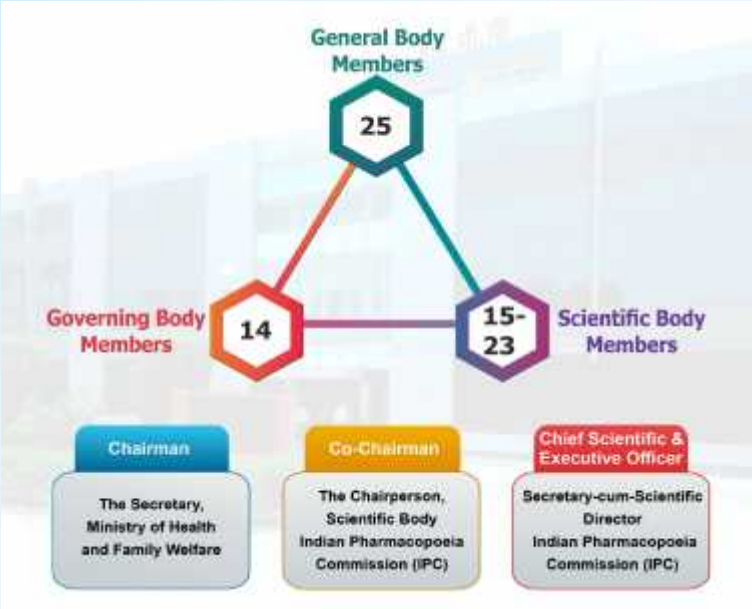


Indian Pharmacopoeia (IP)

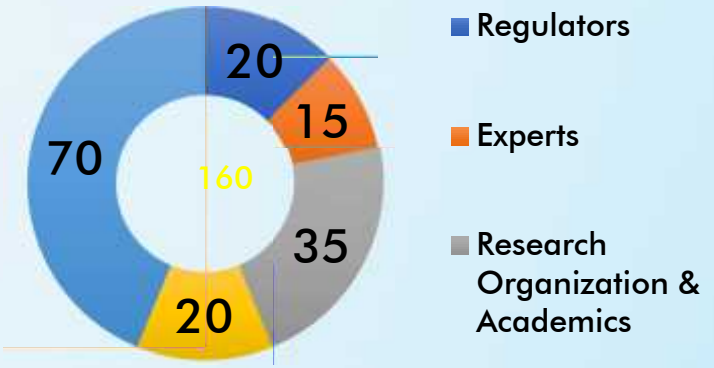


STAKEHOLDERS OF IP

THE EXPERTS BEHIND OUR STANDARDS



160 Scientific- Experts- Volunteers and Government Representatives



- **Leaders in their representative fields in industry, academia, healthcare, regulatory**
- **Together they contribute to standards development through consensus-driven decisions achieved through Expert Committees**
- **Regulators and Government laboratories also contribute through suggesting new methodologies and upgrading existing ones.**

JOURNEY OF IP EDITIONS

1955 — First Edition
1 Volume
986 Monographs
Title of monographs in Latin
Supplement in 1960

1966 — Second Edition
1 Volume
890 Monographs
Title of monographs changed from Latin to English
Supplement in 1975

1985 — Third Edition
1 Volume
886 Monographs
Anti-cancer Monographs Incorporated
Addenda in 1989 & 1991

1996 — Fourth Edition
2 Volumes
1149 Monographs
Addenda in 2000, 2002, and 2005
Veterinary Supplement in 2000

2007 — Fifth Edition
3 Volumes
Published by CIPL
1623 Monographs
Addenda in 2008

2010 — Sixth Edition
3 Volumes
Published by IPC
1968 Monographs
Biotech Monographs Incorporated
Addendum in 2012

2014 — Seventh Edition
4 Volumes
Separate Veterinary Volume
2586 Monographs
Radiopharmaceutical Monographs Incorporated
Addenda in 2015 & 2016

2018 — Eighth Edition
4 Volumes
3060 Monographs
Allergen Monograph Incorporated
Addenda in 2019 & 2021

2022 — Ninth Edition
4 Volumes
Separate Veterinary Volume
3284 Monographs
Radiopharmaceutical Monographs Incorporated
Addenda in 2019 & 2022

