IGDRP
International Generic Drug Regulators Programme

Common ASMF/DMF Submission Form

ASMF/DMF Working Group

Version 1.3 – March 23, 2016

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

Disclaimer

In order to achieve the IGDRP's objective to promote collaboration and convergence in generic drug regulation, the ASMF/DMF working group 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 IGDRP members as model documents.

The implementation of these documents by a given IGDRP member, either as a whole or in part, is not mandatory. Each IGDRP 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 IGDRP member may for practical reasons choose to revise the format or written language of a model document.

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Version 1.1 (final, 2015-11-19)

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.	