



INDIAN PHARMACOPOEIA COMMISSION

DEVELOPMENT OF MONOGRAPHS FOR INDIAN PHARMACOPOEIA

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INTRODUCTION

- ❑ In India, under the Drugs and Cosmetics Act 1940, the current edition of Indian Pharmacopoeia is a book of standards for drugs included therein and the standards as included in the Indian Pharmacopoeia would be official.
- ❑ Also, in several other laws of India, the Indian Pharmacopoeia is recognised as the standard book.
- ❑ Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India.



INTRODUCTION

Contd.

- ❑ IP prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines.
- ❑ The standards of Indian Pharmacopoeia are authoritative and legally enforceable.
- ❑ It intends to help in the licensing of manufacturing, inspection and distribution of medicines.



INTRODUCTION

Contd.

- ❑ The Indian Pharmacopoeia is published in continuing pursuit of the Mission of the IPC to promote public 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.
- ❑ Publication of IP at regular and shorter intervals is one of the main mandates of the Commission.



INTRODUCTION

Contd.

- ❑ Objectives of Indian Pharmacopoeia Commission is to develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices and to keep them updated by revision on a regular basis.
- ❑ To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms.



INTRODUCTION

Contd.

- ❑ To collaborate with pharmacopoeias like the Ph. Eur., BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards.
- ❑ To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/materials.



INTRODUCTION

Contd.

- ❑ IP monograph for an official substance or preparation includes the article's definition, description, identification, packaging, storage, specifications, impurities, assay and specific tests, one or more analytical procedures for each test, acceptance criteria and other requirements etc. Chemical structure, molecular formula alongwith IUPAC name of the substances also mentioned in case of chemical active pharmaceutical ingredient.



HISTORY OF IP

- ❑ The history of the IP began in the year 1833 when a Committee of the East India Company's Dispensary recommended the publication of a Pharmacopoeia and Bengal Pharmacopoeia and General Conspectus of Medicinal Plants were published in 1844, which mainly listed most of the commonly used indigenous remedies.
- ❑ This was followed by IP 1868, which covered both the drugs of British Pharmacopoeia (BP) 1867 and indigenous drugs used in India, with a Supplement published in 1869 incorporating the vernacular names of indigenous drugs and plants.



HISTORY OF IP

Contd.

- ❑ However, from 1885 the BP was made official in India.
- ❑ A Drugs Enquiry Committee appointed in 1927 by the government recommended the publication of a National Pharmacopoeia.
- ❑ After independence, the Indian Pharmacopoeia Committee was constituted in 1948 for publication of IP as its main function, which published the IP in 1955, followed by a Supplement in 1960.



HISTORY OF IP

Contd.

- ❑ This Pharmacopoeia contained both western and traditional system drugs commonly used in India and the same policy continued while preparing the Pharmacopoeia of India 1966 and its Supplement 1975.
- ❑ There had been a phenomenal growth and development of the Indian Pharma industry since independence, especially from early 1970, both in the range of Active Pharmaceutical Ingredients (APIs) and the dosage forms produced.



HISTORY

Contd.

- ❑ This totally transformed the profile of the Indian Pharmaceuticals market and Indian Pharma industry emerged as one of the important global suppliers of pharmaceutical products, both to the developed and developing countries.
- ❑ These developments posed major challenges for the IP to reflect the quality standards of the marketed drugs, which the subsequent editions of IP tried to address.



HISTORY

Contd.

- ❑ In view of these rapid advances, it was decided to publish a new edition of the Pharmacopoeia and its Addenda at regular and shorter intervals for which the Indian Pharmacopoeia Committee was reconstituted in 1978.
- ❑ In the Pharmacopoeia of India 1985, its Addenda 1989 and 1991, inclusion of traditional system of drugs was limited.
- ❑ However, most of the new drugs manufactured and/or marketed were included, while only those herbal drugs which had definitive quality control standards had got place in it.



ROLE OF CIPL IN IP WORK

- ❑ Central Indian Pharmacopoeia Laboratory was established in the year 1965 under Directorate General of Health Services (DGHS), M/o H&FW as sub-ordinate office/laboratory of CDSCO/DCG (I).
- ❑ Drugs Controller was the Member Secretary of IP Committee and Director CIPL was the member of IP Committee.
- ❑ CIPL plays an active role in publication of IP-1985, IP-1996 and its subsequent Addendum in 2000, and 2002, along with other regulatory and Zonal Testing of Drug sample from North Zone of India.



DEVELOPMENT IN IP FOR 21ST CENTURY

- ❑ In view of the continuing rapid increase in the range of drugs produced in India, the IP 1996, its Addendum 2000, Supplement 2000 for Veterinary Products and Addendum 2002 were published.
- ❑ First time emphasis has given to veterinary products also in veterinary supplement 2000 to IP-1996.
- ❑ First time the monographs on Anti-Retroviral Drugs were introduced in the Addendum-2002.



DEVELOPMENT IN IP FOR 21ST CENTURY

Contd.

- ❑ The IP Committee decided to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medical need and extent of use of such articles in the country.



ROLE OF IPC IN FREQUENT PUBLICATION OF IP

- ❑ The Indian Pharmacopoeia Commission was established in year 2005, dissolving the existing I.P. Committee and started working in existing CIPL with its Director as Member Secretary.
- ❑ The Addendum 2005 was published by IPC which, included a large number of antiretroviral drugs and raw plants commonly used in making medicinal products not covered by any other pharmacopoeias, which attracted much global attention.



ROLE OF IPC IN FREQUENT PUBLICATION OF IP

Contd.

- ❑ It provided systematic approach and practices for publication of IP 2007 containing 271 new monographs with focus on those drugs and formulations that cover the National Health Care Programmes and the National Essential Medicines.
- ❑ Addendum 2008 to IP-2007 containing 72 new monographs and amendments published in the year 2008.



ROLE OF IPC IN FREQUENT PUBLICATION OF IP

Contd.

- ❑ Ministry of Health and Family Welfare, Govt. of India submerged the existing Central Indian Pharmacopoeia Laboratory alongwith Indian Pharmacopoeia Commission (IPC) as a fully financed autonomous body from 1st Jan, 2009 located at NCR region in Ghaziabad.
- ❑ It is a three-tier structure comprising of the General Body of 25 members, Governing body of 13 members and Scientific Body of 15-23 members from different related scientific fields.
- ❑ Secretary-cum-Scientific Director of IPC is the Member Secretary of all three bodies of IPC.



