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REGULATORY REQUIREMENTS FOR REGISTRATION OF ACTIVE PHARMACEUTICAL INGREDIENTS IN EUROPE WITH COMPARISON TO US

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ABSTRACT

Pharmaceutical products mainly depend on two basic constituent- Excipients and Active pharmaceutical ingredient (API). In order to regulate the API's quality and development process a systematic documentation of API is required and this is where ASMF (Active Substance Master File), DMF (Drug Master File) plays the major role. DMF is compilation of confidential documents which are essential for the registration of API. Pharmaceutical manufacturer prepare the DMF and submit it to the appropriate regulatory authority. DMF filing is compulsory when there is need for two or more firms to come together and develop or manufacture a new drug. Although DMF provide same purposes across different regulatory authorities, they have different names and specifications. In Europe it is known as a European Drug Master File (EDMF) or Active Substance Master File (ASMF) and in United States it is known as a USDMF. DMF is made up of Applicant Part and Restricted Part. Applicant part gives non-confidential information which is only disclosed to the license holder and

restricted part gives confidential information which is only disclosed to the authorities. This dissertation work includes the DMF preparation and submission requirements and procedures for Europe along with, a brief comparative overview of current API registration requirements across Europe & US.

KEYWORDS: API, DMF, ASMF, EDMF.

INTRODUCTION

Drug Master File

Pharmaceutical products mainly depend on two basic constituent- Excipients and Active pharmaceutical ingredient. APIs are used in the fabrication of the drug products and which has the main pharmaceutical action. API is substance or combination of substances which are used in the manufacture of the pharmaceutical drug product and becomes an active ingredient of drug product. Substances which are used to furnish pharmacological activity or any other direct effect in the treatment, cure, mitigation, diagnosis, or prevention of disease or to affect the structure and function of the body.

Parts of DMF

- **Applicant's Part:** This is open part of DMF which contains the non-confidential information that the license-holder needs to assess the quality and submit a license or amendment application and this information is also helpful to the license holder for API registration and marketing purposes. Information of this part is also provide to the authority as a part of Drug Master File services.

This part contains information like

- ✓ General information
- ✓ Characterization
- ✓ Control of API
- ✓ Reference standards or materials
- ✓ Container closure system
- ✓ Stability

- **Restricted Part:** This is closed part of DMF which contains the confidential information about the manufacturing process of drug substance which is only disclosed to the Regulatory Authority of country.

This part contains information like

- ✓ Manufacture
- ✓ Manufacturer(s)/site of manufacture
- ✓ Detailed description of the manufacturing process and process controls
- ✓ Control of materials (Starting material of the API, reagents, solvents, other materials used)
- ✓ Control of critical steps and intermediates
- ✓ Process validation and/or evaluation
- ✓ Manufacturing process development

History of DMF Guidelines

Table 1: History of DMF Guideline.

Countries	History
US	• Guideline for USFDA is established in September 1989. • **Guidance for Industry:** Generic drug user fee amendments of 2012
Europe	• Guideline for European Drug Master File is established in 1989-1991 which is revised in 2005 and became Active Substance Master File.
Canada	• Guideline for Canadian drug master file established in1994 Revised in September 05, 2008.

Types of DMF in Different Countries

A) UNITED STATE

Originally there where total five types in USFDA but currently type I is no more acceptable by USFDA.

Table 2: Types of DMF in US.

Types	Information include
Type: I	• Manufacturing Site, Facilities, Operating Procedures, and Personnel (No longer applicable)
Type: II	• Drug Substance, Drug Substance Intermediate, and Material Used in their Preparation or Drug Product
Type : III	• Packaging Material
Type: IV	• Excipient, Colorant, Flavor, Essence or Material used in their Preparation
Type: V	• FDA Accepted Reference Information

B) EUROPE

There is no types of DMF but there is types of registration process for DMF.

Table 3: Ways of registration in Europe.

Two ways
1) Certification of suitability to the monograph of the European Pharmacopoeia (CEP)
2) Active substance master file

C) CANADA

Four Types

Table 4: Types of DMF in Canada.