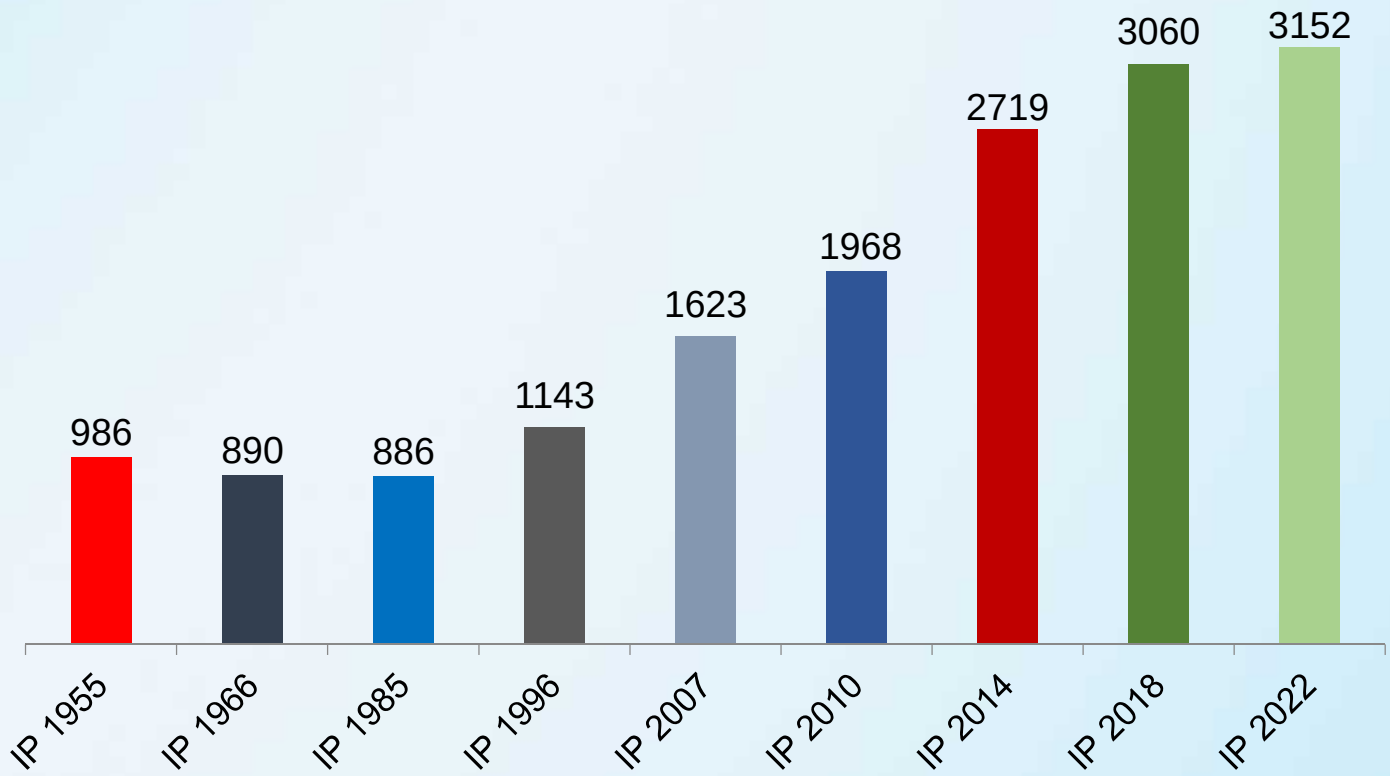
Indian Pharmacopoeia Reference Standards & Impurity Standards

Indian Pharmacopoeia (IP)

