IGDRP
International Generic Drug Regulators Programme

Common ASMF/DMF Submission Form

ASMF/DMF Working Group

Version 1.0 – May 25, 2015

Version	Description of Change	Author	Effective Date
v 1.0	Original publication	ASMF/DMF WG	May 25, 2015

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Version 1.0 (final, 2015-05-26)

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)*	
3	ASMF/DMFs Manufacturer's Internal API code (if applicable)	
4	Status/Submission Type	☐ New ASMF/DMF ☐ Update to an existing ASMF/DMF (list the changes from the previous version in the updated ASMF/DMF)
5	ASMF/DMF Holder *Company Name* *Corporate Address* *Phone* *Fax* *Email*	

6	Contact person for the ASMF/DMF *Title (salutation)* *Names (Family name in CAPITALS)* *Role* *Company Name* *Postal Address* *Phone* *Fax* *Email*	
7 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*	
8	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.*	

9	Sterility Status	☐ Sterile ☐ Non-sterile
10	Quality Standard Claimed for the API *e.g., Pharmacopoeial (state which), or In-House*	
11	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.*		
12	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.	