

डा. राजीव सिंह खड्गवंशी

सचिव-सह-वैज्ञानिक निदेशक

F. No. T.11015/01/2023-AR&D

Dr. Rajeev Singh Raghuvanshi

Secretary-cum-Scientific Director

Date: April 23, 2025

NOTICE

Subject: Change in Monograph Titles and Synonyms in the Indian Pharmacopoeia-reg.

With the objective to align content of the Indian Pharmacopoeia (IP) with current regulatory requirements and best practices, IPC proposes to change the titles of certain IP monographs and their synonyms as listed in Table 1 (Oral Solutions and Syrups in Powder Form), Table 2 (Oral Suspensions in Powder Form), and Table 3 (Injections in Powder Form) in the upcoming edition of the IP 2026 which is expected to be released in December 2025 so as to become effective from July 2026.

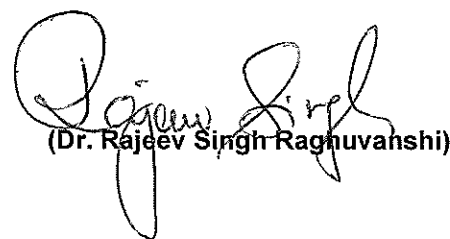
2. Therefore, concerned manufacturers and stakeholders are hereby informed to evaluate the impact of this notification on their existing marketed products and initiate necessary measures for corresponding product label changes, obtaining necessary regulatory approvals, and artwork revision etc. so that compliance with proposed title changes can be ensured once the IP 2026 becomes effective.

3. Further, IPC encourages an early adoption of the proposed title changes by the stakeholders without waiting for publication of the IP 2026. For this, manufacturers are allowed to take necessary regulatory approvals for their affected products as per the list enclosed in Table 1, Table 2, and Table 3.

4. Accordingly, concerned regulatory authorities are also requested to consider applications from the marketing authorization holders and grant approvals for changes in titles in product licenses for alternate names as mentioned in Table 1, Table 2, and Table 3.

5. In order to avoid any regulatory challenges, it is permitted that the 'current title' and the 'proposed title' shall be considered synonyms and can be used interchangeably during the transition phase i.e. from the date of issue of this notice until the effective implementation of the IP 2026.

6. However, all marketed products shall be required to comply with the changed monograph titles and/or their synonyms once the IP 2026 becomes effective and; thereafter, exemptions given in this notice shall not be applicable.



(Dr. Rajeev Singh Raghuvanshi)

To,

1. The Drugs Controller General (India)
2. All State Drug Controllers
3. CDSCO Zonal and Port Offices
4. Members of the Scientific Body of IPC
5. Directors of the Drugs Testing Laboratories
6. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations

IPC is a member of the Pharmacopoeial Discussion Group (PDG)

INDIAN PHARMACOPOEIA
(IP)

Official Book of Drug Standards
in India

IP REFERENCE SUBSTANCES
(IPRS) AND IMPURITIES

Official Physical Standards for
Assessing the Quality of Drugs

NATIONAL FORMULARY OF INDIA
(NFI)

Reference Book to Promote Rational Use
of Generic Medicines

PHARMACOVIGILANCE PROGRAMME OF INDIA
(PvPI)



WHO Collaborating Centre for Pharmacovigilance in
Public Health Programmes and Regulatory Services

Table 1. List of Monographs on Oral Solution and Syrup in Powder Form

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
1.	Title:- Cloxacillin Syrup Synonyms:- Cloxacillin Sodium Syrup; Cloxacillin Elixir; Cloxacillin Sodium Elixir; Cloxacillin Oral Solution; Cloxacillin Sodium Oral Solution;	Title:- Cloxacillin for Oral Solution Synonyms:- Cloxacillin Sodium for Oral Solution;
2.	Title:- Dexchlorpheniramine Oral Solution Synonyms:- Dexchlorpheniramine Maleate Oral Solution	Title:- Dexchlorpheniramine for Oral Solution Synonyms:- Dexchlorpheniramine Maleate for Oral Solution
3.	Title:- Flucloxacillin Oral Solution	Title:- Flucloxacillin for Oral Solution
4.	Title:- Hyoscyamine Oral Solution Synonyms:- Hyoscyamine Sulphate Oral Solution	Title:- Hyoscyamine for Oral Solution Synonyms:- Hyoscyamine Sulphate for Oral Solution
5.	Title:- Stavudine Oral Solution	Title:- Stavudine for Oral Solution