EXISTING BUILDING AT GHAZIABAD



INDIAN PHARMACOPOEIA COMMISSION, SEC-23, RAJ NAGAR, GHAZIABAD



ROLE OF IPC IN FREQUENT PUBLICATION OF IP

Contd.

- ❑ The Secretary, Ministry of Health and Family Welfare, is the Chairman and the Chairman-Scientific Body is the Co-Chairman of the Commission.
- ❑ The Secretary-cum-Scientific Director is the Chief Scientific and Executive Officer of the Commission.
- ❑ The IPC Secretariat and Indian Pharmacopoeia Laboratory (IPL) staff, with the support of different advisory experts committee and expert members of the Scientific body have examined the suitability of the standards for the VIth edition IP-2010.



ROLE OF IPC IN FREQUENT PUBLICATION OF IP

Contd.

- ❑ IP 2010 contained monographs on antiretroviral, anticancer, antituberculosis and herbal drugs. It further emphasized on biological monographs such as Vaccines, Immunoserum for human use, Blood products, Biotechnological and veterinary (Biological and non-biological) preparations.
- ❑ Addendum 2012 to the IP 2010 was published which had taken care of the Amendments to IP 2010 alongwith 52 new monographs.



PUBLICATION OF IP (BY IP COMMITTEE)

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

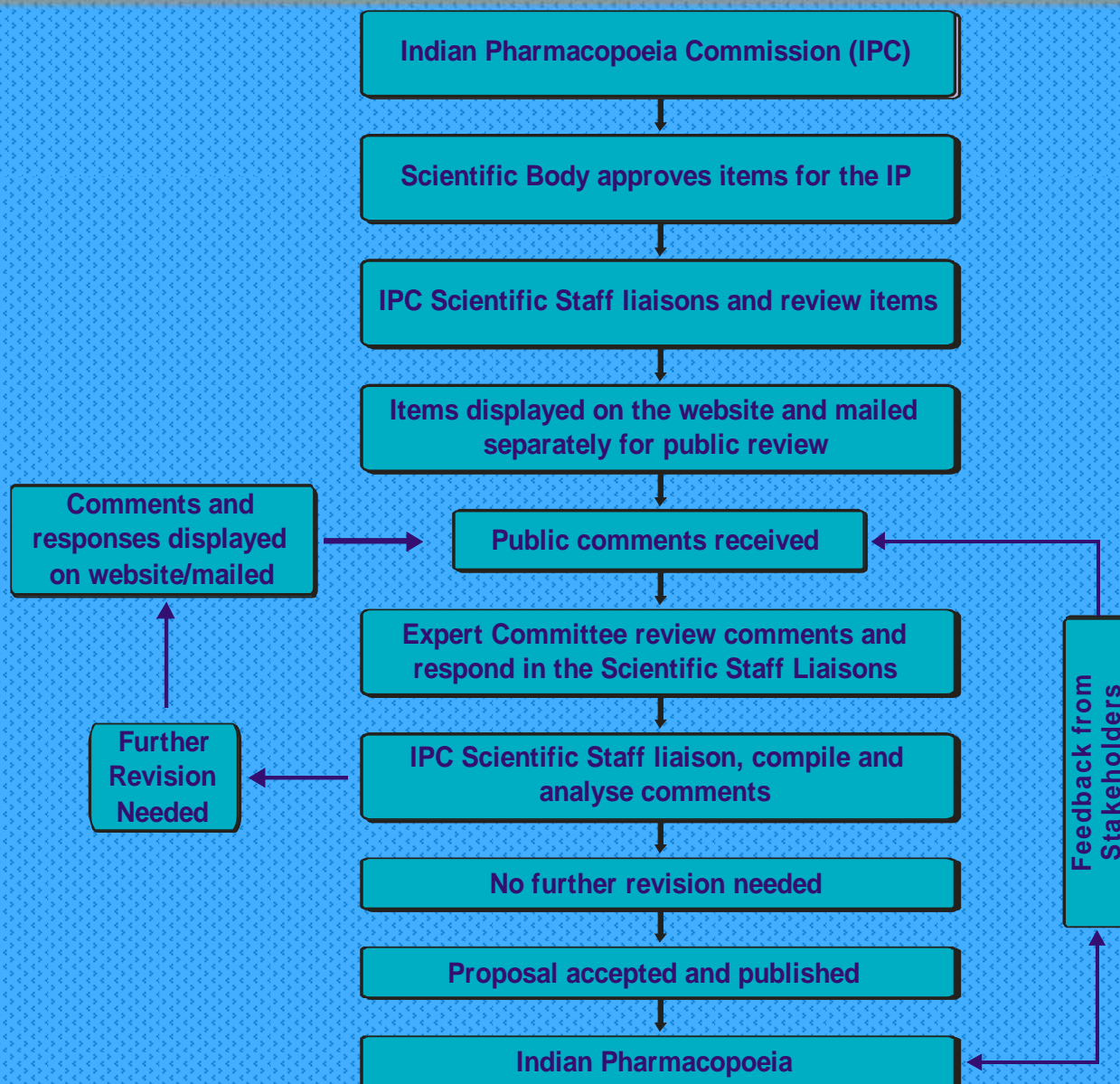


PUBLICATION OF IP (BY IP COMMISSION)

<u>Edition</u>	<u>Year</u>
Addendum	2005
V th	2007
Addendum	2008
VI th	2010
Addendum	2012
VII th (Current Edition)	2014
Addendum (Rec. Pub.)	2015



PROCESS OF IP MONOGRAPHS DEVELOPMENT





PUBLICATION OF IP - 2014

- ❑ Recently, the VIIth edition, IP- 2014 is published in accordance with the principles and designed plan decided by the Scientific Body of the IPC.
- ❑ The standards prescribed in this edition are encouraged to adhere with the concept of harmonization, keeping in view the technological status for manufacture and analysis of drugs and pharmaceuticals in the country without compromising with the quality of the products.
- ❑ 577 new monographs were added in this VIIth edition.



