



10 July 2024

(24-5033)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>THAILAND</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Thai Food and Drug Administration Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: WTO/TBT Enquiry Point and Notification Authority Thai Industrial Standards Institute (TISI), Ministry of Industry Tel.: (662) 430 6831 ext. 2130 Fax: (662) 354 3041 E-mail: thaitbt@tisi.mail.go.th Website: http://www.tisi.go.th
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Herbal products
5. Title, number of pages and language(s) of the notified document: Draft Notification of the Herbal Product Committee Re: The Quality Control Methods and Specifications of Herbal Product and the Criteria, Procedures and Conditions for the Issuance of Certificate of Analysis of Herbal Products (3rd edition) B.E....; (15 page(s), in Thai)
6. Description of content: Amendments to the Notification of the Herbal Product Committee Re: The quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) are made to revise as follows; <ul style="list-style-type: none">• Clause 2 This notification shall come into force as from the day following the date of its publication in the Government Gazette.• Clause 3 The text stated in Clause 4 of the Notification of the Herbal Product Committee Re: The quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) shall be repealed and replaced with the following text: "Clause 4 The quality control methods and specifications of herbal products shall comply with the following criteria: (1) The testing parameters for each dosage form shall be in accordance with Annex 1 to

this Notification.

(2) The test method for each type of testing parameters according to (1) shall be in accordance with Annex 2 to this Notification.

(3) The acceptance criteria for each testing parameter according to (1), shall be in accordance with Annex 2 and 3 to this Notification.

A Certificate of analysis of herbal product according to Clause 3 shall be issued in consequence of the testing reports conducted and issued by laboratories or organizations as specified in Clause 5 or Clause 6 of this Notification"

- Clause 4 The text stated in Clause 5 of the Notification of the Herbal Product Committee Re: the quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) shall be repealed and replaced with the following text:

"Clause 5 Testing reports of the testing parameters on microbial contamination, heavy metals, assay and others shall be conducted and issued by one of the following laboratories or organizations:

(1) Department of Medical Sciences or Regional Medical Sciences Center

(2) Department of Science Service (DSS)

(3) ISO/IEC 17025 Accredited Laboratory

(4) A Laboratory in a licensed manufacturing facility according to the Herbal Product Act B.E. 2562 (2019).

(5) A laboratory in a licensed manufacturing facility according to the Drug Act B.E. 2510 (1967) and its amended version.

(6) Other laboratories granted by the Thai Food and Drug Administration.

In case of necessity, the testing reports from (3) to (6) may include the submission of additional descriptions of methods and method validation reports.

- Clause 5 The text stated in Clause 6 of the Notification of the Herbal Product Committee Re: The quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) shall be repealed.
- Clause 6 The text stated in the second paragraph of Clause 7 of the Notification of the Herbal Product Committee Re: the quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) shall be repealed and replaced with the following text:

"A Certificate of analysis of herbal product according to paragraph one shall be issued in consequence of the testing reports conducted and issued by the laboratories or organizations as specified in Clause 5 of this Notification"

- Clause 7 Annex 1 of the Notification of the Herbal Product Committee regarding the quality control methods and specifications of herbal products, and the criteria, procedures, and conditions for the issuance of a certificate of analysis of herbal products B.E. 2564 (2021), shall be repealed and replaced with Annex 1 of this Notification.
- Clause 8 Annex 2 of the Notification of the Herbal Product Committee Re: the quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) shall be repealed and replaced with Annex 2 of this Notification.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Quality requirements

<p>8. Relevant documents:</p> <ul style="list-style-type: none">Notification of the Herbal Product Committee Re: the quality control methods and specifications of herbal product and the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products B.E. 2564 (2021) <p>https://herbal.fda.moph.go.th/media.php?id=486802552894136320&name=law_herbal6-08.PDF</p>
<p>9. Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: On the day following the date of its publication in the Government Gazette</p>
<p>10. Final date for comments: 60 days from notification</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>WTO/TBT Enquiry Point and Notification Authority Thai Industrial Standards Institute (TISI), Ministry of Industry Tel.: (662) 430 6831 ext. 2130 Fax: (662) 354 3041 E-mail: thaitbt@tisi.mail.go.th Website: http://www.tisi.go.th https://members.wto.org/crnattachments/2024/TBT/THA/24_04443_00_x.pdf</p>