Table 2. List of Monographs on Oral Suspension in Powder Form

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
1.	Title:- Amoxycillin Oral Suspension Synonyms:- Amoxicillin Oral Suspension	Title:- Amoxycillin for Oral Suspension Synonyms:- Amoxicillin for Oral Suspension
2.	Title:- Amoxycillin and Potassium Clavulanate Oral Suspension Synonyms:- Amoxicillin and Potassium Clavulanate Oral Suspension	Title:- Amoxycillin and Potassium Clavulanate for Oral Suspension Synonyms:- Amoxicillin and Potassium Clavulanate for Oral Suspension
3.	Ampicillin Oral Suspension	Ampicillin for Oral Suspension
4.	Azithromycin Oral Suspension	Azithromycin for Oral Suspension
5.	Cefaclor Oral Suspension	Cefaclor for Oral Suspension
6.	Title:- Cefadroxil Oral Suspension Synonyms:- Cefadroxil Mixture	Cefadroxil for Oral Suspension
7.	Cefdinir Oral Suspension	Cefdinir for Oral Suspension
8.	Cefixime Oral Suspension	Cefixime for Oral Suspension
9.	Title:- Cefpodoxime Oral Suspension Synonyms:- Cefpodoxime Proxetil Oral Suspension	Title:- Cefpodoxime for Oral Suspension Synonyms:- Cefpodoxime Proxetil for Oral Suspension
10.	Title:- Cephalexin Oral Suspension Synonyms:- Cephalexin Dry Syrup; Cephalexin Mixture	Title:- Cephalexin for Oral Suspension
11.	Chlorothiazide Oral Suspension	Chlorothiazide for Oral Suspension
12.	Clindamycin Palmitate Hydrochloride Oral Suspension	Clindamycin Palmitate Hydrochloride for Oral Solution
13.	Colistin Sulphate Oral Suspension	Colistin Sulphate for Oral Suspension
14.	Title:- Dicloxacillin Oral Suspension Synonyms:- Dicloxacillin Sodium Oral Suspension	Title:- Dicloxacillin for Oral Suspension Synonyms:- Dicloxacillin Sodium for Oral Suspension
15.	Fluconazole Oral Suspension	Fluconazole for Oral Suspension
16.	Flucytosine Oral Suspension	Flucytosine for Oral Suspension
17.	Ganciclovir Oral Suspension	Ganciclovir for Oral Suspension
18.	Mycophenolate Mofetil Oral Suspension	Mycophenolate Mofetil for Oral Suspension
19.	Title:- Oseltamivir Oral Suspension Synonyms:- Oseltamivir Phosphate Oral Suspension	Title:- Oseltamivir for Oral Suspension Synonyms:- Oseltamivir Phosphate for Oral Suspension

