

RECOGNITION OF AYURVEDIC PHARMACOPOEIA OF INDIA (API) AND AYURVEDIC FORMULARY OF INDIA (AFI) BY SWISSMEDIC

Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) through Ministry of Ayush, Govt. of India is working with Govt. of Switzerland to accord recognition to Ayurvedic drugs. As a first step, inclusion of 41 substances* from Ayurvedic Medicine in the list of Traditional Asian Substances (TAS) has been recently achieved. Now any company having a (Co-)seat in Switzerland can develop and sell Ayurvedic pharmaceuticals out of those 41 substances listed.

Swissmedic (Swiss Agency for Therapeutic Products) is the central Swiss supervisory authority for medicinal products. It is a Bern-based institution affiliated with the Federal Department of Home Affairs and works in accordance with Therapeutic Products Act and federal corporate governance.

The Complementary and Phytomedicine Ordinance, KPAV; SR 812.212.24 has recently been reviewed in view of simplified authorization and reporting procedure for complementary and herbal medicines and revised with effect from 1st July, 2023. The list of documented TAS according to Annex 10 of the ordinance includes substances that are common and established in Asian medicine and that serve as starting materials for medicinal products of the corresponding therapeutic directions without an indication. They have an official pharmacopoeial monograph on quality. In this latest revision, a new distinction is made and a total of 41 substances, for which the use in Ayurvedic medicine is sufficiently documented have been added as second part of this list, taking into account the respective Sanskrit designation.

Further, Appendix 9 of the said ordinance i.e. list of standard works which has references that contain traditional and established classic formulations and recipes for the approval of fixed drug combinations in Asian medicine in a simplified procedure and based on a notification has also been revised. **The revised list now recognises The Ayurvedic Pharmacopoeia of India, Part-II (Formulations), Volume-I (2007) to Volume-IV (2017) and The Ayurvedic Formulary of India, Part-I (2003) to Part-III (2010) as standard works from Ayurvedic medicine that meet the requirements for inclusion. Thus, 202 pharmacopoeial monographs and 985 Formulary specifications of classical Ayurvedic Formulations get a place in the recognition by Swissmedic.**

*List of 41 substances from Ayurvedic Medicine

Sl. No.	Pharmaceutical designation	Designation of the approved parent plants	Designation Sanskrit
1.	Allii sativi bulbus	Allium sativum L.	Lasuna
2.	Althaeae radix	Althaea officinalis L.	Khatmi
3.	Alumen	Potassium aluminum sulfate; KAl(SO ₄) ₂ ·12H ₂ O	Saurastri, Sphatikari
4.	Andrographidis herba	Andrographis paniculata (Burm. f.) Nees	Kalamegha
5.	Anethi fructus	Anethum graveolens DC (syn Anethum sowa Roxb. ex Flem., Peucedanum graveolens Benth, P. sowa Roxb.)	Satahva
6.	Anisi fructus	Pimpinella anisum L.	Anisuna

Sl. No.	Pharmaceutical designation	Designation of the approved parent plants	Designation Sanskrit
7.	Anisi stellati fructus	Illicium verum Hook. f.	Takkola
8.	Arecae semen	Areca catechu L.	Puga
9.	Asa foetida	Ferula assa-foetida L., Ferula foetida (Bunge) Regel., und andere	Hingu
10.	Aucklandiae radix	Saussurea costus (Falc.) Lipsch. (syn. Saussurea lappa C.B.Clarke, Aucklandia lappa Decne., Aucklandia costus Falc.)	Kustha
11.	Calami rhizoma	Acorus calamus L.	Vaca
12.	Carvi fructus	Carum carvi L.	Krisnajiraka
13.	Caryophylli flos	Syzygium aromaticum (L.) Merr. et L.M.Perry (syn. Eugenia caryophyllus (Spreng.) Bullock et S.G.Harrison)	Lavanga
14.	Centellae planta tota	Centella asiatica (L.) Urban	Mandukaparni
15.	Chebulae fructus	Terminalia chebula Retz.; Terminalia chebula Retz. var. tomentella Kurt.	Haritaki
16.	Cinnamomi cortex	Cinnamomum verum J.Presl. (syn. Cinnamomum zeylanicum Blume)	Tvak
17.	Coriandri fructus	Coriandrum sativum L.	Dhanyaka
18.	Croci stigma	Crocus sativus L.	Kunkuma
19.	Curculiginis rhizoma	Curculigo orchoides Gaertn.	Talamuli
20.	Curcumae longae rhizoma	Curcuma longa L. (syn. Curcuma domestica Valetton)	Haridra
21.	Cyperi rhizoma	Cyperus rotundus L.	Musta
22.	Ecliptae planta tota	Eclipta alba (L.) Hassk.	Bhrngaraja
23.	Eucalypti folium	Eucalyptus globulus Labill.	Tailaparna
24.	Foeniculi fructus	Foeniculum vulgare Mill.	Misreya
25.	Inulae radix	Inula racemosa Hook f.	Puskara
26.	Lini semen	Linum usitatissimum L.	Atasi
27.	Liquiritiae radix	Glycyrrhiza glabra L. Die monographierten Arten Glycyrrhiza uralensis Fisch. und Glycyrrhiza inflata Bat. kommen in der ayurvedischen Medizin nicht zur Anwendung.	Yasti
28.	Meliae cortex	Melia azedarach L.	Mahanimba
29.	Myristicae semen	Myristica fragrans Houtt.	Jatiphala

Sl. No.	Pharmaceutical designation	Designation of the approved parent plants	Designation Sanskrit
30.	Piperis fructus	Piper nigrum L.	Marica
31.	Piperis longi fructus	Piper longum L. Die in der Ph. Eur. monographierte Art Piper retrofractum Vahl (syn. P. chaba Hunter and P. officinarum (Miq.) C. DC.) kommt in der ayurvedischen Medizin für Piperis longi fructus nicht zur Anwendung.	Pippali
32.	Psoraleae fructus	Psoralea corylifolia L.	Bakuci
33.	Raphani semen	Raphanus sativus L.	Mulaka
34.	Rubiae radix et rhizoma	Rubia cordifolia L.	Manjista
35.	Santali albi lignum	Santalum album L.	Svetacandana
36.	Sappan lignum	Caesalpinia sappan L.	Pattanga
37.	Sennae folium	Senna alexandrina Mill. (Syn. Cassia acutifolia Delile und Cassia angustifolia Vahl)	Svarnapatri
38.	Tribuli fructus	Tribulus terrestris L.	Goksura
39.	Trigonellae foenugraeci semen	Trigonella foenum-graecum L.	Methi
40.	Zingiberis rhizoma	Zingiber officinale (Willd.) Roscoe	Sunthi
41.	Zingiberis rhizoma recens	Zingiber officinale (Willd.) Roscoe	Ardra