PUBLICATION OF IP – 2014

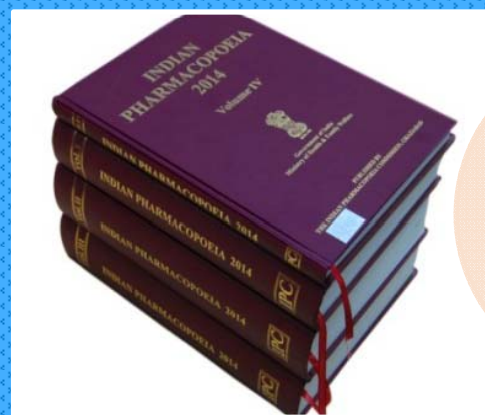
Contd.

- ❑ Number of monographs and appendices are expanded further to incorporate the latest technological advancement and regulatory compliance.
- ❑ Constant efforts have been made to unify the National Drug Standards and to bring them in line with the International Standards progressively by addition of monographs of new drugs and adopting current methodology.
- ❑ IP-2014 was released on 4th Nov, 2013 by honourable Minister of Health & Family Welfare Shri Gulam Nabi Azad in a function at Nirman Bhawan, New Delhi.



PUBLICATION OF IP – 2014

Contd.



IP-2014



SPECIFIC FEATURES OF IP-2014

- ❑ **First time IP-2014 included with DVD-ROM.**
- ❑ **Out of 577 New Monographs, 134 API monographs, 161 formulations monographs, 18 excipient monographs, 43 NDS monographs, 10 antibiotic monographs, 19 anticancer monographs, 11 antiviral monographs are included in this edition.**
- ❑ **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.**



SPECIFIC FEATURES OF IP-2014

Contd.

- ❑ 19 new General Chapters and about 200 new IR spectra's are also added.
- ❑ For the first time in IP, introducing 19 new Radiopharmaceutical Monographs with one General Chapter on Radiopharmaceutical preparations.
- ❑ This time separate volume of veterinary products is also introduced for easy access.
- ❑ 143 monographs on veterinary products along with 16 appendices/General chapter on veterinary products are also introduced.



SPECIFIC FEATURES OF IP-2014

Contd.

□ Now total number of IP Standards is reaching almost 3000 which is almost at par with other international Pharmacopoeias and comprising different categories of drugs and appendices as mentioned below:

□ IP-2014 : Total Standards

- General Monograph on Dosage Forms : 37

- Monographs on Drug Substances, Dosage forms and Pharmaceutical Aids (A to Z)

□ APIs	:	850	} 2013
□ Formulations	:	1035	
□ Excipients	:	128	



SPECIFIC FEATURES OF IP-2014

Contd.

- Monographs on Vaccines and Immunoserum for Human Use	: 63	} 245
- Monographs on Herbs and Herbal Product	: 123	
- Monographs on Blood and Blood-related products	: 29	
- Monographs on Biotechnology Products	: 11	
- Monographs on Radiopharmaceuticals	: 19	

Monograph on Veterinary Products

Non-Biological	: 208	} 290
Biological	: 56	
Diagnostics	: 14	
Immunoserum	: 05	
Surgical	: 07	



SPECIFIC FEATURES OF IP-2014

Contd.

Total Monographs	:	$2585+82 = 2667$
Appendices	:	197
Total Standards	:	$2782+82 = 2864$

- ❑ The Standards prescribed in the Indian Pharmacopoeia are to establish the compliance with regulatory requirements on an article. The criteria to be adhered to are:
 - ❑ (a) the interpretation of a monograph must be in accordance with all the general requirements, testing methods, texts and notices pertaining to it, in the IP and.
 - ❑ (b) a product is not of standard quality unless it complies with all the requirements of the monograph.