Table 3. List of Monographs on Injections in Powder Form

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
1.	Title:- Aciclovir Intravenous Infusion Synonyms:- Acyclovir Intravenous Infusion; Acyclovir Sodium Intravenous Infusion	Title:- Aciclovir for Intravenous Infusion Synonyms:- Acyclovir for Intravenous Infusion; Acyclovir Sodium for Intravenous Infusion
2.	Title:- Amoxycillin Injection Synonyms:- Amoxicillin Sodium Injection; Amoxycillin Sodium Injection	Title:- Amoxycillin for Injection Synonyms:- Amoxicillin Sodium for Injection; Amoxycillin Sodium for Injection
3.	Title:- Amoxycillin and Potassium Clavulanate Injection Synonyms:- Amoxicillin and Potassium Clavulanate injection	Title:- Amoxycillin and Potassium Clavulanate for Injection Synonyms:- Amoxicillin and Potassium Clavulanate for Injection
4.	Amphotericin B Injection	Amphotericin B for Injection
5.	Title:- Ampicillin Injection Synonyms:- Ampicillin Sodium Injection	Title:- Ampicillin for Injection Synonyms:- Ampicillin Sodium for Injection
6.	Artesunate Injection	Artesunate for Injection
7.	Title:- Bendamustine Injection Synonyms:- Bendamustine Hydrochloride Injection	Title:- Bendamustine for Injection Synonyms:- Bendamustine Hydrochloride for Injection
8.	Title:- Benzathine Penicillin Injection Synonyms:- Benzathine Benzylpenicillin Injection; Benzathine Penicillin G Injection	Title:- Benzathine Penicillin for Injection Synonyms:- Benzathine Benzylpenicillin for Injection; Benzathine Penicillin G for Injection
9.	Title:- Fortified Benzathine Penicillin Injection Synonyms:- Fortified Benzathine Benzylpenicillin Injection; Fortified Benzathine Penicillin G Injection	Title:- Fortified Benzathine Penicillin for Injection Synonyms:- Fortified Benzathine Benzylpenicillin for Injection; Fortified Benzathine Penicillin G for Injection
10.	Title:- Benzylpenicillin Injection Synonyms:- Penicillin G Injection	Title:- Benzylpenicillin for Injection Synonyms:- Penicillin G for Injection
11.	Title:- Bleomycin Injection Synonyms:- Bleomycin Sulphate Injection	Title:- Bleomycin for Injection Synonyms:- Bleomycin Sulphate for Injection
12.	Bortezomib Injection	Bortezomib for Injection
13.	Capreomycin Injection	Capreomycin for Injection
14.	Title:- Carbenicillin Sodium Injection Synonyms:- Carbenicillin Injection; Carbenicillin Disodium Injection	Title:- Carbenicillin Sodium for Injection Synonyms:- Carbenicillin for Injection; Carbenicillin Disodium for Injection
15.	Carmustine Injection	Carmustine for Injection
16.	Title:- Cefamandole Injection Synonyms:- Cefamandole Nafate Injection	Title:- Cefamandole for Injection Synonyms:- Cefamandole Nafate for Injection
17.	Title:- Cefazolin Sodium Injection	Title:- Cefazolin Sodium for Injection

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
	Synonyms:- Cefazolin Injection; Cephazolin Sodium Injection; Cephazolin Injection	Synonyms:- Cefazolin for Injection; Cephazolin Sodium for Injection; Cephazolin for Injection
18.	Title:- Cefepime Injection Synonyms:- Cefepime Hydrochloride Injection	Title:- Cefepime for Injection Synonyms:- Cefepime Hydrochloride for Injection
19.	Title:- Cefoperazone Injection Synonyms:- Cefoperazone Sodium Injection	Title:- Cefoperazone for Injection Synonyms:- Cefoperazone Sodium for Injection
20.	Title:- Cefotaxime Sodium Injection Synonyms:- Cefotaxime Injection	Title:- Cefotaxime Sodium for Injection Synonyms:- Cefotaxime for Injection
21.	Title:- Cefpirome Injection Synonyms:- Cefpirome Sulphate Injection	Title:- Cefpirome for Injection Synonyms:- Cefpirome Sulphate for Injection
22.	Ceftriaxone Injection	Ceftriaxone for Injection
23.	Title:- Cefuroxime Injection Synonyms:- Cefuroxime Sodium Injection	Title:- Cefuroxime for Injection Synonyms:- Cefuroxime Sodium for Injection
24.	Cephaloridine Injection	Cephaloridine for Injection
25.	Chloramphenicol Sodium Succinate Injection	Chloramphenicol Sodium Succinate for Injection
26.	Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin for Injection
27.	Title:- Cloxacillin Injection Synonyms:- Cloxacillin Sodium Injection	Title:- Cloxacillin for Injection Synonyms:- Cloxacillin Sodium for Injection
28.	Colistimethate Injection	Colistimethate for Injection
29.	Cyclophosphamide Injection	Cyclophosphamide for Injection
30.	Title:- Cytarabine Injection Synonyms:- β -Cytosine Arabinoside Injection	Title:- Cytarabine for Injection Synonyms:- β -Cytosine Arabinoside for Injection
31.	Dacarbazine Injection	Dacarbazine for Injection
32.	Title:- Daunorubicin Injection Synonyms:- Daunorubicin Hydrochloride Injection	Title:- Daunorubicin for Injection Synonyms:- Daunorubicin Hydrochloride for Injection
33.	Title:- Desferrioxamine Injection Synonyms:- Desferrioxamine Mesylate Injection; Desferrioxamine Mesilate Injection	Title:- Desferrioxamine for Injection Synonyms:- Desferrioxamine Mesylate for Injection; Desferrioxamine Mesilate for Injection
34.	Ganciclovir Injection	Ganciclovir for Injection
35.	Gemcitabine Injection	Gemcitabine for Injection
36.	Hyaluronidase Injection	Hyaluronidase for Injection
37.	Title:- Hydralazine Injection	Title:- Hydralazine for Injection

