| NPRA use only |
|---|
| |

**National Pharmaceutical Regulatory Division (NPRA)**
**Ministry of Health Malaysia**
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor
Tel. No.: 03-78835400 Fax No.: 03-79562924
Email: presubmission@npra.gov.my Website: https://www.npra.gov.my

# PRE-SUBMISSION MEETING (PSM) REQUEST FORM

Please read the instructions below and refer to **GUIDANCE DOCUMENT FOR PRE-SUBMISSION MEETING.**

Please complete each section of this application form and email to presubmission@npra.gov.my at least **8 weeks** before the proposed meeting date.

*Our advice at the meeting is nonbinding and is given without prejudice. As knowledge evolves over time, the advice we gave at the meeting may become out of date or be superseded with time.*

## 1. Applicant

| | |
|---|---|
| Company | |
| Address | |

## 2. Contact person

| | |
|---|---|
| Name | |
| Designation | |
| Address | |
| Phone | |
| Email | |

| |
|---|
| |

## 3. Proposed scheduling information

| | |
|---|---|
| Proposed date | **approximately 8 weeks following the receipt of a complete PSM request form* |
| Proposed time | |
| Proposed meeting length | ** 2 hours maximum, unless agreed otherwise by NPRA* |

## 4. Subject matter for discussion (Please tick (√))

- Product category:

  - New Chemical Entity
  - Biologics (including biosimilars)
  - Natural product with therapeutic claims
  - Health supplement product with disease-risk reduction claims

- Issues to be discussed:

  - Quality aspects (e.g. manufacturing, stability, analytical testing and validation, process validation)
  - Pre-clinical development (e.g. Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) requirements)
  - Clinical development (e.g. Good Clinical Practice (GCP) requirements, First in Human/ Pharmacokinetics/ Pharmacodynamics study requirements, efficacy and safety endpoints, trial design, trial duration, target population, comparator, study design, toxicology, pharmacology, safety and efficacy)
  - Others (please specify)
    _____

## 5. Product Information

| | |
|---|---|
| Product name and strength(s) | |
| Dosage form(s) | |
| Active Ingredient(s) | |
| Product Manufacturer (Name and address) | |

| | |
|---|---|
| API/DS Manufacturer(s) (Name and address) | |
| Indication(s) | |
| Other relevant information | |

## 6. Supporting Documents

Please submit the following documents along with the PSM request form:

| No. | Contents | Applicant *(Please tick √ )* | *For office use only (NPRA)* *(Please tick √ )* |
|---|---|---|---|
| 1. | Meeting agenda:<br>- Include estimated time required for the presentation and the designated speaker(s) | | |
| 2. | Brief statement of purpose(s) and objective(s) of the meeting | | |
| 3. | List of proposed question(s) (grouped by discipline):<br>- Include a brief explanation of the context and purpose of each question | | |

*Notes:

1. The complete PSM request form can be emailed to presubmission@npra.gov.my.
2. NPRA reserves the right to request for additional documents, when necessary.
3. Following confirmation of the meeting date by NPRA, the complete PSM Package is to be provided **2 weeks** prior to the scheduled meeting (please refer to PSM Package Checklist).

## DECLARATION:

I declare that I am aware, in the case that PSM is granted, I am required to prepare PSM notes and submit to NPRA within one week after the PSM date.

| | | | |
|---|---|---|---|
| Name | | | |
| Signature | | Date | |

***For NPRA internal use only**

| **Internal Reference** | |
|---|---|
| Scheduled date and time of meeting | |
| Venue | |