GROWTH OF IP STANDARDS

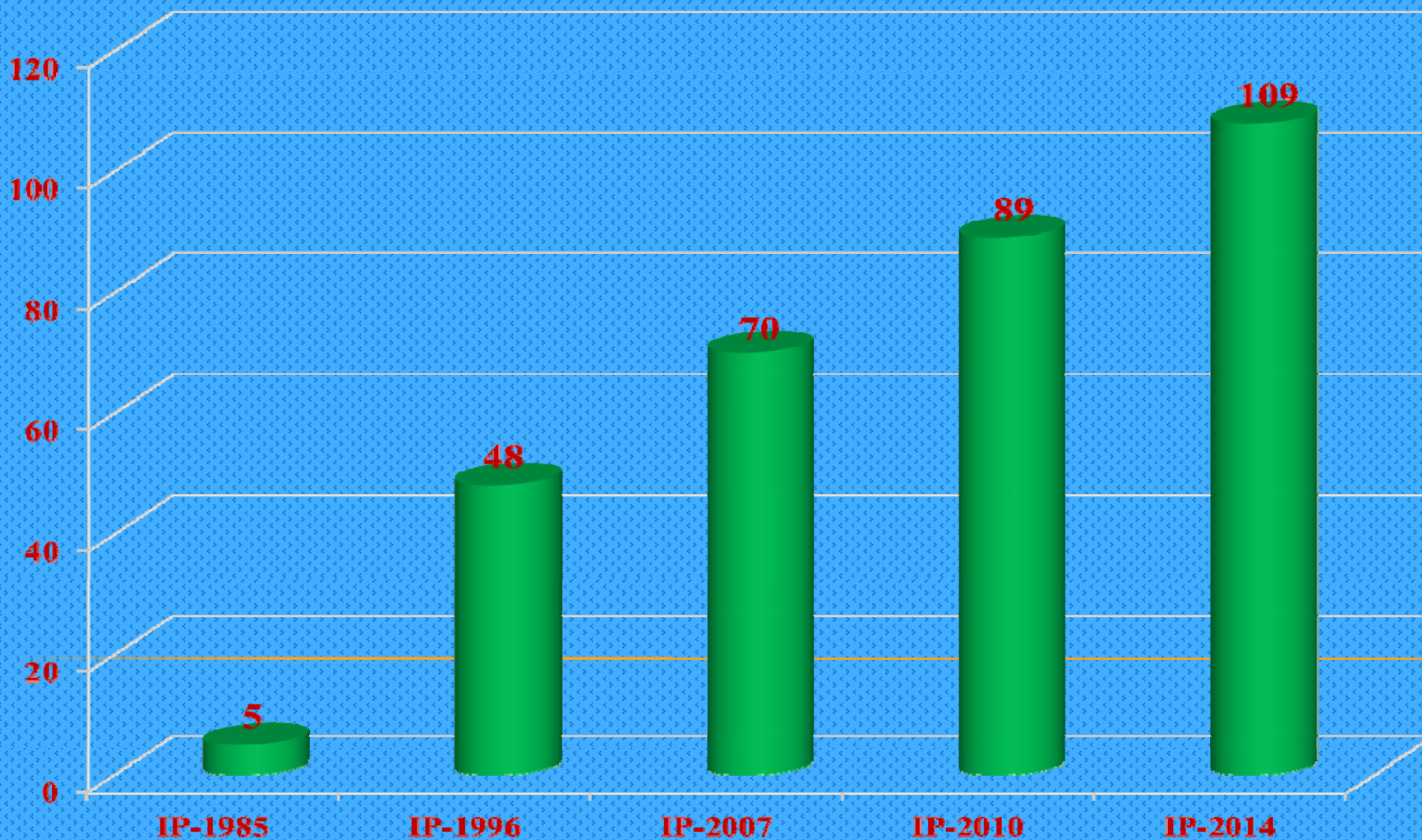
Total number of Monographs





GROWTH OF IP STANDARDS

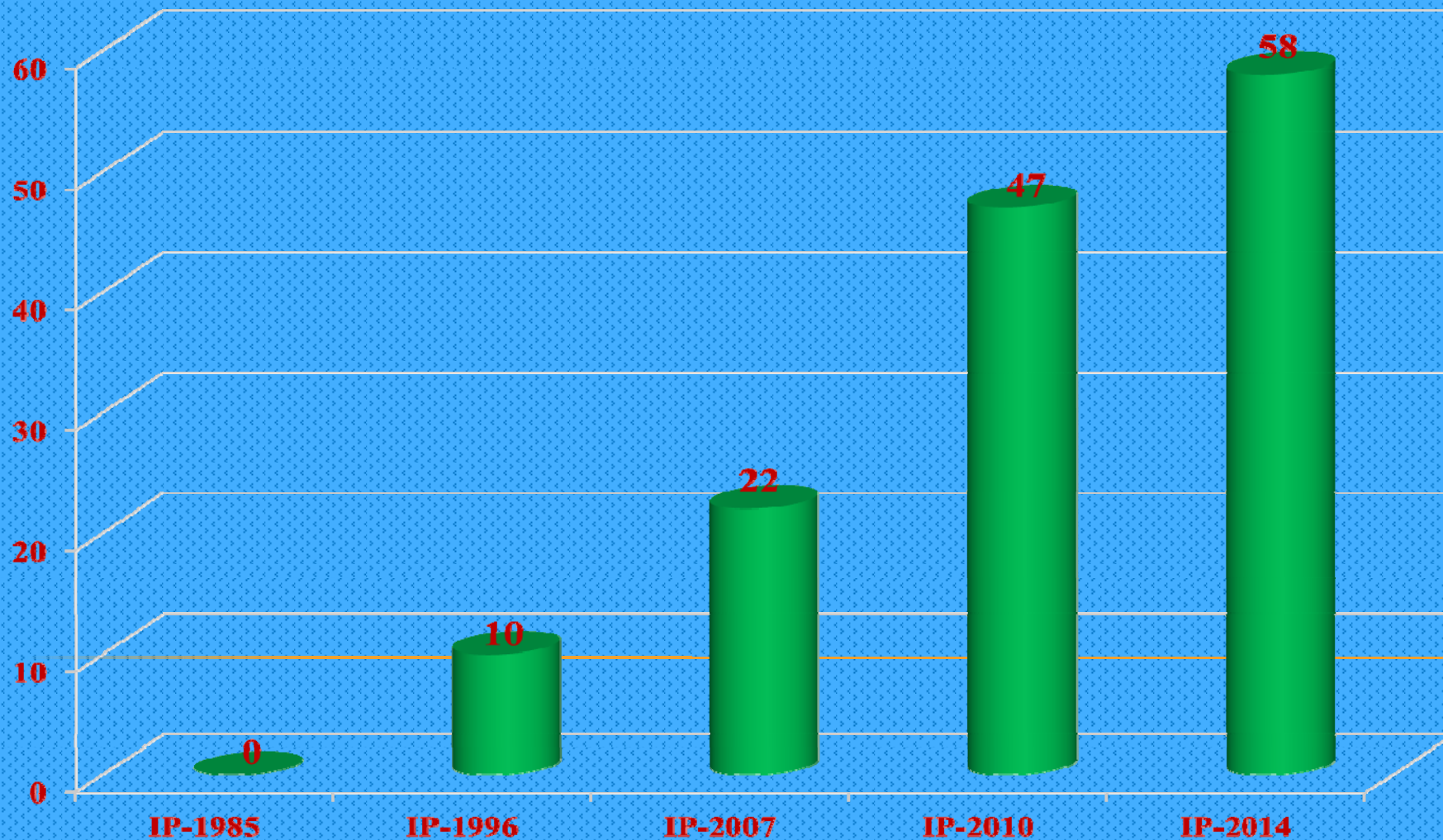
No. of Anticancer Monographs





GROWTH OF IP STANDARDS

