



กรมวิทยาศาสตร์การแพทย์  
Department of Medical Sciences

## **PROFICIENCY TESTING PROGRAM 2023**

**Scheme Code D6616R1**

**Identification of Pharmaceutical Raw Material by FT-IR Spectroscopy**

## **PROFICIENCY TESTING PROTOCOL**

**No. D6616R1**

### **Organized by**

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

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D6616R1: Identification of Pharmaceutical Raw Material by FT-IR Spectroscopy

## 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. 99112  
Fax +66 2580 5733

### **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.

## 2. OBJECTIVE

The objective of this Proficiency Testing (PT) scheme is to demonstrate that participants can accurately perform identification of substances, Caffeine, by Mid-IR spectroscopic measurement.

## 3. SUBCONTRACT

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

## 4. CRITERIA FOR PARTICIPATION

Participants should have competences to perform Mid-IR spectroscopic measurement and use this 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:** 10 – 50 laboratories  
**Type of participants:** Quality control laboratories in pharmaceutical manufacturers and other testing laboratories

## 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 2022
Deadline for registration	31 January 2023
Distribution of samples	March 2023
Deadline for submission of results	30 April 2023
Interim report for comments	May 2023
Final report	June 2023

*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:

Local participants	2,500.- Baht
Oversea participants	200.- USD (Including shipping handling)

### Payment:

#### Local participants-

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

#### Overseas participants-

The payment should be made by bank transfer to

Account name:	DMSc Non-Fiscal Budget Account
Account number:	1301-034924
Bank name:	Krung Thai Bank Public Company Limited
Branch address:	88/20 1st Floor Block E Ministry of Public Health Moo 4 Soi Bamrat Naradul, Tiwanon Road, Talat Khwan, Mueang Nonthaburi, Nonthaburi, 11000
Swift code:	KRTHTHBK



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**Method and Deadline for Registration:**

Participants should register online via the website <https://www.bdn.go.th/pt> within **31 January 2023**. 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.
3. Charge or fee of financial transactions is the responsibility of participant.

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

## **8. PROFICIENCY TESTING SAMPLE**

The PT sample of this scheme are pharmaceutical substances. The appearance are white powder.

## **9. HANDLING OF PT SAMPLE**

Participants will receive (i) a bottle of sample A containing about 100 mg, (ii) a bottle of sample B containing about 100 mg, (iii) a bottle of sample C containing about 100 mg and (iv) a bottle of caffeine reference standard for PT containing about 100 mg.

PT samples and reference standard for PT are packed in tightly closed amber glass bottle and closed with plastic screw cap. They are labeled which show the details of name, amount and storage condition and packed in vacuum plastic package. They are distributed in ambient condition and should be stored between 2-8°C and protected from light and humidity prior to analysis.

*PT samples are sent by express mail for local participants and by courier for oversea participants. It is the responsibility of the participants to contact BDN as soon as possible if they have not received the PT sample within the time schedule. In case of international transport for overseas participants, BDN cannot be responsible for any delays from the custom clearance. Upon receipt of PT sample, participants are requested to check physical conditions of PT sample as well as other substances provided and complete a PT sample acknowledgement form via the website <https://www.bdn.go.th/pt>.*

## **10. TEST METHOD**

Participants should perform the identification test by using Mid-Infrared spectroscopic measurement and report the positive or negative result.

*Details of the method are described in the testing protocol which can be downloaded via Email 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**

1. The sample(s) conforms to the Caffeine reference standard – positive.
2. The sample(s) do not conform to the Caffeine reference standard – negative.

Assigned value will not be disclosed to participants until interim report is issued.

## **12. STANDARD DEVIATION FOR PROFICIENCY ASSESSMENT**

N/A

## **13. PERFORMANCE EVALUATION**

Participants will be evaluated by comparison with the assigned value. The overall performance evaluation will be shown in conclusion of percentage of participants reported satisfactory results for all of the samples.

## **14. POTENTIAL MAJOR SOURCES OF ERRORS**

1. Instrumental performance and settings
2. Suitability of sample handling
3. Environmental condition e.g. humidity
4. Sample preparation technique

## **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 correction and/or comment. The final report is issued via the website <https://www.bdn.go.th/pt> after the correction and/or comment of interim report has 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 sample: description, sample preparation
- Homogeneity and stability assessment

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- Assigned value
- Results: result including statistic summary data
- Discussion of results: conclusion of overall performance and comments on participants' performance
- 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 and performance evaluation 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>. In some cases, the damaged PT sample should be returned to BDN. Replacement will be arranged within 1 week if the PT samples are proved to be lost or not suitable for analysis. The deadline of submitting result will be extended to appropriate date if necessary.