



กรมวิทยาศาสตร์การแพทย์
Department of Medical Sciences

PROFICIENCY TESTING PROGRAM 2024

Scheme Code D6714R1

Sterility Test

PROFICIENCY TESTING PROTOCOL

No. D6714R1

Organized by

Bureau of Drug and Narcotic
Department of Medical Sciences
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Bureau of Drug and Narcotic
Department of Medical Sciences

D6714R1: Sterility Test

1. ORGANIZER

Scheme Provider:

Bureau of Drug and Narcotic (BDN)
Department of Medical Sciences
88/7 Soi Bumrasnaradura Hospital, Tiwanon Road, Nonthaburi,
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Scheme Coordinator:

Ms. Supawadee Surangkul
Pharmacist, Senior professional level
Email: pt_bdn@hotmail.com; pts.bdn@gmail.com
The scheme coordinator is responsible for all activities of the PT scheme.

Scientific advisory:

Ms. Ladda Poolsawat
Pharmacist, Senior professional level
Email: pt_bdn@hotmail.com; pts.bdn@gmail.com
For any technical question, participants can contact scientific advisory.

2. OBJECTIVE

The objective of this Proficiency Testing (PT) scheme is to demonstrate that participants can correctly perform the test for sterility according to the method in the harmonized chapter for Sterility tests in USP, EP (BP) and JP.

3. SUBCONTRACT

BDN has no policy to subcontract in any activity of this proficiency testing scheme.

4. CRITERIA FOR PARTICIPATION

Participants should have competences and perform the test for sterility **by membrane filtration technique** in the routine work. Each participant is able to participate in the program for one set of PT sample.

5. NUMBER AND TYPE OF PARTICIPANTS

Number of participants: 20 – 30 laboratories

Type of participants: Quality control laboratories in pharmaceutical manufacturers and other testing laboratories



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6. SCHEDULE OF PT SCHEME

The frequency of this PT program is at least one round per 2 years. Schedule for the PT activities is as follows:

Activity	Schedule
Call for participation	December 2023
Deadline for registration	31 January 2024
Distribution of samples	27 February 2024
Deadline for submission of results	26 March 2024
Interim report for comments	May 2024
Final report	June 2024

For the best efficiency of PT program, all activities will be operated according to this time frame. Participants are requested to feedback for registration and submission of result according to the schedule. Participants should note that results submitted are not allowed to change or amend in any case.

7. REGISTRATION

Registration Fee: 5,000 Baht

Payment:

The payment should be made by Teller payment system at any branches of Krung Thai Bank Public Company Limited.

Method and Deadline for Registration:

Participants should register online via the website <https://www.bdn.go.th/pt> within **31 January 2024**. Registration by other means e.g. fax, Email will not be accepted.

Terms and Conditions:

1. BDN reserves the right to occasionally delay the issue of PT program or use an appropriate substitute test material with prior warning to participants if the planned PT sample is not available according to the schedule of PT scheme.
2. The registration fees are nonrefundable.

More information can be viewed on the website <https://www.bdn.go.th/pt>.

**** This scheme code is provided for local participants only.****



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8. PROFICIENCY TESTING SAMPLE

The PT samples of this scheme are 0.9% Sodium chloride which may be sterile or non-sterile.

9. HANDLING OF PT SAMPLE

Participants will receive (i) 20 vials containing 5 ml of sample A, (ii) 20 vials containing 5 ml of sample B and (iii) 20 vials containing 5 ml of sample C.

PT samples are packed in tightly closed containers and distributed in ambient condition. Upon receipt of samples, they should be stored at room temperature (below 30°C) and **commence testing as soon as possible** (no later than **12 March 2024**).

PT samples are sent by logistic company. It is the responsibility of the participants to contact BDN within three days if they have not received the PT sample within the time schedule. Upon receipt of PT sample, participants are requested to check physical conditions of PT sample as well as other substances provided, complete a PT sample acknowledgement form via the website <https://www.bdn.go.th/pt>

10. TEST METHOD

Participants should perform the test for sterility by using routine laboratory procedures; **membrane filtration technique**. Performance will not be evaluated if participants perform the test with other techniques. If the sample complies with the test for sterility, report the results “Pass” and if the sample does not comply with test for sterility, report the result “Fail” and specify type(s) of microorganism that found in that sample; “found only aerobic microorganism”, or “found only anaerobic microorganism”, or “found both aerobic and anaerobic microorganisms”.

Details of the method are described in the testing protocol which can be down load via E-mail from website <https://www.bdn.go.th/pt> after sample distribution. PT sample as well as analytical procedure should be handled and operated in the same manner as performing routine work.

11. ASSIGNED VALUE

Sterile samples shall comply with test for sterility “Pass”, whereas inoculated samples shall not comply with test for sterility and correctly type of microorganism shall be found; “Fail, found only aerobic microorganism”, or “Fail, found only anaerobic microorganism”, or “Fail, found both aerobic and anaerobic microorganisms”. **The assigned value will be disclosed to participants on 2 April 2024.**



12. STANDARD DEVIATION FOR PROFICIENCY ASSESSMENT

N/A

13. PERFORMANCE EVALUATION

Participants will be evaluated by comparison with the assigned value. Participant's result comply with the assigned value will be evaluated as satisfactory result.

14. POTENTIAL MAJOR SOURCES OF ERRORS

1. Insufficient cleaning and monitoring test environment
2. Insufficient decontamination of test materials and samples before entry the test environment
3. Complexity of filter unit assembly
4. Procedures of transferring the samples to filtration apparatus
5. The length of time that samples was exposed to environment
6. Insufficient decontamination of drain connection
7. Cross contamination
8. Sterility checks and growth promotion capabilities of media
9. Volume of sample to be examined
10. Adherence of the microorganism to the filtration vessel walls

15. REPORT

An interim report is issued to provide each participant with an early indication of performance. In general, the interim report is issued about two months after the deadline for submission of results via the website <https://www.bdn.go.th/pt>. Participants are requested to check and review for any corrections and/or comments. The final report is issued via the website <https://www.bdn.go.th/pt> after the corrections and/or comments of interim report have been completed.

The report includes the following information.

- Introduction: general description of PT scheme
- Name and contact details of proficiency testing provider and scheme coordinator
- Participation: information of participating laboratories
- PT samples: description, sample preparations
- Assigned values
- Results
- Discussion of results: conclusion of overall performances and comments on participant's performances
- Potential major sources of errors
- Homogeneity and stability assessment



16. CONFIDENTIALITY, COLLUSION AND FALSIFICATION OF RESULTS

The identities of participants are protected by means of laboratory codes which are randomly assigned in each PT round. These codes are confidential and are not disclosed to other persons unless agreed by the participant for a regulatory or recognition purpose. Participants can access their personal information in the website <https://www.bdn.go.th/pt> by using username and password which can keep their information confidentially. For security purpose, participants are recommended to change username and password in case of changing the responsible person who can access the information in the website.

This PT scheme is conducted in the belief that participants will perform the analysis and report results with scientific professional. Where any collusion between participants or falsification of results is proven by BDN, the result of that participant for the PT round concerned will be cancelled for performance evaluation.

17. LOST OR DAMAGED OF PROFICIENCY TESTING SAMPLE

Email will be sent to inform participants after sample distribution. In case of lost or damaged PT sample, participants should immediately inform BDN via <https://www.bdn.go.th/pt>. The damaged samples should be decontaminated by autoclaving and do not return to BDN. Replacement will be arranged before 12 March 2024 if the PT samples are proved to be lost or not suitable for analysis.