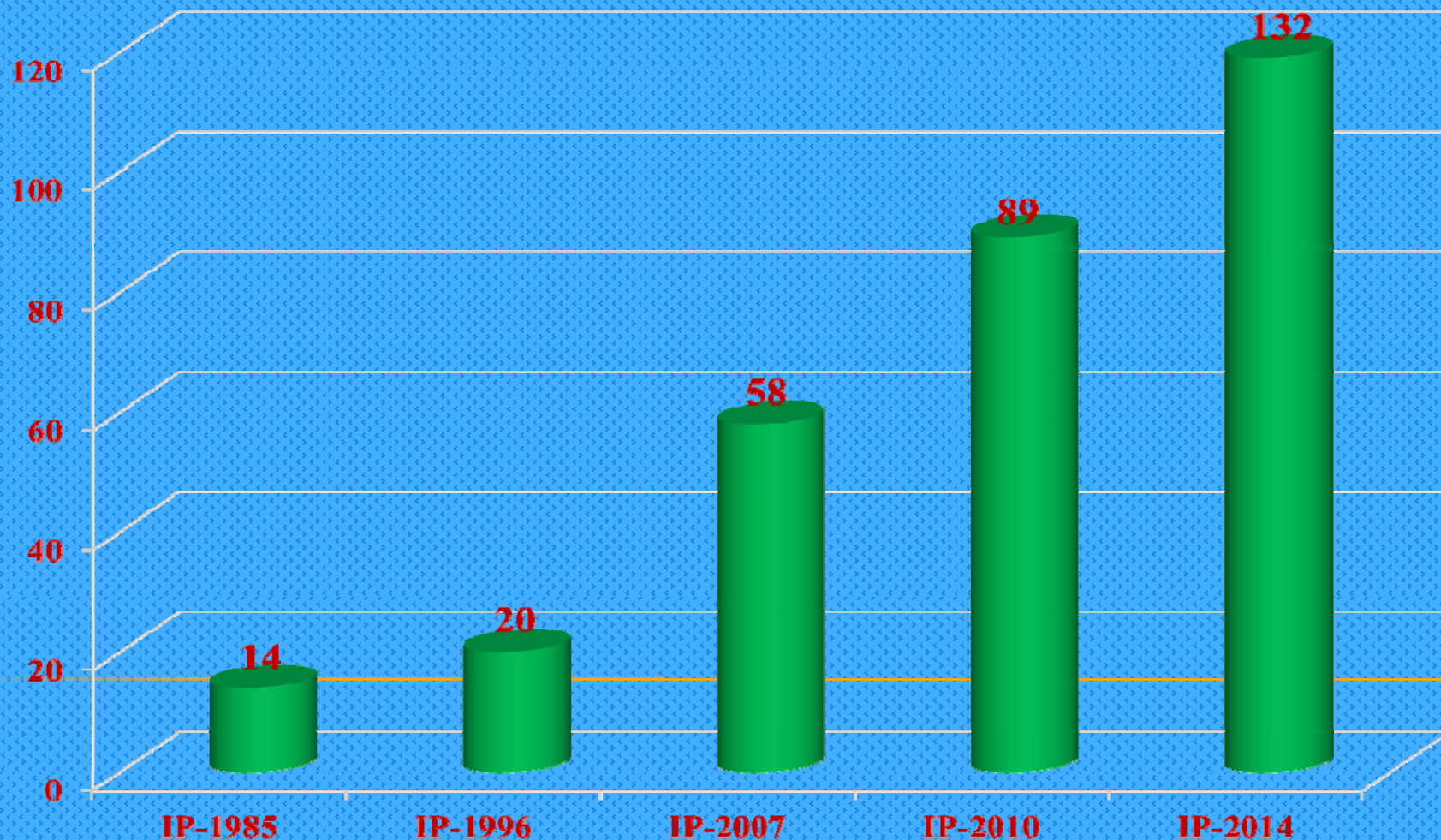
No. of Antiretroviral Monographs





GROWTH OF IP STANDARDS

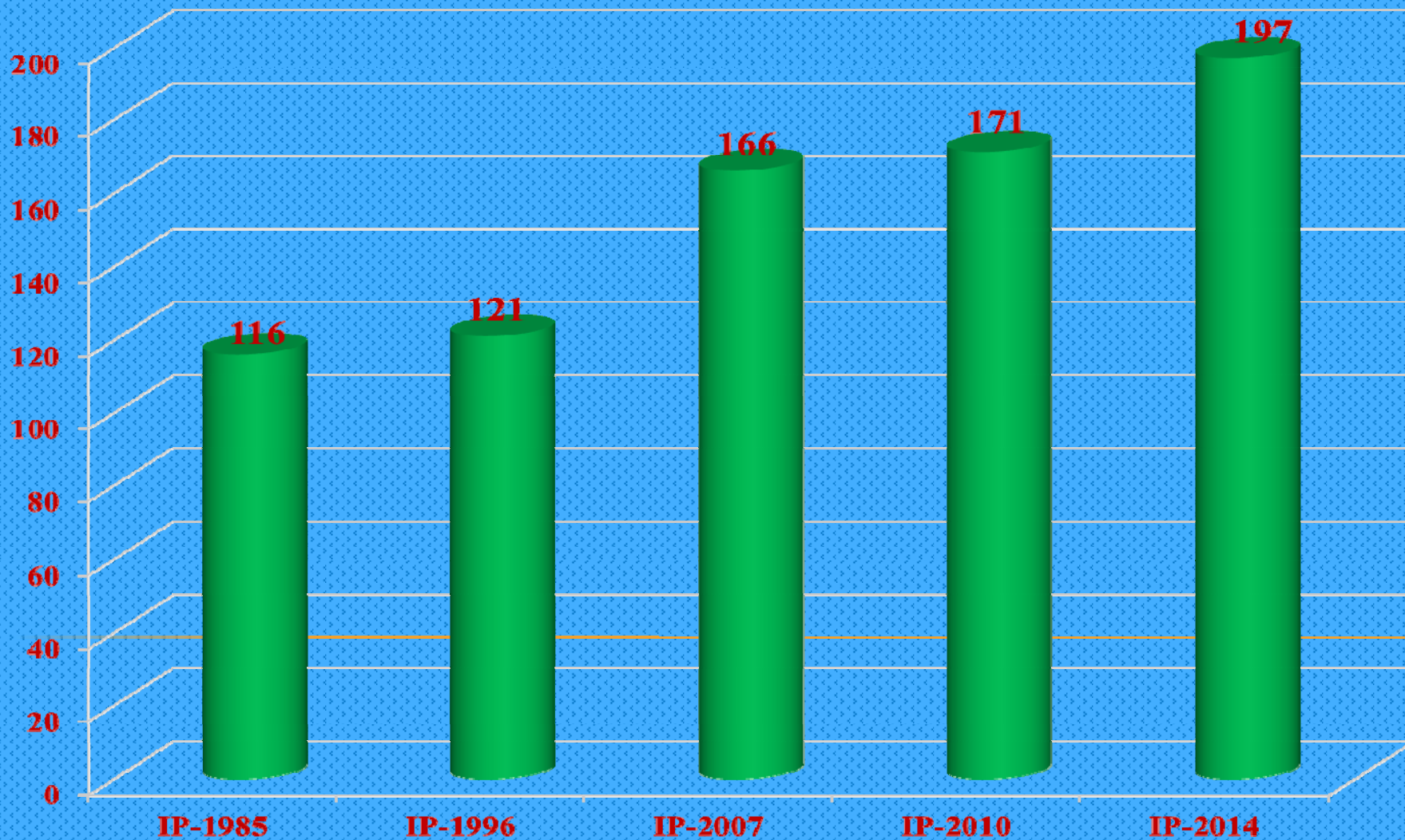
No. of Herbal Monographs





GROWTH OF IP STANDARDS

No. of General Chapters (Appendices)





