To Further Internationalization of Japanese Pharmacopoeia

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Office of Standards and Guidelines Development,
Pharmaceuticals and Medical Devices Agency (PMDA)
1. Introduction: What is JP?
- Article 2 -

The term “drug” in this Law refers to the following items:

1. **Items recognized in the Japanese Pharmacopoeia.**
2. Items (excluding quasi-drugs or cellular and tissue-based products) which are intended for use in the diagnosis, cure or prevention of disease in humans or animals, and which are not equipment or instruments.
3. Items (excluding quasi-drugs or cosmetics) which are intended to affect the structure or functions of the body of humans or animals, and which are not equipment or instruments.
Introduction: Legal Status of JP

- Article 56 -

No drug which comes under any of the following items shall be sold or given, or manufactured, imported, stored, or exhibited for the purpose of sale or giving:

1. The quality or properties are not in conformity with the standards established by Japanese Pharmacopoeia (JP)
# History of JP Edition

<table>
<thead>
<tr>
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Structure of Japanese Pharmacopoeia

● Main Body (Mandatory part)
  1. General Notices - general rules for drafting, interpreting, and utilizing the Japanese Pharmacopoeia
  2. General Rules for Crude Drugs - general rules for drafting, interpreting, and utilizing the official monographs of crude drugs
  3. General Rules for Pharmaceutical dosage forms - common rules and interpretation about preparations
  4. General Tests, Processes and Apparatus - highly common test methods
  5. Official Monographs - specifications and test methods per drug
  6. Infrared Reference Spectra and Ultraviolet-visible Reference Spectra

● General Information
Structure of JP development and implementation

- Pharmaceutical Affairs and Food Sanitation Council (PAFSC)
- Ministry of Health, Labour and Welfare
- JP Secretariat
- JP Expert Committees
- Development of JP

PMDA

Reference Standards

NIID

registration
Notice
Commission
Report

distributor
Organization of JP Expert Committees

Standing Committee

- Com. on Reference Standards
- Com. on Biologicals
- Com. on Crude Drugs (A), (B)
- Com. on Excipients
- Com. on Nomenclature for pharmaceuticals
- Com. on Reference Standards
- Com. on Drug Formulation – 3WGs
- Com. on Physical Methods
- Com. on Biological Methods
- Com. on Physico-Chemical Methods
- Com. on International Harmonization

For Monographs

For General tests
Methodology of developing JP monographs with high transparency

- Determination of Drugs to be listed in JP
  - PMDA
  - Industry Draft
  - Secretariat’s Draft
  - Expert Committees- Review
  - JP Draft for Public Comment
  - JP Final Draft

- Sponsor
- Stakeholders
- MHLW, JP Committee/PAFSC
- Adoption of JP

2016/5/18
India-Japan 2016
Methodology of developing JP General tests with harmonization

