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BUREAU OF INDIAN STANDARDS

AGENDA

# Fifth meeting of the Homoeopathy Sectional Committee (AYD-07)

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| --- | --- | --- | --- | --- | --- |
| **Name of the Committee** | **Meeting Number** | **Day** | **Date** | **Time** | **Venue** |
| **Homoeopathy Sectional Committee AYD-07** | **5** | **Friday** | **06.09.2024** | **10.30 am** | **Blue Room,**  **Manak Bhawan, BIS, Delhi**  **(Hybrid Mode)** |
| **CHAIRPERSON:** **Dr Raj K. Manchanda** | | | **MEMBER SECRETARY:** **Dr. Kumar Vivekanand** | | |

# ITEM 0 GENERAL

**0.1 Welcome**

# 0.2 Opening Remarks by the Chairperson, AYD-07

# ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the 4th Homoeopathy Sectional Committee (AYD-07) meeting held on 26.03.2024 duly approved by the Chairperson were circulated to the committee members through the BIS module. No comments on the accuracy of the recording were received.

***The Committee may kindly CONFIRM the minutes as circulated.***

**ITEM 2 SCOPE, ACTIVITIES AND COMPOSITION**

**2.1 Scope and Activities (Program of Work) of the Committee**

The scope and activities of the AYD-07 is embedded below as **Annex I:**



***The Committee may kindly note.***

**2.2 Composition of the Sectional Committee**

**2.2.1** The present composition of the AYD 07 and the attendance record of the last three meetings are embedded below as Annex II. Panels are created under a Sectional Committee to have a smaller group of experts/professionals with the expertise and skill sets suitable for a standard or a set of standards under development, based on the scope of Sectional Committee. Considering the sub-sectors under Homoeopathy sector, it is proposed to constitute the following Panels under AYD 07:

a. Plant Origin Raw Material

b. Terminology

c. Homoeopathy dosage forms

d. Equipment and Tools Used in Homoeopathy

e. Packing and Dispensing Material

f. Hospital Planning

Working Group is envisaged as a Special Purpose Vehicle to carry out a specific task: one particular subject or a set of related subjects for standardization or an existing standard or a set of related standards for review. The composition of the Expert Working Groups that come under the purview of AYD 07 is embedded below as Annex III.

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***The Committee may kindly deliberate.***

**2.2.2** No nominations have been received from:

1. Central Government Health Scheme (CGHS), New Delhi
2. All India Institute of Medical Sciences (AIIMS), Dept. of Pharmacology, New Delhi
3. National Medicinal Plants Board (NMPB), Ministry of AYUSH, New Delhi
4. Synergy Homeopathic, 201, Dinar, 20 Station Road, Santacruz (W), Mumbai, Maharashtra
5. AYUSHEXCIL (Ayush Export Promotion Council), New Delhi

***The Committee may kindly deliberate.***

**2.2.3** New nominations from the Nehru Homeopathic Medical College and Hospital (NHMC&H), New Delhi, have been received replacing Principal Member as under:

|  |  |  |  |
| --- | --- | --- | --- |
| **S.no.** | **Organization** | **Member** | **Role** |
| **1.** | Nehru Homoeopathic Medical College and Hospital, New Delhi | 1. Dr. Seema Rai | Principal Member |
| 1. Dr. Vandana Chopra | Alternate Member |

Office order is embedded below as **Annex IV:**

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***The Committee may kindly consider.***

**2.2.4** Nominations have also been received from [Govt. of NCT, Directorate of Ayush (Homoeopathic Wing), New Delhi](javascript:;) for the members of the Homoeopathic Sectional Committee (AYD 07):

|  |  |  |  |
| --- | --- | --- | --- |
| **S.no.** | **Organization** | **Member** | **Role** |
| **1.** | [Govt. of NCT, Directorate of Ayush (Homoeopathic Wing), New Delhi](javascript:;) | 1. Dr. Leena Vasant Chhatre | Principal Member |
| 2. Dr. Meeta Gupta | Alternate Member |

Office order is embedded below as **Annex V:**

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***The Committee may kindly consider.***

