

DRUG MASTER FILE (DMF)

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Drug master file (DMF)

Introduction: Drug master file is used to submit data to regulatory authorities for review and approve product for sale. It contains all information about the product including its raw materials.

- The detailed information, which is usually **confidential**, relating to the manufacturing, processing and storing of human drugs is contained in the DMF.
- This report is to be submitted to the **FDA** (Food and Drug Administration); however, it is not a requirement by law.
- The information about any drug is used as a basis to review and approve an (IND or ANDA) Investigational New Drug Application or an Abbreviated New Drug Application.
- If you want to prepare and submit a DMF, **these guidelines** will help you write the exact information required as well as the format to follow and the obligations of the holder.

Types of DMF

There are basically five types of Drug Master files in pharmaceuticals:

- ✓ Type I
 - ✓ Type II
 - ✓ Type III
 - ✓ Type IV
 - ✓ Type V
- Each DMF may contain only one type of information with data that supports it.
 - The DMF can only be written in the English language.
 - There should be a **page number** on each page along with the **date** as well as a **table of contents**, which is updated accordingly.
 - The holder might be submitting an original submission or amendments to an already submitted DMF. The guidelines are slightly different for both these formats.

Type I DMF:

- **The Type I DMF corresponds to Manufacturing Site, Facilities, Operating Procedures and Personnel.**
- **The person writing this type of DMF may provide information to FDA in order to conduct site investigations outside the US.**
- **There should be a complete description of the manufacturing site as well as equipment capabilities and layout.**
- **The holder must provide a physical address of the site along with acreage and a map.**
- **The operational layout can be described with the help of a diagram that illustrates its major production and processing areas.**

Type II DMF:

- The Type II DMF contains **information on a Single Drug Substance, drug Substance Intermediate, material Used in preparation of the Drug, and drug product.**
- The holder must describe **all steps involved** in the manufacturing of the drug under discussion.
- There should be a **detailed account of the chemistry, manufacturing and controls as well as analytical data for methods validation.**

Type III DMF:

- The Type III DMF contains **information on the Packaging Material.** Each material has to be described according to **its use and composition.**
- It is also mandatory to include the **names of the suppliers or fabricators as well as data to support the acceptability of the packaging material** for its intended use.

Type IV DMF:

- The Type IV DMF corresponds to **Preparatory Materials, such as Excipient, Colorant, Flavor, and Essence.**
- These additives must be **described according to their manufacturing method, specifications and testing methods.**
- It is also required to **submit toxicological** data related to these materials in the same DMF.

Type V DMF:

- The Type V DMF contains **FDA accepted reference Information.**
- **Use this type of DMF only when all the other types are not relevant because the FDA strongly discourages the use of Type V DMF for general or duplicate information.**
- The holder is **first required to write a letter of intent and then proceed only if the FDA gives permission.**

Submission of DMF

- All DMFs should be submitted **as an original file as well as a duplicate copy**. Both these files must be fully assembled and **should not be more than 2 inches thick**.
- Each DMF submission should contain a **transmittal letter, administrative information about the submission and the specific information** to be included in the DMF as described.
- It must be in **English language**. If required an **certified English translation** must also be included.
- Each page should be **dated and consecutively numbered**.