Proposal from PDG, Experts, Industries

PMDA

Expert’s Draft

Expert Committees- Review

JP Draft for Public Comment

JP Final Draft

PDG

input

Discussion

Projects in Research Institute, Accumulated knowledge in industries

Public Comments

Stakeholders

MHLW, JP Committee/ PAFSC

Adoption of JP

Public Comments

2016/5/18

India-Japan 2016
Top Sales Drugs in Japan: Many drugs are originated from Japan

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<thead>
<tr>
<th>rank</th>
<th>Drug substance</th>
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<tr>
<td>1</td>
<td>Clopidogrel Sulfate</td>
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<tr>
<td>2</td>
<td>Valsartan</td>
</tr>
<tr>
<td>3</td>
<td>Candesartan Cilexetil</td>
</tr>
<tr>
<td>4</td>
<td>Sitagliptin Phosphate Hydrate</td>
</tr>
<tr>
<td>5</td>
<td>Olmesartan Medoxomil</td>
</tr>
<tr>
<td>6</td>
<td>infliximab (genetical recombination)</td>
</tr>
<tr>
<td>7</td>
<td>Ketoprofen</td>
</tr>
<tr>
<td>8</td>
<td>Bevacizumab (Genetical Recombination)</td>
</tr>
<tr>
<td>9</td>
<td>Lansoprazole</td>
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<tr>
<td>10</td>
<td>Donepezil Hydrochloride</td>
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<tr>
<td>11</td>
<td>Leuprorelin Acetate</td>
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<tr>
<td>12</td>
<td>Telmisartan</td>
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<tr>
<td>13</td>
<td>Loxoprofen Sodium Hydrate</td>
</tr>
<tr>
<td>14</td>
<td>Olanzapine</td>
</tr>
<tr>
<td>15</td>
<td>Darbepoetin Alfa (genetical recombination)</td>
</tr>
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<table>
<thead>
<tr>
<th>rank</th>
<th>Drug substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
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<td>19</td>
<td>Fexofenadine Hydrochloride</td>
</tr>
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<td>20</td>
<td>Etanercept (genetical recombination)</td>
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<tr>
<td>21</td>
<td>Rosuvastatin Calcium</td>
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<td>22</td>
<td>Celecoxib</td>
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<td>Imatinib Mesilate</td>
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<tr>
<td>28</td>
<td>Pemetrexed Sodium Hydrate</td>
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<tr>
<td>29</td>
<td>Vildagliptin</td>
</tr>
<tr>
<td>30</td>
<td>Aripiprazole</td>
</tr>
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</table>

# Top Sales in Japan vs Listing in JP

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<th>rank</th>
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<th>JP</th>
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<tr>
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<tr>
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<td>Valsartan</td>
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<td>3</td>
<td>Candesartan Cilexetil</td>
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</tr>
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<td>4</td>
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2. Internationalization of JP
Policies on Drafting of JP 17th Edition

1. Providing all drugs essential for health care and medical treatment
2. Improving quality by introducing the latest science and technology
3. Promoting internationalization
4. Timely updating and revising as necessary and facilitating smooth administrative operation
5. Ensuring transparency in process and disseminating JP

Administrative Notice, September 13, 2011, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
Background: Gap between JP standards and ICH standards

- ICH-Q guidelines (Q1, Q3, Q5, Q6 etc) addresses the marketing approval of new drug products, and in JP styles are not properly subject to ICH-Q guidelines.

- The specification of the new drug products are changed to JP styles especially in impurity test, as listed in JP monographs.

The style of JP monograph are reevaluated for new drugs to fit in.
Trend 1: Globalization

Globalization of Raw Materials of Drug

Registration of the Drug Master File (DMF) by manufacturers

PMDA, 2011-2014. August

- Japan 24%
- China 14%
- Korea 11%
- Europe 16%
- Taiwan 5%
- India 20%
- Other 10%
Issues of Globalization

- A JP test standard could pose an obstacle to procurement of drug substances from the countries or regions outside of Japan.
- As the supply chains of drug substances are diversified, a risk with raw materials would be directly linked to the Japanese clinical practice.
- Gaps of the policies between JP and other pharmacopoeia could be difficult to understand for people outside of Japan, and could potentially cause mistaken notion of conformity with JP standards.
Trend 2: Diversification and Progress of Quality Control

- A certain period of time has past after application of ICH Q8-Q11.
- The new drugs (e.g. biological products) that require the process controls have increased.
- The formulation development and control of generic drugs have been diversified.

The style of JP monograph are reevaluated for drugs with multiple variety of process-controls to fit in.
Japanese Pharmacopoeia in the Past

Globalization

Standards set in JP

Approved as the drugs that conform to JP

Progress of technology and quality control
Japanese Pharmacopoeia of the 17th edition

Globalization

- Derivation of JP drugs to other countries
- Increase in supply of raw materials from overseas
- Potential Adulteration

Approved as the drugs that conform to JP

Progress of technology and quality control

- Diversification of Quality Control
- Increase in preparations that require in-process controls

Standards set in JP

Increase in supply of raw materials from overseas
Major Revision Points in JP17

- New policies of specification setting of impurities in JP monographs
- New articles about production and quality control
- Introduction of new headings of “Production” and “Potential adulteration”
- Comprehensive regulation of residual solvents.
- Revision of Containers and Packages
- Revision related to the Biological methods
New policies of specification setting of impurities in JP monographs

- The purity test using the reference standards of impurities
  - Chromatographic method using the reference standards of impurities will be adapted in the Purity test.