# ITEM 3 ISSUES ARISING OUT OF PREVIOUS MEETINGS

***During the previous meeting, the following areas were identified and approved:***

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Reference clause in the Minutes of 4th meeting of AYD (07) & decision of the committee** | | ***Action Taken/Status*** |
| **1.** | **7.1 Herbs that have not been addressed by the Pharmacopoeia Commission or are absent in published pharmacopoeias**  The Committee considered the proposal for the formulation of the Indian Standard on Herbs, which has not been addressed by the Pharmacopoeia Commission or is absent in published pharmacopeias. The Committee assigned Panel 1 for standard preparation on the following drugs: | | No P draft prepared as of now. Convener to share updates.  ***The committee may kindly note.*** |
| 1. Anatherum Muricatum 2. Boerhaavia Repens 3. Bryophyllum Calycinum 4. Chaparro Amargoso 5. Cystisus Scoparius | 1. Ficus venosa 2. Gentiana Chirata 3. Ocimum radix 4. Origanum Majorana 5. Saussurea lappa |
| **2.** | **7.2 Standardization related to Ayush Hospitals and wellness centres**  The Committee considered the suggestion of Ayush Division Council and decided to formulate Indian Standard on Ayush Hospitals and wellness centres. The Committee suggested constituting a sub-sector for Hospital Planning, and a Panel ‘Requirements for Homoeopathy Wellness Centres’ for this purpose in consultation with the Chair. | | Due to a lack of clarity, no working group/ panel has been created yet.  ***The committee may kindly***  ***deliberate.*** |
| **3.** | **7.3 Standard Treatment Guidelines (Homoeopathic Stream)**  The Committee considered the proposal and decided to formulate Indian Standards on homoeopathic **Standard Treatment Guidelines (STG)**. The Committee suggested to constitute a new panel for STG in consultation with the Chair. | | Discussed during various forums and BIS secretariate, and decided to drop the matter for now.    ***The committee may kindly consider.*** |
| **4.** | **7.4** During the discussion, the Chairperson expressed the need for standardization of Nosodes and Sarcodes. The Committee decided to formulate an Indian Standard on Nosodes, keeping in view of N1N2 (HPI Vol-IV). The Committee suggested to constitute a new panel for Nosodes/Sarcodes in consultation with the Chair. | |
| **5.** | **7.5** The Committee also felt the need to formulate Indian Standards on cosmetics used in homoeopathy and suggested that Panel 5 may take up the matter along with excipients. | | No P draft prepared as of now. Convener to share updates.  ***The committee may note.*** |

# ITEM 4 INDIAN STANDARDS PUBLISHED/ UNDER PUBLICATION

# 4.1 Doc. AYD 07 (23330) WC Draft Indian Standard - Glossary of Homoeopathy Terminology Standardized Terminology for Commonly Used Terms Related to Homoeopathy

In line with the decision of the Committee in the 4th meeting, the WC draft was finalized with appropriate modifications and sent for publication. The modified draft on the subject is embedded below as **Annex VI.**

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***The Committee may kindly note.***

# ITEM 5 DRAFT STANDARDS FOR FINALIZATION

# 5.1 Doc. [AYD 07 (2](https://www.services.bis.gov.in/php/BIS_2.0/StandardsFormulationV2/Upload3.php?ID=eDI0Vm1VYmlmRVozdTNiVW91WURidz09)4468) WC Draft Indian Standard - Globules for use in Homoeopathy – Specification

# The WC draft was finalized with modifications in the 4th Sectional Committee meeting. Further modifications were done as per the discussion during Panel 5 meeting dated 16 August 2024. The modified draft on the subject is embedded below as Annex VII.

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***The Committee may kindly deliberate.***

**5.2 Doc. AYD 07 (23908) WC Draft Indian Standard - Non-medicated Homoeopathic Tablets – Specification**

The WC draft was finalized with modifications in 4th Sectional Committee meeting. Further modifications were done as per the discussion during Panel 5 meeting dated 16 August 2024. The draft on the subject is embedded below as **Annex VIII.**



***The Committee may kindly deliberate.***

**5.3 Doc. AYD 07 (24851) WC Draft Indian Standard - *Withania Somnifera* Mother Tincture for Use in Homeopathic Medicine - Specification**

