Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: 65 6866 3400 Fax: 65 6478 9076
Website: www.hsa.gov.sg

DMF SUBMISSION FORM

Please complete this form and submit it with the Drug Master File:

Submission type:	
HSA DMF No.: (for DMF update submission)	
Active Pharmaceutical Ingredient Name: (INN and salt/counter ion, solvated state)	
DMF Manufacturer's internal API code: *(if applicable)*	
Drug Master File Holder Name & Address:	
Drug Master File Holder Contact Person: (name, position, phone, fax, email)	
DMF Applicant's Part: (version and date)	
DMF Restricted Part: (version and date)	
Quality standard claimed for the API:	
Sterility status:	
Other relevant information: (e.g. synthesis route identifier, polymorphic form, micronised)	

API Manufacturer Name & Address:
(include block or unit)
(include GPS coordinates, if available)

API Intermediate Manufacturer Name & Address: *(if applicable)*
(include block or unit)
(include GPS coordinates, if available)

Status of this DMF in other regulatory agencies

As drug regulatory agencies progress towards collaborative work-sharing to reduce regulatory burden and faciliate market authorisation of health products, information sharing is a key component for successful work-sharing. If this DMF* has been, or will be, submitted to the listed agencies, please state which agency(ies) and provide the DMF # issued by that agency *(multiple entries are permitted)*:

☐ Australia DMF #

☐ Canada DMF #

☐ Switzerland DMF #

☐ IPRP members other than Australia, Canada and Switzerland

Name of Country(ies):

* The DMF version submitted to HSA can be different from the one submitted to the listed agencies.

Consent from DMF holder

The Health Sciences Authority (HSA) is working with its international regulatory partners (namely, Health Canada, the Therapeutic Goods Administration of Australia and Swissmedic, the Swiss Agency for Therapeutic Products) to develop a work-sharing framework in order to build collaborative processes, converge regulatory requirements and share information with the aim to leverage on regulatory expertise and facilitate market entry.

The DMF Holder consents to HSA sharing confidentially, DMF assessment reports or any information contained in the assessment reports with its regulatory partners for the abovementioned purposes.

☐ Yes, I give consent. ☐ No, I do not give consent.

Authorised Person Name & Title:

Signature Date: