DOSSIER CLARIFICATION SUPPLEMENT

Section 1

a.	Please	comple	ete this	supp	lement	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

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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	EMA/ US FDA/ Health Canada/ TGA/ UK MHRA
agency	(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 ma	_	(/ 1	1	5 1	
	as listed below is(are) t	the same a	s that a	oproved by the sp	ecified reference	
	agency.					
	Manufacturing Activi	Name and Address of the site(s)				
	☐ Manufacturing		[To indic	[To indicate only one site in each row]		
	☐Manufacturing (final	process	[To dupl	icate row if necess	ary]	
	step, e.g. purification/					
	crystallization or micro	nisation)				
		<u> </u>				
	The drug substance	manufactu	ring pro	cess proposed fo	r registration in	
	Singapore is the same a	s that appr	oved by t	he specified refere	nce agency.	
	The drug substance sp	ecification	proposed	for registration in	Singapore is the	
;	same as that approved b	by the spec	ified refe	rence 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						
	specified reference ager	ncy.	pelow are	the same as that		
	specified reference ager Container Closure	•	below are	the same as that		
		•			approved by the	
·	Container Closure	Storage			approved by the Shelf Life	
	Container Closure	Storage			approved by the Shelf Life	
	Container Closure	Storage			approved by the Shelf Life	
	Container Closure System	Storage Condition	ıs	Re-test Period	approved by the Shelf Life (if applicable)	
	Container Closure System b. <u>Drug Product</u>	Storage Condition	is ite(s) pro	Re-test Period	Shelf Life (if applicable)	
	Container Closure System b. Drug Product The drug product manual	Storage Condition	is ite(s) pro	Re-test Period	Shelf Life (if applicable)	
	Container Closure System b. Drug Product The drug product manual as listed below is(are)	Storage Condition	ite(s) pro	Re-test Period	Shelf Life (if applicable) tion in Singapore ecified reference	
	b. Drug Product The drug product manuas listed below is(are) agency.	Storage Condition	ite(s) pro as that a	Re-test Period posed for registrate pproved by the sp	Shelf Life (if applicable) tion in Singapore ecified reference e Site(s)	
	b. Drug Product The drug product manual listed below is(are) agency. Manufacturing Activity	Storage Condition	ite(s) pro as that a	Re-test Period posed for registrate pproved by the speciand Address of the specian control	shelf Life (if applicable) tion in Singapore ecified reference e Site(s) in each row]	
	b. Drug Product The drug product manual isted below is(are) agency. Manufacturing Activity Drug Product Interm	Storage Condition	ite(s) pro as that a	Re-test Period posed for registrate pproved by the speciand Address of the cate only one site in the special poses.	shelf Life (if applicable) tion in Singapore ecified reference e Site(s) in each row]	
	b. Drug Product The drug product manuas listed below is(are) agency. Manufacturing Activity Drug Product Interm Bulk Production	Storage Condition	ite(s) pro as that a	Re-test Period posed for registrate pproved by the speciand Address of the cate only one site in the special poses.	shelf Life (if applicable) tion in Singapore ecified reference e Site(s) in each row]	

	Manufacturing Activity		Name and Address	of the Site(s)	
	Secondary Packaging				
	☐ Batch Release				
·					
	The batch formula and production	uction	batch size(s) propo	osed 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 manufacturi	ng pro	ocess proposed for re	egistration in Singapore	
	is the same as that approved by the specified reference agency.				
\Box	The drug product enceification	on pro	paged for registration	on in Singapara is the	
Ш	The drug product specification	•		3 .	
	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.				
С	ontainer Closure System	Stora	age Conditions	Shelf Life	

c. Other information

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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