Comments on the draft, along with inputs from the Panel, are given below:

| **Sl No.** | **Clause/Sub- clause/ para/table/fig.**  **No. commented** | **Commentator/ Organization/ Abbreviation** | **Type of Comments (General/Editorial/ Technical** | **Justification** | **Proposed Change** | **Observation of Panel 1** |
| --- | --- | --- | --- | --- | --- | --- |
|  | 3.1.1/ 1 | Dr. Karuna Shanker | Editorial | There is a need to update the Withania somnifera root standard IS 18098.  In this standard, no chemical marker was to define the quality of the root. The presence of marker is the indicator for not only authenticity but the efficacy of the product/raw material. |  | Chemical marker has been added to the text. |
|  | 3.2.2 | Dr. Bibaswan Biswas | Technical | Is there be any reason for not including TLC/HPTLC? | The inclusion of TLC/HPTLC may be recommended. | HPTLC is added. |
|  | 3.2.2 | Dr. Bibaswan Biswas | Technical | Wt. per mL is said to be not less than 0.87. As the tincture has both water and alcohol and the total solid for mother tinctures are usually ~1-3%. The alcohol % has profound effect on this value. | Hence, it is requested that a range may be given or say about 0.87. | Wt/ml has been inferred from HPI Volume VI. |
|  |  | Ramakant Ramnayak Yadav | Editorial | Quality control of Raw material and Homeopathic mother tincutres. | A basic coloured image of the plant and the part used should be included in the monograph.  A Regulatory compliance HPTLC Fingerprint technique can be employed to identify the constituents, evaluate the quality, ensure batch-to-batch consistency of the dried fruit raw material to be used in traditional medicine, and further to detect potential adulterants in Ayurvedic medicine.  The Profile comparision from HPTLC can be used to get percentage variation between different batches. Visual image data from HPTLC can be best suited to control the quality of raw material used in traditional medicines as a rapid and green technique. | Not applicable |
|  | 3.3.1 | Dr. Karuna Shanker | General | Please include marker-based quality, e.g., IP and API both have defined the quality based on WIthanolides. At least one marker should be mandatorily considered. | Inclusion of | Marker has been added to the text. |

The draft on the subject has been modified accordingly and embedded below as **Annex IX**:



***The Committee may kindly deliberate.***

**5.4 Doc. AYD 07 (24416) WC Draft Indian Standard - Millefolium (*Achillea millefolium* l.) whole plant for use in homeopathic medicine — Specification**

The Comments on the draft have been resolved by the Panel and are embedded below as **Annex X.**

Accordingly, the modified draft on the subject is embedded below as **Annex XI.**

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For better clarity of the standards, it is suggested to have 02 separate standards (01 for raw drug which may be used by others also and 01 for homoeopathy mother tincture) as given in table, **Annex XII, Annex XIII.**

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| --- | --- | --- | --- |
| **S. No.** | **Doc No.** | **Title of the Draft Standard** | **Annex** |
|  | [AYD 07 (24416](https://www.services.bis.gov.in/php/BIS_2.0/StandardsFormulationV2/Upload3.php?ID=eDI0Vm1VYmlmRVozdTNiVW91WURidz09) ) WC | Millefolium (*Achillea millefolium* l.) for use in traditional medicine — Specification |  |
|  | [AYD 07 (](https://www.services.bis.gov.in/php/BIS_2.0/StandardsFormulationV2/Upload3.php?ID=eDI0Vm1VYmlmRVozdTNiVW91WURidz09)26173) WC | Millefolium mother tincture for use in homoeopathy — specification |  |

***The Committee may kindly deliberate.***

**5.5 Doc. AYD 07 (23521) WC Draft Indian Standard – Plastic Containers and Closures for Packaging and Dispensing of Homoeopathic Medicine – Specification**

The WC draft was finalized with modifications at the 4th Sectional Committee meeting. However, the Ayush Department at BIS has learned that it requires corrections. Therefore, further modifications were done as per the discussion held during the Panel 5 meeting dated 16 August 2024. The modified draft on the subject is embedded below as **Annex XIV.**



***The Committee may kindly deliberate.***

**5.6** **Doc. AYD 07 (23564) WC Draft Indian Standard - Glass Containers and Closures for Packaging and Dispensing of Homoeopathic Medicine – Specification**

The WC draft was finalized with appropriate modifications in 4th Sectional Committee meeting. Further modifications were done as per the discussion during the Panel 5 meeting dated 16 August 2024. The draft on the subject is embedded below as **Annex XV.**



***The Committee may kindly deliberate.***

* 1. **Doc. AYD 07 (24934) WC Draft Indian Standard - Alfalfa [*Medicago sativa* L] for use in Traditional Medicine – Specification**

