DOSSIER CLARIFICATION SUPPLEMENT

Section 1

a. Please complete this supplement if:
   - Submission is for a NDA (chemical or biologic) or GDA
   - Submission is via the abridged route
   - Submission date is within 5 years of approval by any of HSA's reference agencies

b. You need not complete this supplement if:
   - Submission is via the full or verification route
   - Product is not approved by HSA's reference agencies, or approval was > 5 years ago

c. ☐ Please check this box if you are unable to confirm whether the quality aspects proposed for registration in Singapore specified herein are as approved by any reference agency. Please proceed to *section 4 Confirmation*. You need not complete sections 2 and 3.

Section 2: Administrative information

Proposed product name	

The product has been approved by the specified reference agency indicated below within 5 years from submission to HSA (please indicate the approval date):

Specified reference agency	EMA/ US FDA/ Health Canada/ TGA/ UK MHRA *(delete accordingly)*
Approval date	

Section 3: Chemistry Manufacturing Control (CMC) information

Please fill in the required information and confirm by ticking the respective checkbox.

a. Drug Substance *[Please duplicate section (a) if multiple drug substances are proposed]*

Name of drug substance	

☐ The drug substance manufacturing site(s) proposed for registration in Singapore as listed below is(are) the same as that approved by the specified reference agency.

Manufacturing Activity	Name and Address of the site(s)
☐ Manufacturing ☐Manufacturing (final process step, e.g. purification/ crystallization or micronisation)	[To indicate only one site in each row] [To duplicate row if necessary]

☐ The drug substance manufacturing process proposed for registration in Singapore is the same as that approved by the specified reference agency.

☐ The drug substance specification proposed for registration in Singapore is the same as that approved by the specified reference agency.

☐ The container closure system and retest period/ shelf life proposed for registration in Singapore as listed below are the same as that approved by the specified reference agency.

Container Closure System	Storage Conditions	Re-test Period	Shelf Life (if applicable)

b. <u>Drug Product</u>

☐ The drug product manufacturing site(s) proposed for registration in Singapore as listed below is(are) the same as that approved by the specified reference agency.

Manufacturing Activity	Name and Address of the Site(s)
☐ Drug Product Intermediate ☐ Bulk Production ☐ Primary Packaging ☐ Sterilisation	[To indicate only one site in each row] [To duplicate row if necessary]

Manufacturing Activity	Name and Address of the Site(s)
☐ Secondary Packaging ☐ Batch Release	

☐ The batch formula and production batch size(s) proposed for registration in Singapore are the same as that approved by the specified reference agency.

Batch size(s)/ Range of batch size	

☐ The drug product manufacturing process proposed for registration in Singapore is the same as that approved by the specified reference agency.

☐ The drug product specification proposed for registration in Singapore is the same as that approved by the specified reference agency.

☐ The container closure system and shelf life proposed for registration in Singapore as listed below are the same as that approved by the specified reference agency.

Container Closure System	Storage Conditions	Shelf Life

c. <u>Other information</u>

Please provide information on the differences between the drug substance and/or drug product proposed for registration in Singapore and that approved by the specified reference agency.

Quality Aspects	Proposed for registration in Singapore	Approved by specified Reference Agency
[insert more rows if necessary]		

Section 4: Confirmation

I hereby confirm that all information provided by me in this supplement is true and accurate. I acknowledged that if any of the information provided by me in this supplement is false or misleading, I shall be guilty of an offence and shall be liable on conviction to penalties under section 30(10) of the Health Products Act 2007.

_____ _____

(Name/designation and signature) (Date)

REVISION HISTORY

Form Version (Publish Date)

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