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| **Common ASMF/DMF Submission Form**  Quality Working Group for Generics (QWGG)  **Version 1.4 – September 20, 2018** |

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| Version | Description | Author | Effective Date |
| v 1.0 | Original publication | ASMF/DMF WG | May 25, 2015 |
| v 1.1 | Watermark added | ASMF/DMF WG | Nov 19, 2015 |
| v 1.2 | Disclaimer added page 2 | ASMF/DMF WG | Nov 26, 2015 |
| v 1.3 | Correction of field numbers | ASMF/DMF WG | Mar 23, 2016 |
| v 1.4 | Change to reflect QWGG | QWGG | Sep 20, 2018 |

**Disclaimer**

In order to achieve the QWGG’s objective to promote collaboration and convergence in generic drug regulation, the QWGG has developed a series of reference documents covering a number of technical and procedural aspects of ASMF/DMF assessment.

These documents were developed among participating QWGG members as model documents.

The implementation of these documents by a given IPRP QWGG member, either as a whole or in part, is not mandatory. Each QWGG member works within their own specific regulatory setting and some or all aspects of a document may, for a variety of reasons, not be applicable. Equally, a given QWGG member may for practical reasons choose to revise the format or written language of a model document.

**IPRP QWGG**

**Common ASMF/DMF Submission Form**

*(final, 2015-11-19)*

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| **Field Number** | **Description of Information** | | **Required Information** |
| 1 | National ASMF/DMF Reference Number (if known) | |  |
| 2 | Active Pharmaceutical Ingredient (API) Name  *INN, including salts/counter ion, solvated state* | |  |
| 3 | ASMF/DMF Holder’s Version Number and Date  *Applicant’s Part version number and date (yyyy-mm-dd)*  *Restricted Part version number and date (yyyy-mm-dd)* | |  |
| 4 | ASMF/DMFs Manufacturer’s Internal API code (if applicable) | |  |
| 5 | Status/Submission Type | | New ASMF/DMF  Update to an existing ASMF/DMF (list the changes from the previous version in the updated ASMF/DMF) |
| 6 | ASMF/DMF Holder  *Company Name*  *Corporate Address*  *Phone*  *Fax*  *Email* | |  |
| 7 | Contact person for the ASMF/DMF  *Title (salutation)*  *Names (Family name in CAPITALS)*  *Role*  *Company Name*  *Postal Address*  *Phone*  *Fax*  *Email* | |  |
| 8 a, b, c…  (repeat, as needed) | API Manufacturer(s) and Manufacturing Site(s), including API intermediate manufacturing sites  *The steps undertaken at the site:*  *Manufacturer’s name*  *Site address*  *Units and Blocks*  *Street, Town*  *State/Province*  *Post-code*  *Country*  *Phone*  *Fax*  *Email*  *GPS (WGS 84) of site (place to be specified if not main entrance) expressed to 1/10th of a second accuracy* | |  |
| 9 | Is the ASMF/DMF Submitted to Other Referenced Authorities/Jurisdictions?  *Authority or jurisdiction submitted*  *ASMF/DMF number assigned*  *Is this ASMF/DMF identical to the ASMF/DMF filed in the above mentioned country or jurisdiction?*  *If not, ensure that the difference are described in the ASMF/DMF.* | |  |
| 10 | Sterility Status | | Sterile  Non-sterile |
| 11 | Quality Standard Claimed for the API  *e.g., Pharmacopoeial (state which), or In-House* | |  |
| 12 | Other Relevant Information  *e.g., polymorphic form, manufacturing route identifier (e.g., process I), grade (e.g., particle size)* | |  |
| Declarations  *Note: The wording below is indicative only. Each IGDRP member will need to determine appropriate specific wording.* | | | |
| 13 | A declaration permitting the authority to share Confidential Business Information contained in the ASMF/DMF or associated assessment reports with other regulatory authorities/jurisdictions as defined. |  | |