**Name and function: [Fill in here]**

From APIMF holder[[1]](#footnote-1) on headed paper

Attention: South African Health Products Regulatory Authority (SAHPRA)

[Include address as per SAHPRA website, https://www.sahpra.org.za/head-office/]

[Date]

**Submission of documents relating to an APIMF for [Name of API] [SAHPRA APIMF number, if allocated]**

The APIMF (open and closed parts) is submitted in relation to the following application submitted by [Name of applicant] on [planned date of submission]:

Required information:

|  |
| --- |
| [Final product Manufacturer] |
| Name of Product |  |
| Final Product Application number  |  |
| Name of Final product manufacturer |  |
| Final Product applicant  |  |
| Application from Backlog pre-reg /BAU pre-reg /Backlog post-reg/ Backlog post-reg[[2]](#footnote-2) (please tick) | [ ]  Backlog pre-reg[ ]  BAU pre-reg[ ]  Backlog post-reg[ ]  BAU post-reg |
| Type of application  | [ ]  New application[ ]  Response to queries |

|  |
| --- |
| **APIMF holder** |
| APIMF holder name | [Fill in here] |
| Full APIMF holder administrative address | [Fill in here] |
| Site master file number (for API manufacturing site(s) located in South Africa) | [Fill in here] |
| APIMF holders APIMF number, version and date | [Fill in here] |
| Contact person | [Fill in here] |
| Telephone number | [Fill in here] |
| E-mail address | [Fill in here] |

|  |
| --- |
| **API manufacturing site(s)** |
| API manufacturer name | [Fill in here] |
| Manufacturing site name | [Fill in here] |
| Manufacturing site SMF (site master file) number (for API manufacturing site(s) located in South Africa) | [Fill in here] |
| Manufacturing site role[[3]](#footnote-3) | [Fill in here] |
| Manufacturing site physical address (including block / unit / number) | [Fill in here] |
| GPS coordinates[[4]](#footnote-4) of manufacturing site | [Fill in here] |
| Manufacturing site contact person | [Fill in here] |
| Manufacturing site telephone number | [Fill in here] |
| Manufacturing site e-mail address | [Fill in here] |
| It is hereby confirmed that copies of the latest GMP certificate for manufacturer(s) and**/**or a copy of the appropriate manufacturing license(s) have been included |  |

|  |  |
| --- | --- |
|  |  |
| BCS classification of API |  |
| Polymorphic form |  |
| *Packaging* |  |
| *Proposed retest period* |  |
| *Proposed storage conditions* |  |

*Please replicate this table for additional manufacturing sites*. Manufacturing sites are all sites involved in the manufacture of the active substance, from the introduction of starting material(s), including quality control / in process testing sites, intermediate manufacturers, milling, micronisation and sterilisation. Each manufacturing site should be listed in a separate table and its role should be specified.

If the APIMF has been approved by one of SAHPRA’s recognised regulatory authorities (RRAs), please complete the table below.

[Please check the tick-box for Yes, and leave it blank for No. Please duplicate the table for additional RRAs as required.]

|  |  |
| --- | --- |
| **Name of RRA** | {Insert name of RRA} |
| Date of submission | MM/YYYY |
| Is this APIMF identical to the APIMF on file in the above-mentioned RRA? |  [If no, please provide an explanationof changes below.] |
| Are approval letters from the RRA for the APIMF included in this submission? (Module 1.10) |  |
| Are unredacted assessment reports for the APIMF included in this submission? (Module 1.10) |  |

The undersigned hereby declares that all the information herein, and in the Annexes and Modules hereto, are correct and true and are relevant to this particular API, and that all existing data which are relevant to the quality, safety and efficacy of the API have been supplied in the dossier, as appropriate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature for the APIMF holder (above)

Name and function: [Fill in here]

1. API manufacturer [↑](#footnote-ref-1)
2. Pre-reg: Pre registration unit, post-reg: Post registration unit, BAU: Business as usual application. [↑](#footnote-ref-2)
3. Please see text below this table for examples of manufacturing site roles. [↑](#footnote-ref-3)
4. Latitude (S or N) and Longitude (E or W) expressed in Degrees Minutes Seconds to 1 decimal place, alternatively Degrees to at least 5 decimal places, or Degrees Minutes to at least 3 decimal places. [↑](#footnote-ref-4)