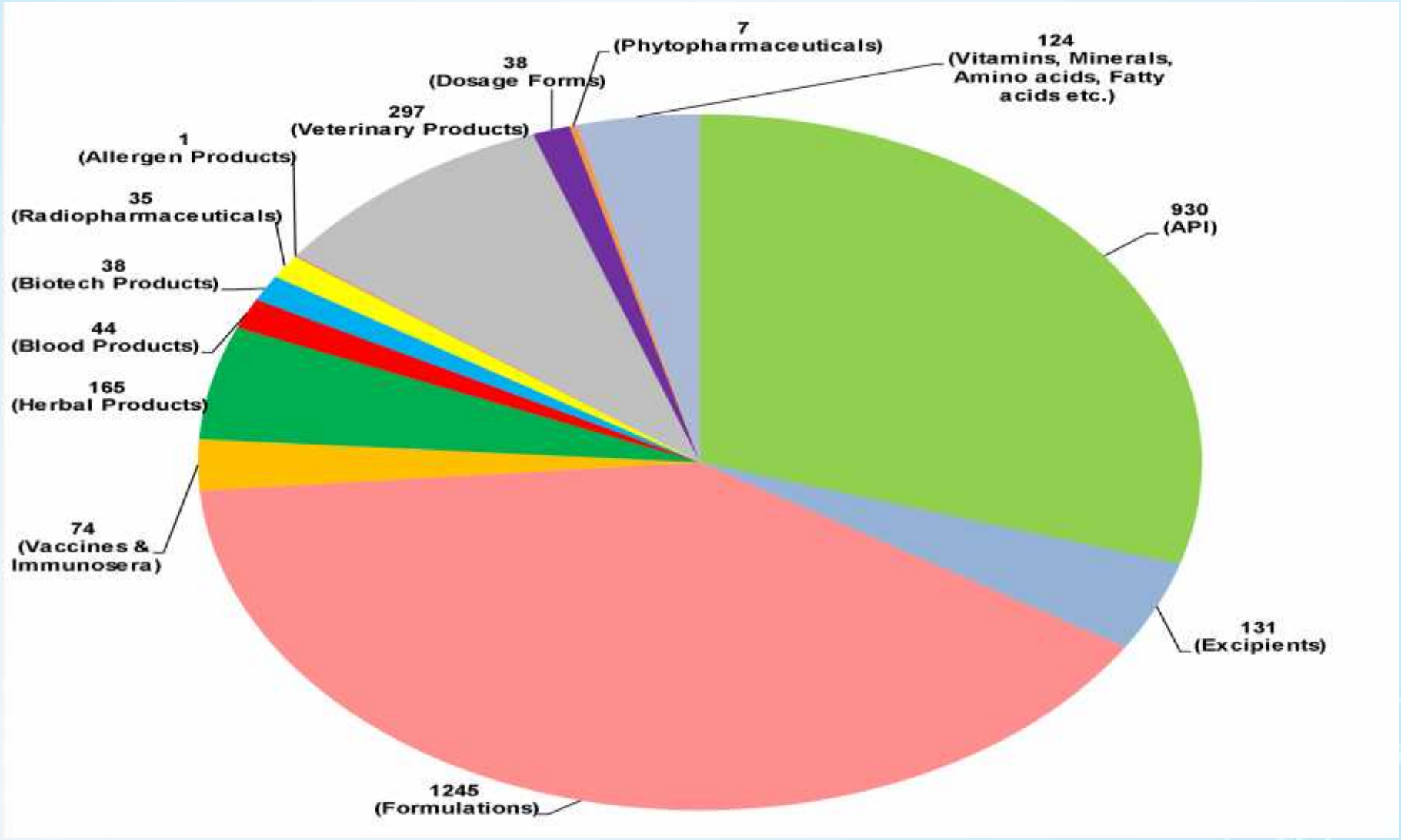
National Formulary of India (NFI)

