Declaration on Good Manufacturing Practice (GMP) Compliance for Active Pharmaceutical Ingredient (API) Intermediate Manufacturer by Competent Person

PART A: Product Details

Product Name	Click here to enter text
Product Reference Number[1]	Click here to enter text
Name of API	Click here to enter text
Name of API Intermediate	Click here to enter text
Chemical name for API Intermediate	Click here to enter text
Commercial name for API Intermediate (if any)	Click here to enter text

PART B: Manufacturing Site of Active Pharmaceutical Ingredient (API) Intermediate

Name of Intermediate Manufacturer	Click here to enter text
Address[2]	Click here to enter text

Other API Intermediate manufacturing site(s) involved:
(e.g. packing process, quality control laboratories, batch release etc.)

Other API Intermediate Manufacturing Site[2] (name & address)	**Manufacturing Operation / Activity**
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

[1] *This refers to the reference number assigned to the finished product submitted for registration with NPRA.*
[2] *State the site name(s) and address(es) in detail, including the building numbers (if applicable).*

PART C: Declaration of Competent Person

I hereby declare that:

i. I have reviewed the manufacturing process of the concerned API intermediate which is stated in Part A & Part B.

ii. I am authorized to release the API intermediate based on the predetermined specification[3] and responsible to put the API intermediate in the market.

iii. I have reviewed the manufacturing process of the raw material[4]/ API intermediate[*] which is received by the manufacturer to be used as API starting material[5] in the manufacturing process of the concerned API intermediate.

iv. I have reviewed the distribution activities conducted by the supplier[6] for the raw material/ API intermediate which is used as API starting material in the manufacturing process of the concerned API intermediate.

v. I hereby confirm that the API intermediate specified in part A & part B has been manufactured in accordance with *Good Manufacturing Practice for medicinal products for human and veterinary use, Part II: Basic Requirements for Active Substances used as Starting Materials*, as well as *PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part II.*

vi. Our local Drug Regulatory Authority (DRA) does not issue any GMP certificates. Attached together the declaration letter from local DRA regarding above matter with reference number (Click here to enter text).

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

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

[3] *The specification of API Intermediate that established by the manufacturer.*
[4] *A general terms used to denote starting material, reagents, solvents and other materials intended for use in the production of intermediates or API.*
[5] *The API starting material is a raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of API.*
[6] *Any party other than the original manufacturer who may trade, store and distribute API starting material which intended to be used in the manufacture of API intermediate.*
* *Please delete whichever is not relevant or not applicable.*

PART D: 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[7]
Signature …… (Together with official stamp of the competent person) Name: Click here to enter text. Designation: 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. Telephone: Click here to enter text. Email: Click here to enter text. Date: Click here to enter text.

[7] *The column may be signed by other competent person/ or the person whom the competent person reporting to.*

*** Competent person: The personnel who responsible to release the API Intermediate and proceed for the next step of API manufacturing process or placing the API in the market.*

Please return this declaration form to API Section, Centre of Product Registration, NPRA.
Please contact the API Section, Centre of Product Registration, NPRA if you have any inquiries.