NEW CHAPTERS ADDED IN IP-2014

2.2 Biological Methods

2.2.17. DNA based Authentication techniques

**2.2.18. Transfusion and Infusion Assemblies & similar
Medical Devices or Sterile Assemblies & medical
Devices**

2.2.19. Amino Acid Analysis

2.3 Chemical Methods

2.3.51. 2-Ethylhexanoic Acid

2.3.52. Assay of Folic Acid

2.3.53. Ammonium

2.3.54. Assay of Alpha tocopherol

2.3.55. Fluorides



2.4 Physical & Physicochemical Methods

2.4.35. Bulk Density and Tapped Density of Powders

2.4.36. Completeness of Solution

2.4.37. Crystallinity

2.4.38. Specific Surface Area

2.4.39. Mass Spectroscopy

2.4.40. Ethylene Oxide and Dioxan

2.4.41. Acetic Acid in Peptides

2.4.42. Inductively Coupled Plasma - Mass Spectroscopy



NEW CHAPTERS ADDED IN IP-2014

Contd.

2.4.43. Characterisation of Crystalline and Partially Crystalline solids by X-ray Power Diffraction

2.4.44. Flash Point

2.5 Pharmaceutical Methods

2.5.11. Polymorphism



ANTICANCER MONOGRAPHS IN IP-2014

1. Bortezomib
2. Carboplatin
3. Carboplatin Injection
4. Docetaxel Anhydrous
5. Gemcitabine Hydrochloride
6. Gemcitabine Injection
7. Imatinib Tablets
8. Lapatinib Ditosylate
9. Lapatinib Tablets
10. Mitomycin
11. Mitomycin Injection
12. Sorafenib Tosylate



ANTICANCER MONOGRAPHS IN IP-2014

Contd.

13. Sorafenib Tablets
14. Premetrexed Disodium
15. Erlotinib Hydrochloride
16. Erlotinib Tablets
17. Fludarabine Phosphate
18. Bicalutamide
19. Bicalutamide Tablets



ANTIVIRAL MONOGRAPHS IN IP-2014

- 1. Famciclovir**
- 2. Famciclovir Tablets**
- 3. Aciclovir Cream**
- 4. Aciclovir Eye Ointment**
- 5. Aciclovir Dispersible Tablets**
- 6. Aciclovir Oral Suspension**
- 7. Adefovir Dipivoxil**
- 8. Adefovir tablets**
- 9. Saquinavir Capsules**
- 10. Arbidol Hydrochloride**
- 11. Tenofovir Fumarate, Lamivudine & Efavirenz Tablets**



EXCIPIENT MONOGRAPHS IN IP-2014

- 1. Acesulphame Potassium**
- 2. Adipic Acid**
- 3. Alfacyclodextrin**
- 4. Ascorbyl Palmitate**
- 5. Betacyclodextrin**
- 6. Carboxymethylcellulose Calcium**
- 7. Corn Oil**
- 8. Cottonseed Oil**
- 9. Ethyl Paraben**
- 10. Ethyl Vanilin**
- 11. Hydrogenated Vegetable Oil**
- 12. Hydroxyethyl Cellulose**



EXCIPIENT MONOGRAPHS IP-2014

Contd.

13. Hydroxypropyl Methylcellulose Phthalate
14. Isopropyl rubbing Alcohol
15. Monobasic Sodium Phosphate
16. Octyl Dodecanol
17. Petrolatum
18. Phenylethyl Alcohol
19. Polacrillin Potassium
20. Polyvinyl Acetate Phthalate
21. Polyvinyl Alcohol
22. Soyabean Oil



RADIOPHARMACEUTICAL MONOGRAPHS IN IP-2014

One General Chapter on Radiopharmaceuticals

1. (^{131}I) Meta-Iodobenzyl Guanidine Injection for Diagnostic Use.
2. (^{131}I) Meta-IodobenzylGuanidineInjection for Therapeutic Use.
3. Fluorodeoxyglucose (^{18}F) Injection
4. Samarium (^{153}Sm) Ethylene DiamineTetramethylene Phosphonate (EDTMP) Injection
5. Sodium Fluoride (^{18}F) Injection
6. Sodium Iodide (^{131}I) Capsules for Diagnostic Use



7. Sodium Iodide (^{131}I) Capsules for Therapeutic Use
8. Sodium Iodide (^{131}I) Solution
9. Sodium Pertechnetate ($^{99\text{m}}\text{Tc}$) Injection (Fission)
10. Sodium Pertechnetate ($^{99\text{m}}\text{Tc}$) Injection (Non-fission)
11. Sodium Phosphate (^{32}P) Injection
12. Technetium ($^{99\text{m}}\text{Tc}$) DMSA Injection
13. Technetium ($^{99\text{m}}\text{Tc}$) DTPA Injection
14. Technetium ($^{99\text{m}}\text{Tc}$) EC Injection
15. Technetium ($^{99\text{m}}\text{Tc}$) ECD Injection
16. Technetium ($^{99\text{m}}\text{Tc}$) Glucoheptonate Injection



18. Technetium (^{99m}Tc) Mebrofenin Injection
19. Technetium (^{99m}Tc) Medronate Complex Injection
20. Technetium (^{99m}Tc) MIBI Injection



IP ADDENDUM-2015 TO IP-2014

- ❑ This Addendum has the same authority as the Indian Pharmacopoeia 2014.
- ❑ The General Notices, Monographs, Appendices and other contents of the Indian Pharmacopoeia that are amended by this Addendum supersede the original matter.
- ❑ This Addendum amends as well as adds new materials to the Indian Pharmacopoeia 2014.
- ❑ The General Notices and Appendices included in the Indian Pharmacopoeia 2014 apply to the contents of this Addendum as well unless specifically stated otherwise.



IP ADDENDUM-2015 TO IP-2014

(CONTENTS)

- ❑ **Notices**
- ❑ **Preface**
- ❑ **Structure of Indian Pharmacopoeia Commission**
- ❑ **Acknowledgements**
- ❑ **Introduction**
- ❑ **General Chapters**
- ❑ **Monographs on dosage forms,**
- ❑ **Monographs on drug substances,**
- ❑ **Monographs on Vaccines and Immunoserum for human use,**
- ❑ **Monographs on Herbs and herbal products,**
- ❑ **Monographs on Radiopharmaceutical preparations and Index.**



IP ADDENDUM-2015 TO IP-2014

(CHANGES)

- ❑ General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.
- ❑ The use of chromatographic methods has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.
- ❑ Most of existing Assays and Related substances tests are upgraded by liquid chromatographic method in view to harmonize with other international Pharmacopoeias.