Types	Information include
Type: I	• Drug Substance or Intermediate in the Manufacture of Drug Substance
Type: II	• Container- Closure system or components
Type : III	• Excipients, colorants, flavours and Other additives
Type: IV	• Dosage forms and drug product intermediates (e.g. blend of drug substance and excipients)

AIM

To study the registration process of API in Europe and compare its regulatory requirement with the US.

OBJECTIVE

- To understand and provide the current API registration requirements for regulatory submission including technical documents, application forms, ways of registration and General registration process.
- The main Objective of the DMF, EDMF or ASMF and MF are to support regulatory requirements of a medicinal product to prove its quality, safety and efficacy. This helps to obtain a Marketing Authorization grant.
- To keep up privacy of restrictive data of DMF holder. (example: Manufacturing procedure)
- To permit submission of confidential data to an authority which can be referenced by a third party such as the sponsor or applicant.
- To analyze the number of Drug Master File of API approvals per year by regulatory authorities.
- To allow review of data by reviewer in the CDER to support application put together by one or more applicant.

- To compare the individual parameters and requirements for Active Pharmaceutical Ingredient.
- To Differentiate the Procedure for Compilation of Drug master File of Active Pharmaceutical Ingredient.
- To collect the information about the various documents and data necessary to submit for registration of Active Pharmaceutical Ingredient in Europe Country.

EU legal framework for pharmaceuticals

- EU legal framework for pharmaceuticals is expected at ensuring a high level of protection of public health. It is based on the principle that the placing of a medicine on the market is subject to the granting of a marketing authorization by the competent authorities. The Community codes for veterinary and human medicines are set out in **Directive 2001/82/EC** and **Directive 2001/83/EC** respectively. They provide the legal framework for the authorization, manufacture and distribution of medicines in the EU.
- The EMA began operating on 26 January 1995.

➢ ***For active substance master file***

CHMP/CVMP guideline on active substance master file procedure which contains the appropriate guidance of active substance. Guideline on active substance master file procedure which is given by EMA:

Table 5: Guideline for ASMF.

Guideline for ASMF	
No. of Revision	**Guideline**
1.	• EMEA/CVMP/134/02 Rev 1 • CPMP/QWP/227/02 Rev 1
2	• EMEA/CVMP/134/02 Rev 2 Consultation • CPMP/QWP/227/02 Rev 2 Consultation
3.	• Committee of Human Medicinal Products CHMP/QWP/227/02 Rev 3/Corr * • Committee of Veterinary Medicinal Products EMEA/CVMP/134/02 Rev 3/Corr *

2) European Directorate for the Quality of Medicines (EDQM)

- EDQM is a directorate of the council of Europe.

➢ *EDQM is responsible for:*

- Preparation of the general chapters and monographs of the European Pharmacopoeia or pharmacopoeia of the EU member state with the groups of experts.
- Implementing the procedure for CEPs for existing active substance which are already include in the Ph.Eur.

MARKETING AUTHORISATION PROCEDURES IN EUROPE

Medicinal products & APIs have to receive a MA from regulatory authority before entered in to the European pharmaceutical market. MA application for drug substance is submitted by the applicant to the regulatory authority through the MA procedure. This process involves the authority reviewing the efficacy, safety and pharmaceutical quality of the drug product and drug substance on the basis of a large body of submitted documentation.

➢ ***Four types***

- **Centralized procedure:** As per the regulation (EC) No 726/2004, Centralized procedure is describe for marketing application of medicinal products. This is a common authorization procedure for all countries in the EU member state with Iceland, Norway and Liechtenstein.
- **Mutual Recognition Procedure:** This procedure is use to obtain marketing authorization in more than one member state where the medicinal product is already authorized in any member state at the time of application.
- **Nationalized Procedure:** which is offered for individual European countries.
- **Decentralized procedure:** Authorization is required simultaneously in multiple European countries. An applicant can go directly to a national marketing authority to obtain permission to market its product in that member state and then seek to have other member states accept the marketing approval of the first member state.