- The second test method for the purity test
  - For the drugs manufactured by a different chemical syntheses and thus having a different impurity profile, the Second Test Method may be adopted in the Purity test.
New articles about production and quality control

- Following articles are to be adopted in General Information
  - “Basic concepts of quality assurance of drug substances and drug products”, which is based on ICH-Q6A and Q6B philosophy
  - “Basic concepts of quality risk managements”, which is based on ICH-Q9 philosophy
Revision regarding the Reference Standards

- Adoption of a new concept for Reference Standards were discussed, considering the consistency with other pharmacopoeias
  - Requirements to set the Reference Standards used for the tests other than the Assay in the Official Monograph
  - Requirements for the specification of the Reference Standards used for non-Assay tests
  - Consideration of influence on the distributors of Reference Standards
- Revision of General Test, <9.01> Reference Standards
· Expediting the global utilization of the Japanese Pharmacopoeia
  - Further expedite harmonization of the JP, USP and EP through the activities of the PDG.
  - Contribute to improving quality of pharmaceuticals that are globally distributed, by proactively incorporating in the JP the concept of quality assurance based on cutting-edge science, and by promoting JP as one of the reference pharmacopoeia in other countries/regions.
3. Initiative of the cooperation with India
India is the largest exporting country of the drug raw materials to Japan.
Further mutual understanding of JP is expected

To establish the conformity to JP, MAH and manufacturers are highly encouraged to understand the policies and details of JP.

JP provides the standardization and homogenization of quality for Japanese market.
Further mutual understanding between IP and JP is expected

To convergence the regulation for drug approval, basal concepts of the review and evaluation process of drugs referring the compendial standards should be shared.
Considering globalization of drug supply chain and progress and diversification of quality control, there is a need to change the quality of Japanese Pharmacopoeia (JP) as well as the JP’s position in the reviews of marketing applications.

Keeping qualitative fulfillment, JP will proactively make international development.

To convergence the regulation for drug approval, basal concepts of the review and evaluation process of drugs referring the JP should be shared with IP.
Indian Pharmacopoeia

India – Japan Regulatory Symposium

18th May 2016, New Delhi

Dr. P. L. Sahu
Principal Scientific Officer,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare, Government of India
Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Development Programs
- Way Ahead 2020
Overview

- **Indian Pharmacopoeia Commission**
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Development Programs
- Way Ahead 2020
Introduction

• The Commission has become operational from 1st Jan., 2009 as an Autonomous Body, 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 and the Member Secretary of the all the three bodies of IPC.
Composition of Commission

Secretary cum Scientific Director

- Governing Body
  Members- 13

- General Body
  Members- 25

- Scientific Body
  Members- 15-23
Vision & Mission

**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.
Overview

- Indian Pharmacopoeia Commission
- **Indian Pharmacopoeia and NFI**
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Developments Programs
- Way ahead 2020
Indian Pharmacopoeia

• Indian Pharmacopoeia plays a significant role by providing the Standards for Drugs and Pharmaceuticals.

• The Monographs of Drugs are official standards.

• Indian Pharmacopoeia (current edition, IP-2014) is a compilation of Monographs and other Standards that are being used in Pharma and Life Science industry as Standards.
<table>
<thead>
<tr>
<th>Edition</th>
<th>Year</th>
<th>Addendum</th>
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IP Monographs development
Indian Pharmacopoeia Commission

Scientific Body approves item for the IP

IPC scientific staff liaison and review item

Items displayed on the website and mailed separately for public review

Comment received

Expert committee review comments and respond in the scientific staff liaison

IPC Scientific Staff liaison, compile and analyze comment

No further revision needed

Proposal accepted and published

Indian Pharmacopoeia Commission

Feedback from stakeholder

Further revision needed

Comments and responses displayed on website/mailed
During developing standards for IP 2014, tried to harmonize it with other Pharmacopoeias of the world without compromising with the quality of the products.
IP-2014: Salient features

- 577 New Monographs added comprising of 134 API monographs, 161 Formulations monographs, 18 Excipients monographs, 43 NDS monographs, 10 Antibiotic monographs, 19 Anticancer monographs, 11 Antiviral monographs

- Also 31 Herbal monographs, 05 monographs on Vaccine & immunosera for human use, 06 monographs on Insulin products and 07 monographs on biotechnology products are included.

