الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Drug Master File (DMF): Guidance for Submission

Version 4.0

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Drug Sector

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for the latest update

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
0.1	Regulatory Affairs	11/6/2014	Initial draft for internal consultation
0.2	Evaluation department	7/8/2014	1st review
0.3	Regulatory Affairs	17/8/2014	2nd review
1.0	Regulatory Affairs	18/8/2014	Approved, and published for comments
1.1	Regulatory Affairs	22/6/2016	Initial draft for internal consultation
1.2	Evaluation department	19/9/2016	1st review
1.3	Regulatory Affairs	17/10/2016	2nd review
1.4	Regulatory Affairs	16/12/2016	Final Revision
2.0	Regulatory Affairs	20/4/2017	Update
3.0	Executive Directorate of Regulatory Affairs	13/05/2019	New Address has been updated
4.0	Executive Directorate of Regulatory Affairs	23/08/2020	Update (Next page shows the updated details)

What is New in version no. 4?

The following table shows the update to the previous version:

Section	Description of change
Presentation of the DMF	- Update the online procedure.
Delivery to SFDA	- Deleted
Procedure	- Update the process of submission to the SFDA.

Table of Content:

1. INTRODUCTION

The Drug Sector in the Saudi Food & Drug Authority (SFDA) has developed this document, '*Drug Master File (DMF): Guidance for Submission*', to provide assistance for Applicants and/or DMF holder on how to submit DMF file. This document is an administrative instrument that outlines the requirements of DMF submissions to be submitted to the SFDA.

It is important to note that the SFDA reserves the right to request information, material or defined conditions not specifically described in this document, in order to allow the administration to adequately assess the safety, efficacy and quality of drug products. The SFDA is committed to ensuring that such requests are justifiable and decisions are clearly documented.

This document should be read in a conjunction with the other relevant and applicable guidance documents.

The SFDA is fully committed to an orderly process for the review and authorization of pharmaceutical products, and we are working to develop procedures to implement those aspects of the initiative. We are also committed to assuring that stakeholders remain fully informed of our progress as we implement the initiative.

2. SCOPE

This guidance document applies to Drug Substance, Drug Substance Intermediate, and Material Used in their Preparation.

3. DEFINITIONS

Agent or representative	Any person who is appointed by a DMF holder to serve as the contact for the DMF holder.
Applicant	The company or its representative.
Authority	The Saudi Food and Drug Authority (SFDA).
Drug Master File (DMF)	A file that is used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. DMFs usually cover the Chemistry, Manufacturing and Controls (CMC) of a component of a drug product e.g. drug substance, Excipient, packaging material.
Drug product	Finished dosage form tablet, capsule, or solution etc… which contain a drug substance.
GCC-DR	Gulf Cooperation Council Drug Registration
DMF Holder	Person who owns a DMF.
Letter of access	written statement by the holder or designated agent or representative permitting SFDA to refer to information in the DMF in support of another Applicant's submission.
Reference number [1]	Any combination of letters and numbers that is assigned to the transaction in order to follow it.
Registration number	A number (or combination of letters and numbers) that is given to a registered product by the SFDA.

1) [1] All drug application is given certain abbreviation with a sequence number according to their type as follows:
   HN: Human – New drug
   HB: Human – Biological drug
   HG: Human – Generic drug

4. REQUIREMENTS OF THE DRUG MASTER FILE

The content of the submitted DMF shall be composed of the following:

4.1 DMF Form:

The following included in the DMF Form: (All fields required)

a) Identification of submission: new, resubmission, renewal or variation
b) Procedure Type: National (SFDA) or Central (GCC-DR) procedure
c) Reference number[2]
d) Date of submission[2]
e) Active substance name
f) Pharmacopeial reference
g) Trade name[2] (Specific product covered by the DMF)
h) DMF holder name
i) DMF version number and date (yyyy-mm-dd) for the applicant's part and restricted par.
j) Manufacturer name (if different from DMF holder name)
k) Manufacturer Address
l) Typewritten name and title of the signer
m) Signature of the authorized representative

A soft copy of DMF (Restricted part) Form is available on SFDA website-Drug sector-forms

[2] Information can be obtained from the applicant who submitted a file to SFDA

4.2 Letter of Access:

Before SFDA can review DMF information in support of an application, the DMF holder shall submit a letter of authorization permitting SFDA to reference the DMF.

The letter of access should include the following:

a) Identification of submission: new, resubmission, renewal or variation
b) Procedure Type: National (SFDA) or Central (GCC-DR) procedure
c) Registration or Reference number[1]
d) Active substance name
e) Pharmacopeial reference
f) Trade Name[3](Specific product covered by the DMF)
g) DMF holder name
h) DMF version number and date (yyyy-mm-dd) for the applicant's part and restricted part.
i) Manufacturer Name (if different from DMF holder name)
j) Manufacturer Address
k) Typewritten name and title of the signer
l) Signature of the authorized representative
m) If no changes were made within the last five years, a letter indicating that the DMF remains current.

Notes:

- A signed statement by the holder certifying that the DMF is current and that the DMF holder will comply with the statements made in it should be submitted
- DMF Form and letter of access must be on company official paper.
- List of all manufacturing sites must be provided.
- An application incorrectly submitted will be rejected

[3] Information can be obtained from the applicant who submitted a file to SFDA

5. PRESENTATION OF THE DMF

A softcopy (Online procedure) of the DMF including (DMF Application Form and latter of accesses) are only required. No need to send the soft copy or the Hard copy.

5.1 Language:

Information and documents supporting a drug application – such as certificates and approval letters– must be including in Arabic or in English. If documents are neither in Arabic nor in English, a translation to English (from an authorized translation office) must be included.

5.2 Requirements:

5.2.1 Softcopy:

- DMF (pdf)
- DMF application form (word format)
- Letter of access

5.2.1.1 Media:

Refer to the 'Guidance for Submission' the latest version.

6. PROCEDURE OF SUBMISSION

- Send an email to (sdr.drug@sfda.gov.sa) with DMF application form to ask for the secure link.
- Receive an email with the secure link.
- Upload the files.
- Send a reply email to confirm the uploading of files.
- Receive an acknowledgment email.

7. CONTACT ADDRESS

For any question, send an email to: (sdr.drug@sfda.gov.sa)

8. DMF FORM

DMF (Restricted part) Form[4]

Identification of submission	**☐ New ☐ Resubmission ☐ Renewal ☐ Variation**		
Procedure Type	**☐ National (SFDA) ☐ Central (GCC-DR)**		
Reference No.[5]			
Date of submission[5]			
Active substance name			
Pharmacopeial Reference			
Trade name[5] (Specific product covered by the DMF)			
DMF holder name			
Version No. "AP"		**Date**	
Version No. "RP"		**Date**	
Manufacturer name			
Address			

Name: ……

Title: ……

Email[6]: ……

Signature: ……

[4] This form can be filled electronically. It is available on SFDA website – Drug Sector – Forms

[5] Information can be obtained from the applicant who submitted a file to SFDA

[6] Notification will be sent to this email after receiving DMF
AP: Applicant Part
RP: Restricted part.