Declaration on Good Manufacturing Practice (GMP) Compliance for Investigational Medicinal Product (IMP) Manufacturer by Competent Person[1]

PART A: IMP Details

Name (include strength, dosage form)	1. 2.
Batch/Lot No.	1. 2.

PART B: Manufacturing Site of IMP

Name of the IMP(s)	Name and address[2] of Manufacturing site(s) (include local business licence/manufacturing licence number)	Manufacturing Operation / Activity (including packaging, labelling, testing and release)
Click here to enter text		Click here to enter text
Click here to enter text		Click here to enter text
Click here to enter text		Click here to enter text

PART C: Details of Audit

I declare that compliance with at least equivalent to ICH or PIC/S GMP has been verified on the basis of:

(i) Audit

Name and address[2] of Manufacturing site	Auditing Party	Date of last audit (completion)
Click here to enter text		Click here to enter text

(ii) If an audit of the site has not been performed, please provide a written assessment that standards at least equivalent to ICH or PIC/S GMP are being followed at the site.

Name and address[2] of Manufacturing site	Justification
Click here to enter text	Click here to enter text

PART D: Declaration of Competent Person

I hereby declare that:

i. I have reviewed the manufacturing process of the concerned IMP which is stated in Part A.

ii. Each batch of the IMP shall be tested against and comply with the specifications established by the IMP manufacturer's quality management system.

iii. I am authorized to release the IMP based on the predetermined specifications established by the manufacturer for clinical trial purposes.

iv. I have reviewed the manufacturing process of the raw material[3]/drug substance/IMP which is received by the manufacturer to be used as IMP.

v. I hereby confirm that the IMP specified in Part A & Part B has been manufactured in accordance with ICH Good Manufacturing Practices (GMP) requirements or PIC/S GMP GMP Guide for Medicinal Products and its related annexes including Annex 13.

vi. I agree that the manufacturing site may be subjected to inspection by the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health, Malaysia if required.

vii. I understand that any false declaration and/or omission of material facts may result in the rejection of the clinical trial application or legal action by the National Pharmaceutical Regulatory Agency (NPRA).

viii. The information provided herewith is certified, accurate and complete.

PART E: Name and Signature of Competent Person Responsible for this Declaration

This declaration is submitted by the following Competent Person of the manufacturing site (stated in Part B):

Obligatory	Superintendent signature[4]
Signature …… (Together with official stamp of the competent person) Name: Click here to enter text. Designation: Click here to enter text. Staff ID: Click here to enter text Telephone: Click here to enter text. Email: Click here to enter text. Date: Click here to enter text.	Signature …… (Together with official stamp of the superintendent person) Name: Click here to enter text. Designation: Click here to enter text. Staff ID: Click here to enter text Telephone: Click here to enter text. Email: Click here to enter text. Date: Click here to enter text.

[1] Competent person: The personnel who is responsible to release the IMP for clinical trial purpose.
[2] State the site name(s) and address(es) in detail, including the building numbers (if applicable).
[3] A general term used to denote starting material, reagents, solvents and other materials intended for use in the production of IMP.
[4] The column may be signed by other competent person/ or the person whom the competent person is reporting to.