Comments on the draft along with inputs from the Working Group, are given below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sl.**  **No.** | **Clause/Sub- clause/ para/table/fig.**  **No. commented** | **Commentator/ Organization/ Abbreviation** | **Type of Comments (General/Editorial/ Technical)** | **Justification** | **Proposed change** | **Observation** |
|  | B-2- , 2.3.3/ 1 | Anchrom Enterprises Private Limited, Mumbai | Technical | B-2\_ Thin Layer Chromatography  2.3.3- TLC/ HPTLC  1) To ensure a better and more effective comparison of quality of extracts, two or more different extracts of Medicago sativa should be applied at the same concentration and volume on same plate.  2) The bands of standard amino-butyric acid and leucine are showing dragging due to an excessive on plate amount applied. Reducing the concentration and application volume of the both standard soilutions, will minimize the dragging to an acceptable level. | Two or more sample extracts of Medicago sativa need to apply on same plate for comparison and more effective quality control. | This will be discussed during the meeting. |
|  | B-2, B-2.3.3/ 1 | Anchrom Enterprises Private Limited, Mumbai | Technical | 1. The Rf values of the prominent bands detected in the fingerprint of the Medicago sativa extract sample need to mention.  2. The Rf values for the standard leucine and γ-aminobutyric acid have not been provided.  3. Since this is an Indian standard, the possible Rf value of threonine should be provided in separate comments below the plate image, rather than on the image itself. Additionally, if the possibility is mentioned, the reference data used to predict this value should also be provided. | Since this is an Indian standard, the possible Rf value of threonine should be provided in separate comments below the plate image, rather than on the image itself. Additionally, if the possibility is mentioned, the reference data used to predict this value should also be provided. | This will be discussed during the meeting |

The draft on the subject have been modified accordingly and embedded below as **Annex XVI.**



***The Committee may kindly deliberate.***

# ITEM 6 DRAFT INDIAN STANDARDS UNDER WIDE CIRCULATION

The following items/drafts of Indian standards have been completed Preliminary draft circulation of 14 days and now have been circulated as Wide Circulation draft for 60 days as under:

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Doc No.** | **Title of the Draft Standard/WC-Draft** | **WC completion date** |
|  | [AYD 07 (](https://www.services.bis.gov.in/php/BIS_2.0/StandardsFormulationV2/Upload3.php?ID=eDI0Vm1VYmlmRVozdTNiVW91WURidz09)26186) WC | Alfalfa Mother Tincture for Use in Homoeopathy – Specification | 12th October 2024 |
|  | AYD 07 (25872) WC | Hydrocotyle asiatica mother tincture for use in homoeopathy – specification | 13th October 2024 |
|  | AYD 07 (26024) WC | Gymnema sylvestre mother tincture for use in homoeopathy – specification | 12th October 2024 |

***The Committee may kindly note.***

# ITEM 7 DRAFTS UNDER PREPARATION

During the first and second Sectional Committee Meetings held on 17th May & 05th October 2023, the following panels were constituted to prepare P drafts. Drafts under preparation by the panels are given below:

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Panel/WG**  **Number** | **Subject** | **Status** |
|  | AYD07/WG1 | Single Herbs and Mother Tincture | Following drafts on plant drug specifications for use in homoeopathy from the list of frequently used drugs are under preparation:   * Jaborandi (Raw drug and Mother Tincture) Specification for use in Homoeopathy * Echinacea angustifolia (Raw drug and Mother Tincture) Specification for use in Homoeopathy * Sabal Serrulata (Raw drug and Mother Tincture) Specification for use in Homoeopathy |
|  | AYD07/WG2 | Glossary of Terms and Abbreviations | P Draft of Abbreviations of homoeopathic medicines is under preparation. |
|  | AYD07/WG3 | Generic formulations | No P draft prepared as of now. However, the road map has been discussed for formulations in Homoeopathy, which can be taken up for standardization work. |
|  | AYD07/WG4 | Potentization process, devices and Machines | P draft titled ''Standardization for the process of potentization'' is under preparation. |
|  | AYD07/WG5 | Plastic and Glass containers and closures | Drafts completed WC stage and on the stage of finalization. |
|  | AYD07/WG6 | Homoeopathic Software | No P draft prepared as of now. |
|  | AYD07/WG7 | Vehicles and Excipients used in homoeopathy | P-drafts on the Sugar of Milk and Excipients are under preparation. |
|  | AYD07/WG8 | Methods of Preparation of Mother Tincture | No P draft prepared as of now. |

***The Committee may kindly note and deliberate.***

# ITEM 8 NEW WORK ITEM PROPOSALS FOR STANDARDIZATION

The committee may suggest any other new areas for standards formulation and suggest experts for the same.