National Coordination Centre-Pharmacovigilance Programme of India

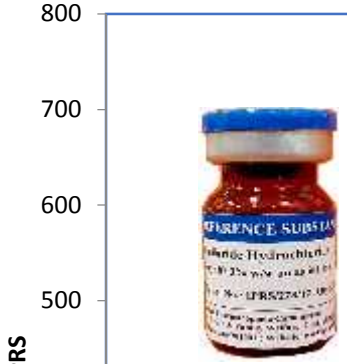
IP Monograph Development



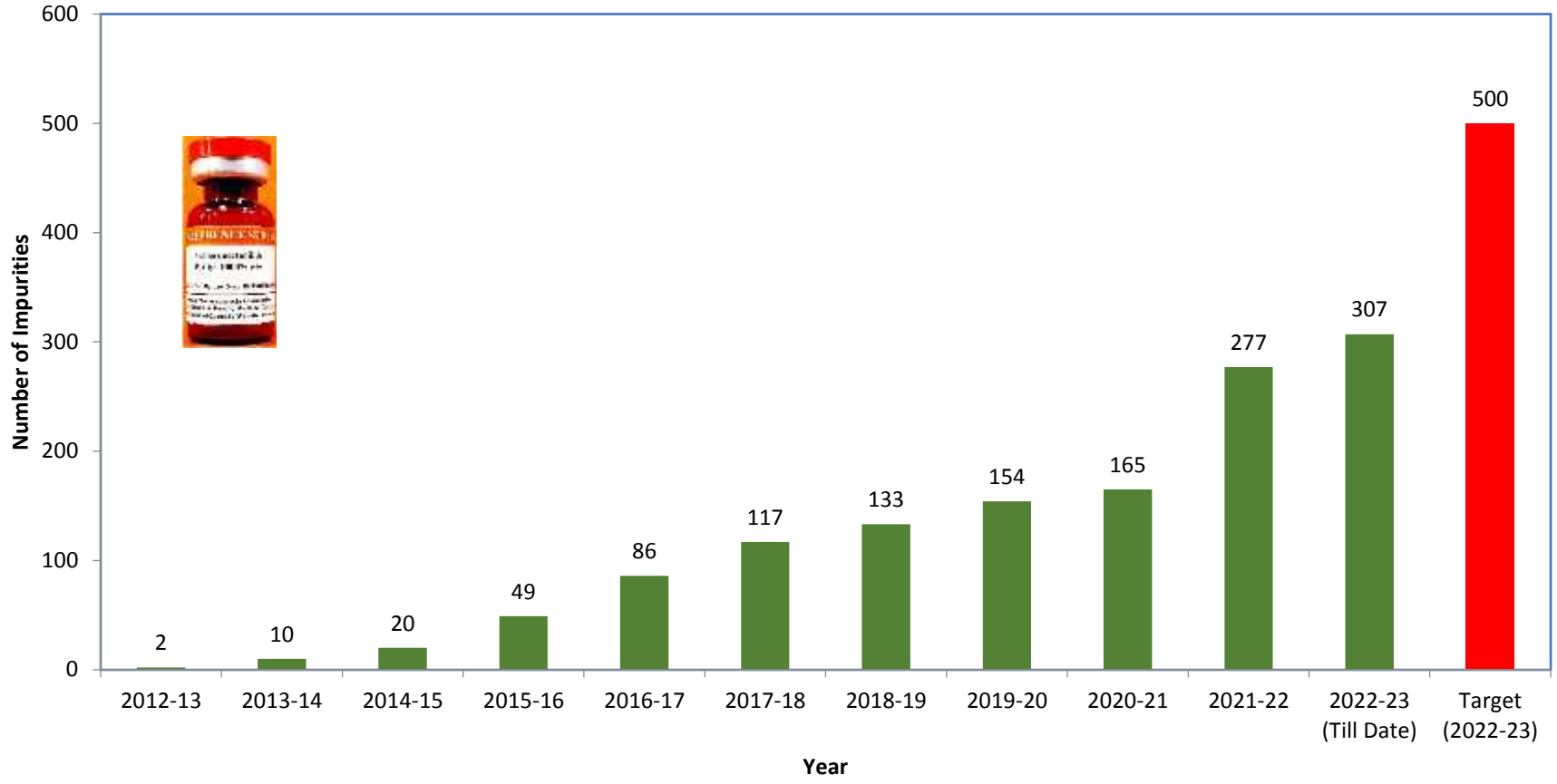
IP 2022 : Monograph Status



Built-up of IPRS Inventory



Built-up of Impurity Standard Inventory



ROLE OF PHARMACOPOEIAL STANDARDS

- Mandatory Public standards and legally authoritative
- Provide **independent assessment** of identity, quality, strength, and purity of therapeutics
- **Quality at par with international quality standards**
- Integrate **harmonized testing** into a public standard so that safety and quality are preserved
- Scope of testing from **production to consumption**

IP's COVERAGE OF DIFFERENT DRUG LISTS

1	COVERAGE OF NLEM DRUGS	95.8 %
2	COVERAGE OF TOP 300 BRANDS	73%
3	COVERAGE OF WHO ESSENTIAL DRUGS LIST	66%

ALBENDAZOLE – A CASE STUDY

- Albendazole is an effective treatment for a range of parasitic diseases
- Till 2018 IP, Albendazole monograph was not having dissolution test
- Disintegration test does not address concerns about the efficacy of tablets
- For Albendazole chewable tablets, disintegration testing cannot replace dissolution testing as the solubility of Albendazole is reported to be low
- In absence of dissolution test, the bioavailability of the product is unpredictable, leading to ineffective products in use for mass administration
- Surveys have shown that the dissolution properties of

