Application for Active Pharmaceutical Ingredient (API) Prequalification based upon Previous Stringent Regulatory Authority (SRA) Assessment — History of Changes

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| WHO application number |  |
| Date |  |
| Manufacturer |  |
| API |  |
| Version number of AP master file (APIMF) submitted to WHO: |  |

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| History of original submission to SRA |
| Name of authority |  |
| Date of original submission to SRA |  |
| Date of responses to SRA |  |
| Date of approval |  |

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| Document versions |
| Identifying document version number of APIMF originally submitted to SRA |  |
| Identifying document version number of APIMF finally accepted by SRA. |  |
| Identifying document version number of APIMF current held by SRA |  |

IMPORTANT NOTE:

When completing this form please keep in mind that the primary purpose of requesting this information is that the SRA assessment report will often mention APIMF details that are not stated in the current APIMF. This form should allow the assessor to quickly determine what has changed, when this change occurred, for what reason and by what mechanism.

The assessor must reconcile those details assessed originally by the SRA and those details currently proposed. It is important therefore to:

1. identify the differences between the details mentioned in the assessment report and those stated in the APIMF submitted to WHO
2. explain why these details are different, i.e. whether they were changed at the request of the SRA during assessment, by post-approval variation, or for the purpose of submission to WHO.

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|  History of changes table |
| Common Technical Document (CTD) section | APIMF Details originally submitted to the SRA | APIMF details accepted by the SRA at time of initial approval | APIMF details currently accepted by the SRA for this APIMF | APIMF details being proposed to WHO |
| **Current details accepted by SRA** | **Reason for change** | **Notification type** | **Date of notification to SRA** |
|  |  |  |  |  |  |  |  |
| *For example* |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| *3.2.S.4.1* | *Original API specifications**V001 – Aug-11* | *Updated specifications to include a test for residual solvents**V003 – Nov-11* | *V004 – Feb-12* | *Tightening of solvent limit* | *Type IA* | *24th January 2012* | *V004 – Feb-12* |
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