



भारत सरकार
आयुष मंत्रालय
भारतीय चिकित्सा एवं होम्योपैथी भेषज संहिता आयोग
(भारतीय चिकित्सा एवं होम्योपैथी केन्द्रीय औषधि प्रयोगशाला)
कमला नेहरू नगर, गाजियाबाद (उ.प्र.) एन.सी.आर. दिल्ली - 201002
Government of India
Ministry of Ayush
Pharmacopoeia Commission for Indian Medicine & Homoeopathy
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Date: 21.12.2023

NOTIFICATION

AMENDMENT LIST - 1 (2023) TO AYURVEDIC PHARMACOPOEIA OF INDIA (API), PART-I & II

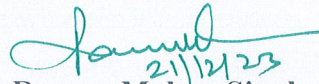
1. Towards continued improvisation of the Ayurvedic Pharmacopoeia of India and taking necessary cognisance of the technical suggestions received from various experts of the field, following Amendments in the published versions of Ayurvedic Pharmacopoeia of India, Part-I & II are hereby notified and appended as 'AMENDMENT LIST - 1 (2023) TO AYURVEDIC PHARMACOPOEIA OF INDIA (API), PART-I & II'.
2. The Amendments notified herein shall come into effect after 01 (One) year from the date of issue of this notification namely 'Amendment List - 1 (2023) to Ayurvedic Pharmacopoeia of India (API), Part-I & II (including their volumes)', and the Ayurvedic Pharmacopoeia of India (API), Part-I & II (including their volumes) hitherto stand construed to be amended to that extent superseding the published versions.
3. The amendments so notified shall also be applicable to any reference to/quote of the monographs under concern in the respective part of Ayurvedic Pharmacopoeia of India wherever the context permits.
4. Details of the published versions so amended are as follows:
 - API, Part-I, Vol.-I, 1986 (Revised)
 - API, Part-I, Vol.-II, 1999
 - API, Part-I, Vol.-III, 2001
 - API, Part-I, Vol.-IV, 2004
 - API, Part-I, Vol.-V, 2006
 - API, Part-I, Vol.-VI, 2008
 - API, Part-I, Vol.-VIII, 2011 (Hydro-alcoholic & water extracts)
 - API, Part-I, Vol.-IX, 2016 (Hydro-alcoholic & water extracts)
 - API, Part-II, Vol.-I, 2007 (Formulations)
 - API, Part-II, Vol.-II, 2008 (Formulations)
 - API, Part-II, Vol.-III, 2010 (Formulations)
 - API, Part-II, Vol.-IV, 2017 (Formulations)
5. The 'Amendment List - 1 (2023) to Ayurvedic Pharmacopoeia of India (API), Part-I & II' becomes applicable for compliance to any/all regulatory provisions under Drugs and Cosmetics Act, 1940 and the Rules thereunder wherever applicable. However, the Drug manufacturing licenses issued prior to issue of this notification of 'Amendment List - 1 (2023) to Ayurvedic Pharmacopoeia of India (API), Part-I & II' where any reference to monographs under amendment is quoted, shall stand valid for 01 (One) year from the issue of this notification.
6. This issues with the approval of competent authority (M/o Ayush letter No. Y-11015/04/2023-LP Dated 20.12.2023).

21/12/23
Dr. Raman Mohan Singh
Director

Enclosure: Amendment List - 1 (2023) to Ayurvedic Pharmacopoeia of India (API), Part-I & II

To:

1. Secretary (Ayush), Ministry of Ayush, Ayush Bhawan, B-Block, GPO Complex, INA, New Delhi – 110023
2. Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Directorate General of Health Services, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002
3. Adviser (Ay.), Drug Policy Section, Ministry of Ayush, Office Complex, NBCC Building, Plate-A, Block-3, IInd Floor, Kidwai Nagai, New Delhi - 110 023
4. Director General, Central Council for Research in Ayurvedic Sciences (CCRAS), 61-65, opp. D' Block, Institutional Area, Janakpuri, New Delhi - 110058 with a request to upload the notification to website of CCRAS
5. Under Secretary, L&P Section, Ministry of Ayush, Ayush Bhawan, B-Block, GPO Complex, INA, New Delhi – 110023 with a request to upload the notification to website of Ministry of Ayush
6. All the members of Scientific Advisory Board (SAB), Pharmacopoeia Committee (PC) and its sub-committees under PCIM&H
7. All the State/UT Ayurveda Licensing Authorities
8. Ayurveda Drugs Manufacturers Associations
9. Website coordinator, PCIM&H for uploading to website of PCIM&H


21/12/23
Dr. Raman Mohan Singh
Director

**AMENDMENT LIST - I (2023) TO AYURVEDIC PHARMACOPOEIA OF INDIA (API),
PART-I & II**

- 1. Context: Abbreviation indicated as 'Fr. P.' for Pericarp in the Pharmacopoeial Monographs / Appendices / List of abbreviations for Parts used of plant origin drugs, appearing in API, Part-I & II (including their volumes)**

The abbreviation 'Fr. P.' for Pericarp of plant origin drugs stands revised as 'P.' in all the Pharmacopoeial Monographs / Appendices / List of abbreviations for Parts used of plant origin drugs, appearing in API, Part-I & II (including their volumes), wherever applicable.