ALBENDAZOLE – A CASE STUDY

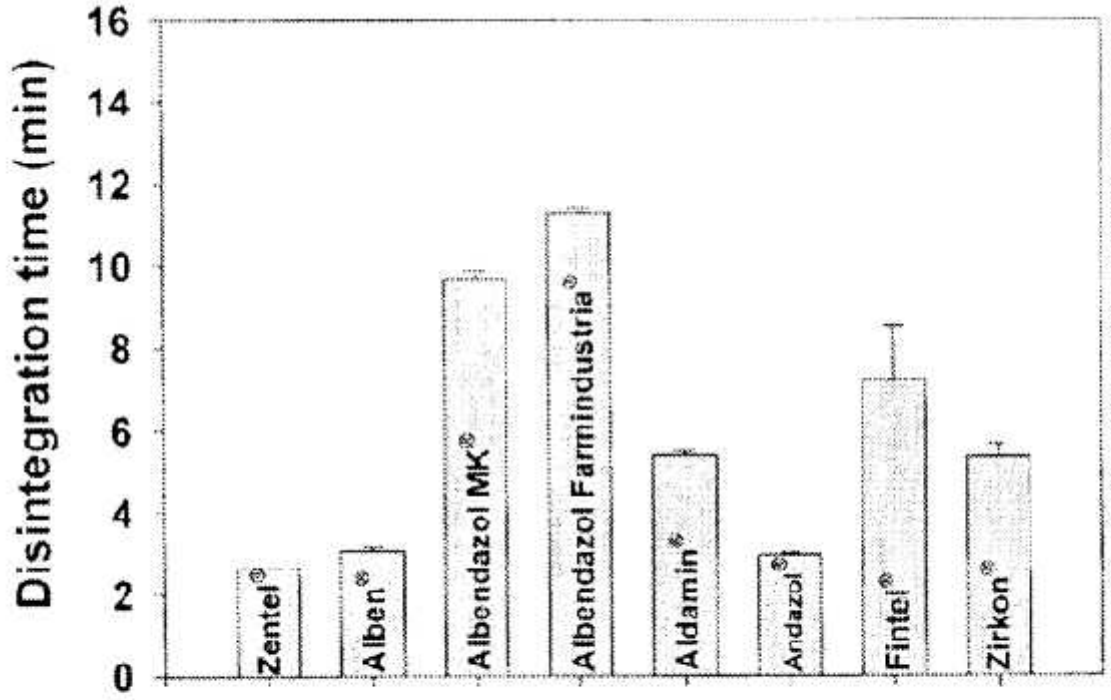


Fig. 5. Mean disintegration times of all tested albendazole products (n = 3; ± SD). The EP acceptance criterion is completion of disintegration within 15 minutes.

Ref: Albendazole Generics-A Comparative In Vitro Study; Dressman et al, Pharm. Res., 16(12), 1999, 1871-1875

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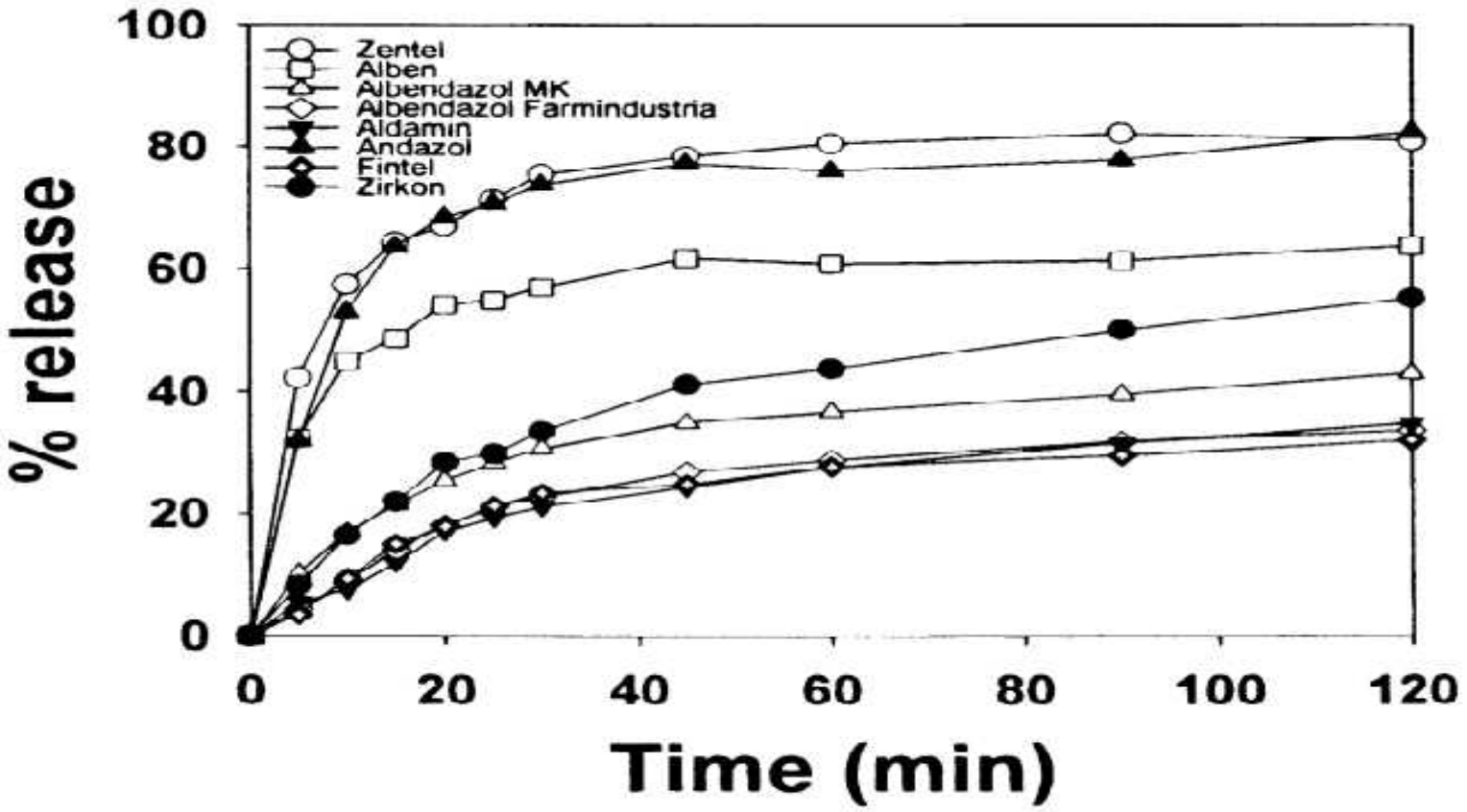