- 19 New General Chapters and about 200 New IR spectra’s are also added

- **First time** 19 new Monographs on Radiopharmaceutical with one General Chapter on Radiopharmaceutical preparations included

- A **separate volume** of veterinary products is also introduced for easy access which include 143 monographs on veterinary products along with 16 General chapter
**IP-2014: Salient features**

- **Anticancer** monographs incorporated in IP are not available in other Pharmacopoeias.

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<th>S. No</th>
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<tr>
<td>1</td>
<td>Anastrazole Tablets</td>
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<td>Imatinib Tablets</td>
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<tr>
<td>2</td>
<td>Bortezomib</td>
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<td>Lapatinib Ditosylate</td>
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<td>3</td>
<td>Erlotinib Hydrochloride</td>
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<td>Lapatinib Tablets</td>
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<td>Erlotinib Tablets</td>
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<td>Sorafenib Tablets</td>
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<td>5</td>
<td>Gefitinib</td>
<td>12</td>
<td>Sorafenib Tosylate</td>
</tr>
<tr>
<td>6</td>
<td>Gefitinib tablets</td>
<td>13</td>
<td>Topotecan Hydrochloride</td>
</tr>
<tr>
<td>7</td>
<td>Imatinib capsules</td>
<td>14</td>
<td>Topotecan Injection</td>
</tr>
</tbody>
</table>
IP-2014: Salient features

- **Anti Tubercular** monographs incorporated in IP are not available in other Pharmacopoeia.

  - S. No.  | Anti Tubercular drugs                      
           | S. No.  | Anti Retroviral drugs                    
           |         |                                  
           | 1       | Nelfinavir Tablets                      
           | 2       | Stavudine & Lamivudine Tablets           
           | 3       | Nelfinavir Mesylate                     
           | 4       | Nelfinavir Mesylate Oral Powder         
           | 5       | Tenofovir & Emtricitabine Tablets       
           | 6       | Tenofovir Disoproxil Fumarate          
           | 7       | Tenofovir Disoproxil Fumarate Tablets  

- **Anti Retroviral** monographs included in IP are not available in other Pharmacopoeia.
**IP-2014: Salient features**

- **Radiopharmaceutical monographs included in IP are not present in other Pharmacopoeia**

<table>
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<tr>
<th>S. No</th>
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<td>Technetium ($^{99m}$Tc) EC Injection.</td>
</tr>
<tr>
<td>2</td>
<td>Technetium ($^{99m}$Tc) Trodat- 1 Inj.</td>
</tr>
<tr>
<td>3</td>
<td>Technetium ($^{99m}$Tc) HYNIC TOC Inj.</td>
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</tbody>
</table>

- **Biotechnology Product monographs incorporated in IP are not present in other Pharmacopoeia**

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<tbody>
<tr>
<td>1</td>
<td>Biphasic Insulin Aspart Injection</td>
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<td>Recombinant Streptokinase Bulk Solution</td>
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<tr>
<td>3</td>
<td>Recombinant Streptokinase for Injection</td>
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<td>4</td>
<td>Filgrastim Injection</td>
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</table>
Release of IP-2014

Indian Pharmacopoeia Commission
Release of IP Addendum-2015

Released on 28th Nov. 2014 by Sh. Lov Verma, Secretary, MoH & FW and Chairman, IPC at Nirman Bhawan, New Delhi.
No. of Monograph for Anticancer

- 1985: 5
- 1996: 48
- 2007: 70
- 2010: 89
- 2014: 114
No. of Monographs for Antiretroviral

![Bar chart showing the number of monographs for antiretroviral drugs from 1985 to 2014. The chart indicates a significant increase from 1985 with 0 monographs, to 2014 with 60 monographs.](chart.png)
No. of Monograph for Herbal

![Bar Chart]

- 1985: 14
- 1996: 20
- 2007: 58
- 2010: 89
- 2014: 146

No of Monographs

Indian Pharmacopoeia Commission
General Chapters

No of Gen Chapters

IP


116 121 166 171 199

Indian Pharmacopoeia Commission
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
- 20 New IR spectra
**Addendum 2015 (Salient features)**

