Variation to a Prequalified Finished Pharmaceutical Product (FPP): Major, Minor or Immediate Notification

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

# Application details

## Variation type: (tick all applicable options)

Immediate notification (IN)  Minor variation (Vmin)  Major variation (Vmaj)

## Grouping of variations

Single variation  Grouped variations

## Associated finished pharmaceutical product (FPP) name /PQ ref. number(s):

*e.g. Isoniazid Tablets 100mg – TB 173*

## Applicant details

Please note that the contact listed in the table below will be the primary contact for communication for this specific application.

|  |  |
| --- | --- |
| Applicant |  |
|  |  |
| **Primary contact person responsible for this application** | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

If there are other contacts who should be routinely copied into correspondence for this application they should also be listed below.

|  |  |
| --- | --- |
| Additional contact person | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

|  |  |
| --- | --- |
| Additional contact person | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

# Summary of proposed changes

*For multiple variations (grouped variations), reproduce this section and provide separate summaries for each proposed variation.*

## Variation title and number:

*e.g. Minor variation # 30a:*

*Change in batch size of the finished product — up to and including a factor of ten (10) compared to the biobatch*

## Summary of current and proposed details:

|  |  |
| --- | --- |
| Current details | Proposed details |
|  |  |

## Reason for change:

## Date of implementation (for Immediate Notifications only):

## If relevant to the variation, list the supporting active pharmaceutical ingredient master file (APIMF) number:

# Documentation checklist

The following documents have been submitted together with this application form:

|  |  |
| --- | --- |
| Note: All documents must be provided for this application to be valid. |  |
| Quality Information Summary (QIS)  *For FPPs that have an agreed upon QIS, the QIS should be revised and submitted with any revised sections highlighted. A QIS should be completed in its entirety (irrespective of the proposed change). It should include information on all strengths, with any changes highlighted (e.g. in red type).* | *Yes*  *No agreed QIS*  *No change to QIS* |
| Supporting documentation  *All supporting documents as stipulated for the change in the* [Guidelines on variations to a prequalified product](http://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex3TRS-981.pdf?ua=1) *are included in this submission* | *Yes* |

# Declaration

*Please check all declarations that apply.*

I declare that:

For each change all conditions as stipulated in the *Guidance on Variations to a Prequalified Product* for the change requested are fulfilled.

There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

The information submitted is true and correct.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_