Fig. 3. Mean dissolution profiles of various albendazole formulations in SGF_{sp} at 100 rpm.

Ref: Albendazole Generics-A Comparative In Vitro Study; Dressman et al, Pharm. Res., 16(12), 1999, 1871-1875

RAPID MICROBIOLOGICAL METHODS

Chapter 2.2.30 [IP 2022]

Approach to alternative micro-biological methods. New chapter incorporated in harmonization with USP, BP and EP.

NEW INNITIATIVES AT IPC WITH HIGH IMPACT ON PUBLIC HEALTH

1 DIGITAL IP – SHOULD BE AVAILABLE BY END OF FY'23

2 INCREASING INVENTORY AND STAKEHOLDER AWARENESS ON IMPURITY STANDARDS USE AND IMPORTANCE

4 IMPURITY LIMITS HARMONIZED WITH ICH RECOMMENDATION

5 JOINING PDG PILOT – GLOBAL INITIATIVE TOWARDS HARMONIZATION OF PHARMACOPOEIA

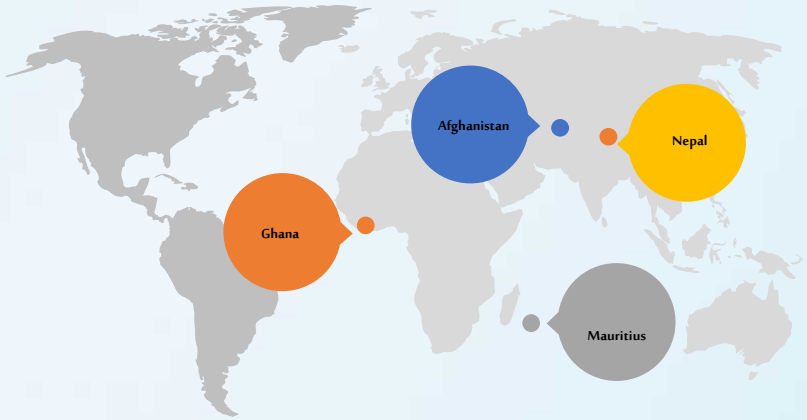
PHARMACEUTICAL DISCUSSION GROUP (PDG)

ORIGINALLY, GROUP OF 3 PHARMACOPOEIAS

USP, EP & JP

INDIAN PHARMACOPOEIA HAS BEEN RECENTLY ADDED TO THE GROUP. ONLY PHARMACOPOEIA IN THE WORLD TO GET SELECTED FOR PILOT PROGRAM FOR PDG EXPANSION

RECOGNITION OF IP IN FOREIGN COUNTRIES



IP has been accepted as a book of standards in a total of four countries

Thank You

USE OF IP & IPRS IS SOCIAL AND LEGAL OBLIGATION

FOR “IP” PRODUCTS