- The Following monographs included in this addendum and not present in any other Pharmacopoeias.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Monograph Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Brimonidine Tartrate Eye Drops</td>
</tr>
<tr>
<td>2</td>
<td>Citicoline Prolonged release Tablet</td>
</tr>
<tr>
<td>3</td>
<td>Citicoline Sodium Tablets</td>
</tr>
<tr>
<td>4</td>
<td>Dutasteride Capsules</td>
</tr>
<tr>
<td>5</td>
<td>Eslicarbazepine Tablets</td>
</tr>
<tr>
<td>6</td>
<td>Illoperidone Tablets</td>
</tr>
<tr>
<td>7</td>
<td>Ketotifen Fumarate Tablets</td>
</tr>
<tr>
<td>8</td>
<td>Rabeprazole Injection</td>
</tr>
<tr>
<td>9</td>
<td>Tolterodine Tartrate Tablets</td>
</tr>
</tbody>
</table>
IP Addendum -2016

- 64 New Chemical Monographs
- 14 New Herbal Monographs
- 03 New Human Vaccines Monographs
- 03 Radiopharmaceutical Monographs
- 04 Biotechnology Products
- 01 Blood and Blood Products
- 18 New IR Spectra
- 12 TLC Chromatogram
- 20 HPLC Chromatograms
**Addendum 2016 (Salient features)**

- The Following monographs incorporated in this addendum and not present in any other Pharmacopoeias.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Monograph Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Zolmitriptan Nasal Spray</td>
</tr>
<tr>
<td>2</td>
<td>Drotaverine Hydrochloride</td>
</tr>
<tr>
<td>3</td>
<td>Bendamustine Hydrochloride</td>
</tr>
<tr>
<td>4</td>
<td>Bendamustine Injection</td>
</tr>
<tr>
<td>5</td>
<td>Bortezomib Injection</td>
</tr>
<tr>
<td>6</td>
<td>Abiraterone Acetate</td>
</tr>
<tr>
<td>7</td>
<td>Pemetrexed disodium Injection</td>
</tr>
<tr>
<td>8</td>
<td>Teicoplanin Injection</td>
</tr>
<tr>
<td>9</td>
<td>Pirfenidone Tablets</td>
</tr>
<tr>
<td>10</td>
<td>Pirfenidone</td>
</tr>
<tr>
<td>11</td>
<td>Exemestane</td>
</tr>
<tr>
<td>12</td>
<td>Exemestane Tablets</td>
</tr>
</tbody>
</table>
Release of IP Addendum-2016 to IP-2014
National Formulary of India

• A guidance document to Medical Practitioners Pharmacist, Nurses, Medical and Pharmacy Students, other Healthcare Professionals and stakeholders in healthcare System.
NFI- Special Features

• All drugs of **National List of Essential Medicines (NLEM)** 2011

• **New Chapters:**
  – Basics of medical emergencies
  – Drugs for oral health
  – Medicines banned in sports
NFI- Special Features

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

Storage
Store protected from light at temperature not exceeding 30°C.

Lidocaine (Lignocaine)* (Refer Page No. 417)

Pregnancy Category- B

Indications
Ventricular arrhythmias (especially after myocardial infarction), local anaesthesia.

Availability
INJECTIONS: vial 30 ml (1%, 2% w/v), 50 ml (21.3 mg/ml); 2%/50 ml ampoule 5%/2 ml.
JELLY 2% w/v.

Dose
Adult—Ventricular arrhythmias: loading dose of 50 to 100 mg (or 1 to 1.5 mg/kg) at a rate of 25 to 60 mg/min by intravenous injection, followed immediately by intravenous infusion of 1 to 4 mg/min, with ECG monitoring of all patients (reduce infusion dose if required for longer than 24 h).

Note: Following intravenous Injection, Lidocaine has a short duration of action (of 15 to 20 min). If it cannot be given by intravenous infusion immediately, the initial intravenous injection of 50 to 100 mg can be repeated if necessary once or twice at intervals of not less than 10 min.

Contraindications
Sino-atrial disorder; any grade of atrioventricular block or any other type of conduction disturbances, severe myocardial depression, acute porphyria, arrhythmia, bradyarrhythmia, cardiac decompensation.

Precautions
Lower dosage in congestive heart failure, bradycardia, ECG monitoring must during therapy, pediatric; hypotension; renal impairment; porphyria; dopamine; bradycardia; hepatic impairment (Appendix 7b); marked hypotension; severe respiratory depression; following cardiac surgery and in elderly; lactation; Interactions (Appendix 6c); pregnancy (Appendix 7d).