MUTUAL RECOGNITION PROCEDURE

The MRP is to be used in order to get MA in several MS where the drug product in question has received a MA in any MS at the time of application. The procedure to be followed will depend upon whether it is a MS who triggers or the MAH who initiates the mutual recognition. MS have to approve during the MRP the AR, the SPC, the PL and the label according to Directive 2001/83/EC.

➢ ***Mutual Recognition Procedure is divided in the following steps***

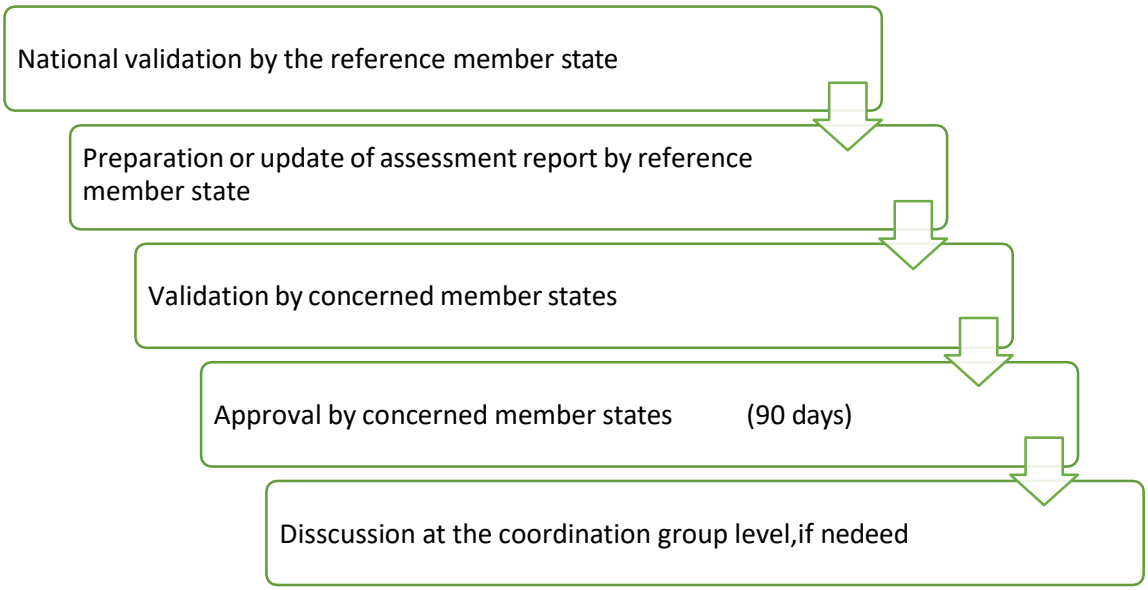

Figure 1: Steps for MRP.

National procedure

Independent national procedures will continue, but are strictly limited to drug product which are unauthorized in more than one MS. In addition, harmonization of authorizations for medicinal products authorized in the Union is to be promoted via a coordinated approach for referring medicinal products, for which divergent decisions have been adopted, to the EMA and the CHMP. Independent national procedures can also be used for extensions of authorized medicinal products as far as no a priori harmonization has been achieved for the initial MA. The CAs of the MSs are responsible for granting MA for medicinal products, which are placed on their markets, except for medicinal products which may only be authorized via mandatory scope. The NP is the preliminary stage for the MRP and DCP. In order to obtain a national MA, an applicant must submit an application to CA of only one MS. When the MA is issued nationally, it is valid only in that country where it has been issued and can be placed on the market only in that country.

➢ **API variations of Quality Part in Europe**

Table 6: API variation in Quality Part.

