



กรมวิทยาศาสตร์การแพทย์  
Department of Medical Sciences

## **PROFICIENCY TESTING PROGRAM 2018**

**Scheme Code D6114R1**

**Sterility Test**

**Protocol No. D6114R1**

**Revision No. 1**

**Organized by**

Bureau of Drug and Narcotic  
Department of Medical Sciences  
88/7 Soi Bumrasnaradura Hospital, Tiwanon Road, Nonthaburi, 11000  
THAILAND  
Tel. +66 2951 0000 ext. 99137  
Fax +66 2580 5733  
Email: pt\_bdn@hotmail.com; pts.bdn@gmail.com



Bureau of Drug and Narcotic  
Department of Medical Sciences

Proficiency Testing Program 2018 - Scheme code D6114R1: Sterility Test

## 1. ORGANIZER

### Scheme Provider:

Bureau of Drug and Narcotic (BDN)  
Department of Medical Sciences  
88/7 Soi Bumrasnaradura Hospital, Tiwanon Road, Nonthaburi,  
11000, THAILAND  
Tel. +66 2951 0000 ext. 99137  
Fax +66 2580 5733

### Scheme Coordinator:

Ms. Siriphorn Laomanacharoen  
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 harmonized pharmacopeia.

## 3. SUBCONTRACT

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

## 4. SCHEDULE OF PT SCHEME

Schedule for the PT scheme activities is as follows:

Activity	Schedule
Call for participation	December 2017
Deadline for registration	31 January 2018
Distribution of samples	July 2018
Deadline for submission of results	15 August 2018
Interim report for comments	September 2018
Final report	September 2018



## 5. 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 2018**. 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.\*\****

## 6. CRITERIA FOR PARTICIPATION

Participants should have competency and perform the test for sterility in the routine work.

## 7. NUMBER AND TYPE OF PARTICIPANTS

**Number of participants:** 20 – 40 laboratories

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

## 8. PROFICIENCY TESTING SAMPLE

The PT samples of this scheme are 3 aqueous solutions represented as liquid parenteral preparations which may or may not contain microorganisms at low levels.



## 9. HANDLING OF PT SAMPLE

Participants will receive (i) 20 vials containing 3 ml of sample A, (ii) 20 vials containing 3 ml of sample B, (iii) 20 vials containing 3 ml of sample C and (iv) a Testing protocol.

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.

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

## 10. TEST METHOD

Participants perform the test for sterility by using routine laboratory method.

## 11. ASSIGNED VALUE

Sterile samples shall comply and inoculated samples shall not comply the test for sterility.

## 12. STANDARD DEVIATION FOR PROFICIENCY ASSESSMENT

N/A

## 13. PERFORMANCE EVALUATION

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

## 14. POTENTIAL MAJOR SOURCES OF ERRORS

1. Carried out under aseptic conditions.
2. Sterility checks and growth promotion capabilities of media
3. Period time between PT samples preparation and initiation of testing
4. Volume of sample to be examined



## 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
- Homogeneity and stability assessment
- Assigned values
- Results:
- Discussion of results: conclusion of overall performances and comments on participant's performances
- Potential major sources of errors

## 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 test 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

In case of lost or damaged PT samples, participants should immediately inform BDN. The damaged PT samples should be returned to BDN. Replacement will be arranged if the PT samples are proved to be lost or considered not suitable for analysis.



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**Remark :** This revision of protocol was revised from Protocol No. D6114R1. The schedule of PT scheme in topic 4 and details of PT sample in topic 9 were changed.