**Drug Master File / Certificate of Suitability Application Form**

This form is intended to be completed by active ingredient manufacturers.

A completed and signed copy of this form must accompany any new or updated Drug Master File (DMF) or Certificate of Suitability (CEP).

Note: there is a separate application form for Plasma Master Files.

Documents must be submitted electronically via the Medsafe Electronic File Transfer (EFT) system. The dossier must be in the ICH CTD format and must meet functional requirements.

Information regarding the electronic submission of applications via the EFT system can be found on the Medsafe website at: <https://www.medsafe.govt.nz/medicines/EFTAccess/SubmittingApplicationsElectronically.asp>

Hard copy correspondence will not be accepted.

**Section 1: Substance details**

|  |  |
| --- | --- |
| Active ingredient (INN): |  |
| Salt form or hydrate (if applicable): |  |
| CAS number: |  |
| Medsafe TT60 file number (if allocated): |  |
| Name and address of substance manufacturing site(s): |  |

**Section 2: DMF/CEP holder contact details**

|  |  |
| --- | --- |
| Name and job title of the applicant: |  |
| Applicant email address:All correspondence about the application will be sent to the applicant at this email address. |  |
| DMF / CEP holder company name and address: |  |

**Section 3: Application details**

### This submission is:

|  |  |
| --- | --- |
| ***Check box*** | ***Description*** |
|[ ]  **A new Drug Master File**DMF Applicant’s Part version number: DMF Restricted Part version number: |
|[ ]  **An updated Drug Master File**DMF Applicant’s Part version number:DMF Restricted Part version number: |
|[ ]  **A new Certificate of Suitability**CEP number: |
|[ ]  **An updated Certificate of Suitability**CEP number: |

**IMPORTANT** - Please ensure the proposed DMF version number (both Applicant’s and Restricted Parts) or CEP version number is included above. For updates, please ensure that the previous version number of the DMF or CEP is noted in the submission.

### Does this submission relate to:

|  |  |
| --- | --- |
| ***Check box*** | ***Description*** |
|[ ]  **A New Medicine Application?**Product name:Medsafe TT50 number (if known):Application ID number (if known): |
|[ ]  **A Changed Medicine Notification?**Product name:Medsafe TT50 number:Application ID number (if known): |

**Section 4: Required documents checklist**

**IMPORTANT** - Documents must be submitted electronically via the Medsafe Electronic File Transfer (EFT) system. The dossier must be in the ICH CTD format and must meet functional requirements.

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Hard copy correspondence will not be accepted.

|  |
| --- |
| **Documents required with submissions:** |
|[ ]  Cover letter |
|[ ]  Letter of Access (for DMF) |
|[ ]  Copy of valid CEP including a signed declaration of access or separate letter of access |
|[ ]  Copies of both the Applicant’s and Restricted Parts of the DMF (for DMF only)  |
|[ ]  Detailed summary of changes between DMF (Both AP and RP) or CEP versions (for updates only) |
|[ ]  Justifications for the proposed changes (for updates only) |

**Section 5: Declarations and commitments**

|  |
| --- |
| Complete the checkbox for each declaration and/or commitment that is relevant to this application. The signature section located at the end of the section must be completed to validate the submission. |
|[ ]  **All required information is present.** All documents required for this application have been provided in a suitable electronic format.  |
|[ ]  **The relevant New Zealand medicine sponsors have been informed.**The New Zealand sponsor(s) for medicines associated with this DMF / CEP has been notified of the submission of, or update to, the DMF / CEP. |
|[ ]  **For a new DMF / CEP, any future updated versions of the DMF / CEP will be submitted to Medsafe.** This includes revisions to DMFs resulting in a new version number of the Applicant’s and/or Restricted Part, or revisions to CEPs resulting in an updated CEP number.  |
| **Signature:** |
|  | **I certify all sections of this form have been completed accurately.**Signature: Date:  |