Adverse effects
Dizziness; confusion; ataxia; bradycardia; hypotension; nausea; vomiting; constipation; palpitations; jaundice; hepatitis; dysuria.

Storage
Store protected from light. Store injection in single dose containers.

Procainamide *

Pregnancy Category- C

Indications
Severe ventricular arrhythmias, especially those resistant to lidocaine or those appearing after myocardial infarction: atrial tachycardia, atrial fibrillation, maintenance of sinus rhythm after cardioversion of atrial fibrillation.

Availability
TABLET 250 mg; INJECTION 10 ml ampoule/ vial (100 mg/ml).

Dose
Adult—Ventricular arrhythmias: up to 50 mg/kg daily in divided doses every 3 to 6 h, preferably controlled by monitoring plasma-procainamide concentration (therapeutic concentration usually within range of 3 to 10 μg/ml).

Atral arrhythmias: higher doses may be required.

Slow intravenous injection.
NFI 2016 released by Hon’ble Health Minister at IPC on Nov 14th, 2015
Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
  - **Indian Pharmacopoeia Reference Substances (IPRS)**
- International Cooperation
- International Harmonization
- Skill Developments Programs
- Way ahead 2020
Indian Pharmacopoeia References Substances (IPRS)

- A Reference Substances of the Indian Pharmacopoeia is only suitable for the intended use in the relevant monograph
- They are used by the regulatory agencies and Pharmaceutical manufactures to ensure identity, strength, quality and purity of the product as per official IP monograph
Process Flow of IPRS

Candidate material received → Preparation & approval of test protocol

- Lab-1 (IPL)
- Lab-2
- Lab-3

Sampling as per designed protocol → Issuing of candidate material to concerned laboratory

Data evaluation by Quality Control Laboratory Head

Review of data by Quality Assurance

Final approval of Results of Analysis

Indian Pharmacopoeia Commission
IPRS & Impurity Standards
Availability of IPRS

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of IPRS</th>
<th>Expected IPRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-10</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>2010-11</td>
<td>57</td>
<td></td>
</tr>
<tr>
<td>2011-12</td>
<td>112</td>
<td></td>
</tr>
<tr>
<td>2012-13</td>
<td>273</td>
<td></td>
</tr>
<tr>
<td>2013-14</td>
<td>347</td>
<td></td>
</tr>
<tr>
<td>2014-15</td>
<td>422</td>
<td></td>
</tr>
<tr>
<td>2015-16</td>
<td>466</td>
<td></td>
</tr>
<tr>
<td>2016-17</td>
<td>550</td>
<td></td>
</tr>
</tbody>
</table>
Launching of In-house Synthesized Impurity Standards

Launched on 3rd Dec. 2014 presence of Padmashree. Dr. Nitya Anand, Prof. B. Suresh, Prof. Lal Ji Singh and other SB Members & Sci. Staff. of IPC during 29th SB Meeting held in IPC.
Availability of Impurity Standards

The chart shows the number of impurity standards available from 2012-13 to 2016-17.

- **2012-13**: 10
- **2013-14**: 20
- **2014-15**: 30
- **2015-16**: 50
- **2016-17**: 100

The expected number of impurity standards is also indicated for each year.
Distribution of IPRS

Year | IPRS Vials
--- | ---
2009-13 | 2222
2013-14 | 2894
2014-15 | 4461
2015-16 | 6453
Indian Pharmacopoeial Laboratory

- Indian Pharmacopoeial Laboratory is fully equipped with modern Analytical Instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMR (500 MHz)</td>
<td>Atomic absorption spectrometer</td>
</tr>
<tr>
<td>LC-MS/MS-QTOF</td>
<td>UV/Vis spectrophotometer</td>
</tr>
<tr>
<td>GC-MS Triple Quad</td>
<td>FT-IR Microscope spot light 200</td>
</tr>
<tr>
<td>GC-HS</td>
<td>TGA/DSC</td>
</tr>
<tr>
<td>CHNS-elemental analyzer</td>
<td>ICP-MS</td>
</tr>
<tr>
<td>Polarimeter</td>
<td>HPLCs, UPLCs</td>
</tr>
<tr>
<td>Ion chromatograph</td>
<td>Caulometric auto-titrator</td>
</tr>
<tr>
<td>Particle size analyzer</td>
<td>Dissolution test apparatus</td>
</tr>
<tr>
<td>Viscometer</td>
<td>Disintegration test apparatus</td>
</tr>
<tr>
<td>KF auto-titrator</td>
<td></td>
</tr>
</tbody>
</table>
Instruments in IP Lab
IPRS Containerisation Machine
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.
Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Developments Programs
- Way ahead 2020
International Cooperation

