



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<http://www.tga.gov.au/about/tga-information-to.htm>>.

Module 1.6.1 Drug master file, plasma master file and/or EDQM certificates of suitability

Details form

Please note: This form is to be completed and included in Module 1.6.1 for prescription medicine applications that make reference to one or more of the following:

- drug master files (DMF) – complete Part A
- plasma master files (PMF) – complete Part A
- EDQM Certificates of Suitability (CEP) – complete Part B

Part A - Drug master files and plasma master files

Drug substance 1

Name of substance:

Manufacturer's business name:

Full street address of manufacturing site:

Manufacturer's client ID (if known):

TGA DMF/PMF file number:

Manufacturer's letter of access included in module 1.6.3: Yes No

Drug substance 2

Name of substance:

Manufacturer's business name:

Name of substance:

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Full street address of manufacturing site:

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Manufacturer's client ID (if known):

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TGA DMF/PMF file number:

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Manufacturer's letter of access included in module 1.6.3: Yes No

Note: for additional drug substances, attach a separate page with the required details as above.

Part B - EDQM certificates of suitability (CEP)

Drug substance 1

Name of substance:

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Manufacturer's business name:

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Full street address of manufacturing site:

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Manufacturer's client ID (if known):

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CEP number and version:

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Manufacturer's letter of access included in module 1.6.3: Yes No

Drug substance 2

Name of substance:

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Manufacturer's business name:

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Full street address of manufacturing site:

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Manufacturer's client ID (if known):

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CEP number and version:

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Manufacturer's letter of access included in module 1.6.3: Yes No

Note: for additional drug substances, attach a separate page with the required details as above.

Part C - Applicant information

Authorised officer's name:

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Applicant's name:

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Signature:

	Date:	
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