IP ADDENDUM-2015 TO IP-2014

(GENERAL CHAPTERS)

- ❑ Keeping in view the essential requirement for harmonization of analytical methods with those adopted internationally, steps have been taken for monitoring the quality of drug.
- ❑ According we have revised general chapters on volumetric glasses, peptide mapping, sterility testing, conductivity, solubility, dissolution test, bulk density and tapped density of powders.
- ❑ For controlling the microbial quality of all the medicinal product general chapters on microbial contamination in non-sterile products and test for colony forming units have been revised.



IP ADDENDUM-2015 TO IP-2014 (NEW ADDITIONS)

Monographs on Drug substances, Dosage forms & Pharmaceutical aids (A to Z)

APIs	:	43	}	57	}	82
Formulations	:	14				
Other Monographs						
Herbal Monographs	:	13	}	25	}	
Vaccines & immunosera for human use	:	02				
Radiopharmaceuticals Preparations	:	10				



IP ADDENDUM-2015 TO IP-2014

(SPECIFIC FEATURES)

Added:

- I. 57 new Chemical monographs**
- II. 13 new Herbal monographs**
- III. 02 new Human Vaccines Monographs**
- IV. 10 Radiopharmaceutical Monographs**
- V. 06 Revised monographs**
- VI. 29 Revised tests**
- VII. About 20 new IR spectras**



IP ADDENDUM-2015 TO IP-2014

(CHEMICAL MONOGRAPHS- “57”)

- 1) Aripiprazole Tablets**
- 2) Barium Sulphate Suspension**
- 3) Brimonidine Eye Drops**
- 4) Brimonidine Tartrate**
- 5) Budesonide Inhalation**
- 6) Budesonide Powder for Inhalation**
- 7) Calcuim Pantothenate Tablets**
- 8) Citicoline Prolonged-release Tablets**
- 9) Citicoline Injection**
- 10) Citicoline Sodium Tablets**
- 11) Clemastine Oral Solution Bitmap**
- 12) Dorzolamide Eye drops**
- 13) Dorzolamide Hydrochloride**
- 14) Ebastine Tablets**



IP ADDENDUM-2015 TO IP-2014

Contd.

- 15) Esclicarbazepine Tablets
- 16) Ifosfamide
- 17) Ifosfamide Injection
- 18) Iloperidone Tablets
- 19) Isotretinoin Capsules
- 20) Ketotifen Fumarate Tablets
- 21) Lacidipine
- 22) Lacidipine Tablets
- 23) Lactulose Oral Powder
- 24) Metformin Oral Solution
- 25) Methadone Oral Solution
- 26) Methylphenidate HCl Prolonged-release Tablets
- 27) Methylphenidate Hydrochloride
- 28) Metolazone
- 29) Metolazone Tablets
- 30) Mirtazapine



IP ADDENDUM-2015 TO IP-2014

Contd.

- 31) Mirtazapine Tablets
- 32) Nabumetone
- 33) Nabumetone Tablets
- 34) Rabeprazole Injection
- 35) Raloxifene Hydrochloride Tablets
- 36) Sitagliptin Phosphate
- 37) Sitagliptin Tablets
- 38) Tadalafil
- 39) Tadalafil Tablets
- 40) Tamsulosin Prolonged-release Capsules
- 41) Terazosin Tablets
- 42) Tolterodine Tablets
- 43) Torsemide



IP ADDENDUM-2015 TO IP-2014

Contd.

- 44) Torsemide Tablets
- 45) Voriconazole
- 46) Voriconazole Tablets
- 47) Brinzolamide Ophthalmic Suspension
- 48) Ranitidine Oral Solution
- 49) Dorzolamide and Timolol Eye Drops
- 50) Entacapone Tablets
- 51) Tibolone
- 52) Tibolone Tablets
- 53) Sodium Nitrite
- 54) Sodium Nitrite Injection
- 55) Netilmicin Sulphate Injection
- 56) Dutasteride Capsules
- 57) Sterile Water for Inhalation



IP ADDENDUM-2015 TO IP-2014

(HERBAL MONOGRAPHS- “13”)

1. Hingu
2. Birmi
3. Shankpushpi
4. Draksha
5. Lodhra
6. Sahajana Leaf
7. Sahajana stick
8. Ginseng
9. Ginseng Dry Extract
10. Bassant
11. Bassant Dry Extract
12. Asthisamhrta
13. Mirch



IP ADDENDUM-2015 TO IP-2014 (HUMAN VACCINES MONOGRAPHS- “02”)

1. BCG for Immunotherapy
2. Influenza vaccine (Human, live attenuated)



IP ADDENDUM-2015 TO IP-2014

(REVISED MONOGRAPHS- “06”)

- 1. Gelatin**
- 2. Dopamine Injection**
- 3. Dobutamine Injection**
- 4. Cisplatin**
- 5. Cisplatin Injection**
- 6. Barium Sulphate for Suspension**



IP ADDENDUM-2015 TO IP-2014 (PURCHASE OF INDIAN PHARMACOPOEIA)

Addendum 2015 to IP-2014 can be procured from the office of the Secretary-cum-Scientific Director, IP Commission at IPC Campus, Raj Nagar, Sector 23, Ghaziabad – 201 002 (UP), India or from our distribution network (see website: www.ipc.gov.in).

Other Distribution Centres:

(1) M/s Educational Book Centre

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IP ADDENDUM-2015 TO IP-2014

(YOUR PARTICIPATION IN IP)

Interested parties can participate in the following ways:

- ❑ Submit draft monographs along with supporting documents**

The Indian Pharmacopoeia encourages you to submit draft monographs. Your draft may be the starting point for an official public standard.

- ❑ Propose Revisions to Existing General Chapters and Monographs**

You can propose revisions to the general chapters and monographs in the current official edition of the Indian Pharmacopoeia.