- World Health Organization (WHO)

- European Directorate for the Quality of Medicines (EDQM)

- Japanese Pharmacopoeia (JP)

- United States Pharmacopeia (USP)
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
- Stakeholders meeting: 19 April
2nd International Meeting of World Pharmacopoeias
International Meeting of World Pharmacopoeias

- 5th International Meeting of World Pharmacopoeias co-hosted by WHO & USP
  20-22 April, 2015 in Rockville, Maryland and Washington D.C.

- 6th International Meeting of World Pharmacopoeias co-hosted by Chinese Pharmacopoeia, China, 21-23 September, 2015

- 7th International Meeting of World Pharmacopoeias co-hosted by Japanese Pharmacopoeia, Tokyo, Japan, Sept. 2016
6th International Meeting of World Pharmacopoeias

(China- Sept, 2015)
PMDA - IPC Meeting

➢ PMDA (Japanese Pharmacopoeia) team visited IPC on 28th May 2015
PMDA - IPC Meeting

Group photo of IPC and PMDA team
European Pharmacopoeia Observers- Meeting (Strasbourg, France - March, 2016)
Skill Development Program for Overseas Professionals

2 Weeks Training Program for Medicine Control Laboratory Analysts from Mangolia to IPC Ghaziabad (16.11.2015 to 30.11.2015)
Skill Development Program for Overseas Professionals
High Level Ghana Delegation visited IPC on 25\textsuperscript{th} April 2016
High Level Ghana Delegation visited IPC on 25th April 2016
International Cooperation

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

- Indian Pharmacopoeia Commission
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- Way ahead 2020
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 Harbel Monographs
• Active participation in development of International Chemical Reference Standards organised by EDQM and WHO
Overview

- Indian Pharmacopoeia Commission
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- Skill Developments Programs
- Way Ahead 2020
IPC organizes skill development programs/ workshops for professional:

- Analysts (Hands on training)
- Drug Regulators
- Research Students
- Stakeholders
Skill Development

- Offers training for Analysts and Regulators from SAARC & ASEAN countries

- Offers support for Standards setting in Pharmaceuticals
## Skill Development

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Participants</th>
<th>No. of Trainings /workshops</th>
<th>No. of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drug Analyst Trainings</td>
<td>5</td>
<td>213</td>
</tr>
<tr>
<td>2</td>
<td>Drug Inspector Trainings</td>
<td>3</td>
<td>113</td>
</tr>
<tr>
<td>3</td>
<td>Assistant Drug Controller Training</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>4</td>
<td>Stakeholders Workshop</td>
<td>2</td>
<td>395</td>
</tr>
<tr>
<td>5</td>
<td>Quality Analysts (Mongolia) Technical Study Tour/Training</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>Government Analyst NABL Training</td>
<td>3</td>
<td>83</td>
</tr>
</tbody>
</table>
Skill Development
Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Developments Programs

- Way Ahead 2020
Way Ahead: 2020

- Targeting for 800 IPRS.
- Targeting 300 Impurity Standards
- Enhancing the scope of Green Analytical Chemistry.
- Establishing regional offices in Pharma-major Indian Cities like Ahmadabad, Mumbai, Hyderabad, Bangalore and Chennai etc.
- Establishing the State-of-the-art laboratory as Referral Laboratory for Analytical investigations.
Hon’ble Health Minister Sh. J. P. Nadda laid the foundation stone of Advanced Level Research Center at IPC in presence of Gen. (Dr.) V. K. Singh, Minister of State, Dr. (Prof.) Jagdish Prasad DG & Dr. G. N. Singh
Way Ahead: 2020

- To make functioning the Advanced Level Research Center by 2017
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.
Proposal for Cooperation Between IPC & PMDA

- 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.
• For any queries kindly visit us at www.ipc.gov.in

• or email at ipclab@vsnl.net
Thank you!!

ありがとうございます