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
	Synonyms:- Hydralazine Hydrochloride Injection	Synonyms:- Hydralazine Hydrochloride for Injection
38.	Title:- Hydrocortisone Sodium Succinate Injection Synonyms:- Cortisol Sodium Succinate Injection	Title:- Hydrocortisone Sodium Succinate for Injection Synonyms:- Cortisol Sodium Succinate for Injection
39.	Ifosfamide Injection	Ifosfamide for Injection
40.	Imipenem and Cilastatin Injection	Imipenem and Cilastatin for Injection
41.	Melphalan Injection	Melphalan for Injection
42.	Meropenem Injection	Meropenem for Injection
43.	Mitomycin Injection	Mitomycin for Injection
44.	Title:- Mustine Injection Synonyms:- Mustine Hydrochloride Injection	Title:- Mustine for Injection Synonyms:- Mustine Hydrochloride for Injection
45.	Oxytetracycline Hydrochloride Injection	Oxytetracycline Hydrochloride for Injection
46.	Title:- Pamidronate Disodium Injection Synonyms:- Pamidronate Disodium Pentahydrate Injection	Title:- Pamidronate Disodium for Injection Synonyms:- Pamidronate Disodium Pentahydrate for Injection
47.	Pemetrexed Injection	Pemetrexed for Injection
48.	Title:- Pentamidine Injection Synonyms:- Pentamidine Isethionate Injection	Title:- Pentamidine for Injection Synonyms:- Pentamidine Isethionate for Injection
49.	Title:- Phenytoin Injection Synonyms:- Phenytoin Sodium Injection; Diphenylhydantoin Sodium injection	Title:- Phenytoin for Injection Synonyms:- Phenytoin Sodium for Injection; Diphenylhydantoin Sodium for Injection
50.	Piperacillin Intravenous Infusion	Piperacillin for Intravenous Infusion
51.	Piperacillin and Tazobactam Injection	Piperacillin and Tazobactam for Injection
52.	Pralidoxime Chloride Injection	Pralidoxime Chloride for Injection
53.	Title:- Fortified Procaine Penicillin Injection Synonyms:- Procaine Penicillin with Benzylpenicillin Injection	Title:- Fortified Procaine Penicillin for Injection Synonyms:- Procaine Penicillin with Benzylpenicillin for Injection
54.	Title:- Rabeprazole Injection Synonyms:- Rabeprazole Sodium Injection	Title:- Rabeprazole for Injection Synonyms:- Rabeprazole Sodium for Injection
55.	Remdesivir Injection	Remdesivir for Injection
56.	Sodium Nitroprusside Injection	Sodium Nitroprusside for Injection
57.	Streptokinase Injection	Streptokinase for Injection
58.	Title:- Streptomycin Injection	Title:- Streptomycin for Injection

Sr. No.	Monograph Titles and Synonyms in the IP 2022	Proposed Monograph Titles and Synonyms in the IP 2026
	Synonyms:- Streptomycin Sulphate Injection	Synonyms:- Streptomycin Sulphate for Injection
59.	Teicoplanin Injection	Teicoplanin for Injection
60.	Temozolomide Injection	Temozolomide for Injection
61.	Title:- Thiopentone Injection Synonyms:- Thiopentone Sodium Injection; Thiopental Injection	Title:- Thiopentone for Injection Synonyms:- Thiopentone Sodium for Injection; Thiopental for Injection
62.	Thiotepa Injection	Thiotepa for Injection
63.	Tigecycline Injection	Tigecycline for Injection
64.	Vancomycin Intravenous Infusion	Vancomycin for Intravenous Infusion
65.	Vecuronium Bromide Injection	Vecuronium Bromide for Injection
66.	Title:- Vinblastine Injection Synonyms:- Vinblastine Sulphate Injection	Title:- Vinblastine for Injection Synonyms:- Vinblastine Sulphate for Injection
67.	Title:- Vincristine Injection Synonyms:- Vincristine Sulphate Injection	Title:- Vincristine for Injection Synonyms:- Vincristine Sulphate for Injection
68.	Voriconazole Injection	Voriconazole for Injection
69.	Zoledronic Acid Injection	Zoledronic Acid for Injection