IP ADDENDUM-2015 TO IP-2014

(ROAD MAP FOR ADDENDUM-2016)

❑ Work Plan for Addendum- 2016

1. The monographs which were not taken in IP-2014 but was in the compiled list considering monographs which are CDSCO approved, available in NLEM & Drug Today, received from Stakeholders etc.
2. API's whose formulations are missing and Formulations whose API monographs are missing in IP-2014 and Addendum-2015.
3. Up-gradation of existing monographs of IP-2014.
4. Preparation of draft proposal for Amendments in response of the queries received.
5. Preparation of IR spectra's, Structures, Nomenclature, category, Dose, Usual strengths, Solubilities, reagents & Solutions etc of new monographs.
6. Verification of new monographs/ Revised tests whose sample/ Std's are available.
7. Up-gradation of General Chapters/ Appendices like Dissolution, Uniformity of Dosage Units etc.



IP ADDENDUM-2015 TO IP-2014 (ROAD MAP FOR ADDENDUM-2016)

□ Working Time Schedule for the Addendum- 2015

- Preparation of list of new monographs/revised tests - Upto Sept. 2014
- Acquisition/verification of new monographs - Dec. 2014
- Drafting of new monographs - March 2015
- Compilation of Amendments - April 2015
- Comments from stakeholders and
- Preparation of manuscript - June 2015
- Checking of manuscript & handover to printer - August 2015
- Release of Addendum - Sep. 2015
- Implementation date of Addendum 2015 - 1st Jan., 2016



DEVELOPMENT OF IP REFERENCE SUBSTANCES

- ❑ IPC provides the official Indian Pharmacopoeia Reference Substances (IPRS) as primary reference standards to the stakeholders.
- ❑ These are specifically required in many pharmacopoeial tests and assays.
- ❑ They are highly characterized substances selected for their critical attributes and suitability for the intended purpose as prescribed in the Pharmacopoeia and are not necessarily suitable in other circumstances.



DEVELOPMENT OF IP REFERENCE SUBSTANCES

Contd.

- ❑ Biological Reference Substances, also abbreviated to IPRS and Standard Preparations of antibiotics are issued by agencies authorised by the IPC.
- ❑ They are standardized against the International Standards and Reference Preparations established by the World Health Organization (WHO).



DEVELOPMENT OF IP REFERENCE SUBSTANCES

Contd.

- ❑ Indian Pharmacopoeia Laboratory is a modern analytical laboratory capable of doing chemical and microbiological analysis, qualification testing of candidate reference materials and containerization of such reference materials which become Indian Pharmacopoeia official Reference Materials to be used in conjunction with the official documentary standards published in the Indian Pharmacopoeia.
- ❑ IPC is providing more than 350 IPRS including impurities and the list of available IPRS is updated on the website of IPC www.ipc.gov.in from time to time.



DEVELOPMENT OF IP REFERENCE SUBSTANCES

Contd.

- ❑ Facilities for their storage and containerization is already developed at IPL.
- ❑ Microbial reference cultures as per pharmacopoeial requirements are very important for quality control in pharmaceutical industries. These cultures are required for establishing acceptable performance of media, validating methods, verifying the suitability of test methods and assessing or evaluating performance in sterility testing, microbial bioassay and microbial limit test etc. IPC and CSIR-IMTECH, Chandigarh signed the MOU to provide authenticated and certified microbial reference cultures at reasonable cost as per IP requirements. The detail list of available microbial cultures is also available on our website.

DEVELOPMENT OF IP REFERENCE SUBSTANCES

Contd.





ISO/IEC 17025:2005 NABL ACCREDITED LABORATORY

- ❑ Indian Pharmacopoeia Laboratory is accredited for both chemical and biological testing from Sept.2011 by National Accreditation Board for testing and calibration laboratories (NABL) of DST, New Delhi for complying ISO/IEC 17025: 2005.
- ❑ The IPL successfully reassessed for its second extension for NABL accreditation this year and granted the extension from 29 Sept., 2013 for the next two years.



- ❑ The IPL have different divisions for its different activities e.g. Analytical Research & Development Division, Monographs Development Division, Reference Standards Development Division and Quality Assurance Division.
- ❑ IPL is well equipped with modern analytical instruments like HPLC, HPTLC, GC, GC-MS, GC-HS, FTIR, TGA-DSC, LC-MSMS, ICP-MS, CHN-S, NMR, Polarimeter, Autotitrator, KF Titrator, Microbalances etc.



ISO/IEC 17025:2005 NABL ACCREDITED LABORATORY

Contd.





ISO/IEC 17025:2005 NABL ACCREDITED LABORATORY

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ISO/IEC 17025:2005 NABL ACCREDITED LABORATORY

Contd.





RESEARCH FACILITY AND TRAINING

- ❑ Analytical Research and Development Division published more than 50 Research papers/ articles in different national and International journals on the method development for drug and Pharmaceutical and provided research facility and guided by supervising for 05 Ph.D. and 30 P.G. students for their research projects.
- ❑ AR&D team has awarded for Best Research Papers in the field of Pharmaceutical Analysis for their research paper published in Indian Drugs in the year 2013 by IDMA.



RESEARCH FACILITY AND TRAINING

Contd.

- ❑ In IPL hundreds of students of pharmacy and analytical sciences along with several analysts from private and govt. sector provided training on the modern analytical instruments.
- ❑ IPC conducted two induction training programme last year for 90 newly recruited Drug Inspectors in CDSCO with their collaboration at IPC, Ghaziabad. Also conducted a training programme on Regulatory Aspects for State and Central Drug Inspectors in this year.



RESEARCH FACILITY AND TRAINING

Contd.

- ❑ Recently IPC conducted two training programmes in this year for Govt. Drug Analyst of different central and state drug testing laboratories for hands-on training on various Modern Analytical Instruments for Drug Testing.
- ❑ IPC-IPL also provided the Pharmacopoeial Training to the WHO National and International fellow from time to time.
- ❑ Provided Pharmacopoeial training to WHO fellows from DPR, Korea.



SUMMARIZING

- ❑ Now, IPC has started the work for developing monographs for IP Addendum 2015 of IP-2014.
- ❑ By all these scientific activities IPC-IPL is playing a very important role for maintaining the quality and efficacy of the drugs & Pharmaceuticals in India by publishing the Indian Pharmacopoeia at regular intervals, providing the IP reference substances to the stakeholders and giving training to the analysts.



IP ADDENDUM-2015 TO IP-2014

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Thanks