**Active Pharmaceutical Ingredient Master File (APIMF) or Drug Master File (DMF)**

**Letter Of Access**

[Insert date]

[Insert API name]

[Insert APIMF holder’s name]

[Insert APIMF holder’s address]

[Insert API manufacturing site(s)]

[Insert APIMF version number]

[Insert APIMF holders name] hereby authorizes the relevant [insert regulatory authority name] staff members and external experts to refer to and review the above-mentioned APIMF (and subsequent versions) in support of application(s) submitted by [insert applicants name and address] for the following product:

[Insert Finished Pharmaceutical Product (FPP) *(product generic name), (strength) and (dosage form)* (regulatory authority-assigned reference number if known)]

The aforementioned Active Pharmaceutical Ingredient master file holder is committed to ensuring batch-to- batch consistency and to informing [insert applicants name] and [insert regulatory authority name] of any change in the Open or Closed parts of the APIMF before any significant change is made to the site of manufacture, manufacturing procedure or quality control specifications of the API. Except as permitted by [insert regulatory authority name] guidelines relating to changes to medicines, such changes will not be made to the API to be used in manufacture of the medicine destined to be distributed in [insert country] before written approval is granted by [insert regulatory authority name].

It is understood that the consequences of failure to obtain approval for changes where approval is necessary may include de-registration and recall of batches of medicines.

Sincerely,

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

[Insert name, title of the quality person or responsible officer]

[Insert company name]

[company stamp, if required]