- 2. Context: Pharmacopoeial Monograph of Vidārī from API Part-I, Vol. - II & Pharmacopoeial Monograph of Vidārīkanda from API Part-I, Vol. - V**

Owing to repetition of monographs, the Vidārīkanda monograph from API, Part-I, Vol.-V prevails while that of Vidārī from API, Part-I, Vol. - II stands nullified.

- 3. Context: Pharmacopoeial Monograph of Karañja from API Part-I, Vol. - II**

A. Existing version:

Dose - for external use only

B. Revised version:

Dose: 1-3 g;

Q.S. for external use

- 4. Context: Pharmacopoeial Monograph of Palāśa (Seed) from API Part-I, Vol. - IV & Pharmacopoeial Monograph of Palāśaḥ (Seed) from API Part-I, Vol. - V**

Owing to repetition of monographs, the Palāśa (Seed) monograph from API, Part - I, Vol.-IV prevails while that of Palāśaḥ (Seed) from API, Part-I, Vol.-V stands nullified.

- 5. Context: API Part-I, Vol. - VI Pharmacopoeial monograph of JALA (Potable Water)**

A. Existing version:

Microbial Limits

Coliform Organisms - Absent (Complies to appendix 2.4 of API Part - I, Vol. - VI)

E. coli - Absent (Complies to appendix 2.4 of API Part - I, Vol. - VI)

B. Revised version:

Microbial Limits

Total Microbial Plate Count (TPC) / Total Aerobic Microbial Count (TAMC): 10^2 CFU/ml; (To be determined as per Appendix 2.4 of API Part - I, Vol. - VI)

Staphylococcus aureus: Absent (Appendix 2.4 of API Part - I, Vol. - VI)

Pseudomonas aeruginosa: Absent (Appendix 2.4 of API Part - I, Vol. - VI)

Escherichia coli: Absent (Appendix 2.4 of API Part - I, Vol. - VI)

Salmonella sp.: Absent (Appendix 2.4 of API Part - I, Vol. - VI)

- 6. Context: API Part-II, Vol.-III Pharmacopoeial monograph of BRĀHMĀRKA**

A. Existing version:

Therapeutic uses: Buddhimandatā, Smṛtibhrama

B. Revised version:

Therapeutic uses: Buddhimandatā, Smṛtibhrama, Pralāpa

7. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Gulābārka

A. Existing version:

Formulary reference: AFI Part - III, 2:3

B. Revised version:

Formulary reference: AFI Part - III, 2:4

8. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Gulābārka

A. Existing version:

Therapeutic uses: Dāha, Tṛṣṇā, Hṛllāsa, Netraroga

B. Revised version:

Therapeutic uses: Dāha, Tṛṣṇā, Hṛllāsa, Netraroga, Varṇya

9. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Kākamācyarka

A. Existing version:

Therapeutic uses: Hṛdroga, Yakṛdroga, Śoṭha, Chardi, Netraroga

B. Revised version:

Therapeutic uses: Hṛdroga, Yakṛdroga, Śoṭha, Chardi, Netraroga, Arśas, Udararoga, Pāṇḍu, Kāmalā, Jvara

10. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Parpaṭārka

A. Existing version:

Therapeutic uses: Kaphajvara, Tṛṣṇā, Atisāra, Dāha, Raktapitta, Bhrama

B. Revised version:

Therapeutic uses: Kaphapittajvara, Tṛṣṇā, Atisāra, Dāha, Raktapitta, Bhrama, Tvagvikāra, Visphoṭa, Pāmā, Vicarcikā, Svedādhikya

11. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Punarnavārka

A. Existing version:

Therapeutic uses: Jalodara, Śoṭha, Netraroga, Grāhī, Raktapitta

B. Revised version:

Therapeutic uses: Jalodara, Śoṭha, Netraroga, Grāhī, Raktapitta, Atisāra, Kāmalā, Pāṇḍu, Halīmaka, Udararoga, Mūtrakṛcchra, Prameha, Yakṛt-śoṭha, Bastiśoṭha, Garbhāśayaśoṭha

12. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Śatāhvārka

A. Existing version:

Formulary reference: AFI Part - III, 2:15

B. Revised version:

Formulary reference: AFI Part - III, 2:14

13. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Vanyājamodārka

A. Existing version:

Formulary reference: AFI Part - III, 2:14

B. Revised version:

Formulary reference: AFI Part - III, 2:13

14. Context: API Part-II, Vol.-III Pharmacopoeial monograph of Bṛhat Saindhavādya Taila, Physico-chemical parameters

A. Existing version:

Refractive index at 40⁰: 1.4601 to 1.4670 (Complies with Appendix 3.1)

B. Revised version:

Refractive index at 40⁰: 1.4700 to 1.4810 (Complies with Appendix 3.1)

Bibliography

1. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-I (Revised), 1986
2. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-II, 1999
3. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-III, 2001
4. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-IV, 2004
5. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-V, 2006
6. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-VI, 2008
7. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-VIII (Hydro-alcoholic & water extracts), 2011
8. Ayurvedic Pharmacopoeia of India, Part-I, Vol.-IX (Hydro-alcoholic & water extracts), 2016
9. Ayurvedic Pharmacopoeia of India, Part-II, Vol.-I (Formulations), 2007
10. Ayurvedic Pharmacopoeia of India, Part-II, Vol.-II (Formulations), 2008
11. Ayurvedic Pharmacopoeia of India, Part-II, Vol.-III (Formulations), 2010
12. Ayurvedic Pharmacopoeia of India, Part-II, Vol.-IV (Formulations), 2017