***The Committee may kindly deliberate.***

# ITEM 9 TECHNICAL ISSUES

**9.1** Letter from Indian Homoeopathic Drug Manufacturers of India received citing the concern of duplication of standard development of homoeopathic pharmacopoeial Monographs. Letter embedded as **Annex XVII.**



The matter has been discussed at the BIS secretariat to explore potential avenues for cooperation. Some initial suggestions regarding the scope, content, and development process of these standards are listed below:

A) The Bureau of Indian Standards (BIS) is a National Standards Body that develops Indian Standards (IS) in collaboration with all stakeholders, considering their opinions/viewpoints through a systematic consultation process and decisions through a consensus approach. All IS are voluntary, and its implementation is not mandatory unless these are notified by the Government bodies for their strict compliance. It is at the discretion of the industry to take certification or not.

B) With respect to the industry concern regarding the duplication of pharmacopeial monographs, the following is submitted:

1. The standards are prepared in consultation with manufacturers and PCIMH, considering parameters stated in the pharmacopeias, so that the industry may not struggle to conform to two different standards. This will also help the industry to get certified raw materials which will have an impact on the quality of the final products. These standards are prepared in align with the ‘one herb, one standard’ initiative of the Central Govt. In the future, if any new parameters are added by the BIS or PCIMH, the same shall be adopted by the other stakeholders to avoid any confusion in the market.
2. The standards development process actively involves the industry representatives in its sectional committee, and if the industry finds any ambiguity, inconsistency, or errors in implication, these can be revised even after an IS is published. If the sectional committee finds that IS requires modification, the change can be implemented by a published amendment.
3. Indian standards will not be a mere duplication of pharmacopeial monographs but an evolved form of the same to ensure improved quality of homeopathic products made from genuine raw drugs, benefitting the homeopathic fraternity and patients. Despite the available pharmacopeial monographs, the industry has pointed out various instances of their struggle in procuring genuine raw materials. IS by the BIS, thus an attempt to address such gaps. Not only at the level of homoeopathic drug manufacturers but quality can also be ensured at the level of raw drug dealers.
4. It is also stated that IS does not inhibit any manufacturers from following the Drugs and Cosmetics Act and Rules made thereunder.
5. With the explicit directions of the Ministry of Ayush and collaboration with PCIM&H, BIS is working to establish internationally acceptable standards and regulatory mechanisms for conformity assessment and needs your support in this regard. With such standards, the technical barriers to international trade due to diversified standards can be addressed, and the Indian industry can have better access to overseas markets. Moreover, it is also intended to have a Technical Committee at the ISO level for Ayush products, and BIS, being the Nodal Agency for the national standards and participating members of ISO, can facilitate the same. Such measures will positively impact the growth of trade and business opportunities in times of increasing global demand for natural and traditional medicinal products. In this regard, the same matter was discussed with the regulatory bodies on 3rd May 2024 also, and it was decided to continue to develop standards on the raw material of single herbs and mother tinctures. The meeting minutes are embedded below as **Annex XVIII.**

** *The Committee may kindly consider.***

**9.2** Status of Annual Action Plan (2024-25) of AYD 07 is embedded below as **Annex XIX.**

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***The Committee may kindly consider.***

**9.3** Five-year roadmap for AYD 07 2024 to 2029 has been drafted and is embedded below as **Annex XX.**

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***The Committee may kindly deliberate.***

# ITEM 10 DATE AND PLACE OF THE NEXT MEETING

BIS has formulated a meeting calendar and it has been proposed to conduct a meeting of each Sectional Committee on a quarterly basis. Accordingly, the next meeting of the committee may be organized during Nov - Dec 2024 in consultation with the Chairperson.

***The Committee may kindly note.***

# ITEM 11 ANY OTHER BUSINESS

# The Committee may discuss any other item with the permission of the Chair.

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