Topic/scope of changes	Section of CTD Modules in API
Manufacture	2.3.S.1
	3.2.S.2
Control of active substance	2.3.S.4
	3.2.S.4
Container closure system	2.3.S.6

	3.2.S.6
Stability	2.3.S.7
	3.2.S.7

REGISTRATION OF ACTIVE PHARMACEUTICAL INGREDIENTS IN EUROPE

European guideline for drug master file is established in 1989- 1991 which is Revised in 2005 and became ASMF (Active Substance Master File) after implementation of CTD in EU Applicable only to active substances. "European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property or 'know-how' of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the Applicant or Marketing Authorization (MA) holder to take full responsibility for the medicinal product and the quality and quality control of the active substance."

CLASSIFICATION OF ACTIVE PHARMACEUTICAL INGREDIENTS IN EUROPE

1) New Active Substances
2) Existing active substances which are included in the European Pharmacopoeia (Ph. Eur.) or The pharmacopoeia of an EU Member State
3) Existing active substances which are not included in the European Pharmacopoeia (Ph. Eur.) or The pharmacopoeia of an EU Member State

REQUEST FOR NEW CERTIFICATE OF SUITABILITY

To obtain a Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP), application send to the EDQM. EDQM accept the paper copy & electronic submission in pdf, NeeS, eCTD format. For getting approval of new CEP application applicant send following documents to the to the Certification of Substances Division (DCEP) of the EDQM.

ACTIVE SUBSTANCE MASTER FILE

The main objective of the Active Substance Master File (ASMF) procedure, formerly known as the European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property or 'know-how' of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the Applicant or Marketing Authorization (MA) holder to take full responsibility for the medicinal product and the quality and quality control of the active substance.

EMA thus have access to the complete information that is necessary for an evaluation of the

suitability of the use of the active substance in the medicinal product.

Detailed scientific information describe in the overall content of the ASMF as indicated under the various headings of the pertinent Notice to application for marketing authorization for medicinal product in the member states of the European Union. Active Substance Master File is related to the substance of the human medicinal product & it must be presented in the CTD format.

Scientific Information which is describe in the ASMF it must be divided in to two parts

1) ***The Applicant's Part (AP)***

Information which is non-confidential to the Applicant/MA holder according to the ASMF holder can be found in AP. AP is considered as confidential document and which can not be submitted to any third party without consent of ASMF holder. In all cases the AP should contain sufficient information to enable the Applicant/MA holder to take full responsibility for an evaluation of the suitability of the specification for the active substance to control the quality of this active substance for use in the manufacture of a specified medicinal product.

2) ***The Restricted Part (RP)***

The RP may contain the detailed information on the individual steps of the manufacturing method of drug substance (reaction conditions, temperature, validation and evaluation data of critical steps) and the quality control during the manufacture of the active substance.

Difference between CEP & ASMF

Table 7: Difference between CEP & ASMF.

Criteria	CEP	ASMF/EDMF
Guideline Title	Certificate of suitability to the monograph of the European pharmacopeia.	Guideline on Active substance master file
Definition	CEP stands for Certification of suitability of European Pharmacopoeia monographs. COS means the same and, even if often used, is not the official acronym.	ASMF procedure or EDMF procedure is to allow valuable confidential intellectual property or 'know-how' of the ASM to be protected while at the same time allowing the Applicant or MAH to take full responsibility for the medicinal product and the quality and quality control of the active substance.

Legal Basis	Resolution AP-CSP (07) 1 on CEP (revised version) (Adopted by the Public Health Committee (CD-P-SP) on 21/02/2007)	• 2001/83/EC as amended part I • Directive 2001/82/EC as amended part 2.C.1 general requirements

COMPARATIVE SUMMARY OF ASMF/EDMF & USDMF

Table 8: Comparison of ASMF/EDMF & USDMF.

Sr.No.	CRITERIA	ASMF/EDMF	USDMF
1.	**For API**	• European Drug Master File • Active Substance Master File	• United State Drug Master File
2.	**Definition**	• EDMF is "to allow valuable confidential intellectual property or 'know-how' of the manufacturer of the ASM to be protected, while at the same time allowing the Applicant or MA holder to take full responsibility for the medicinal product and the quality and quality control of the active substance. It is also called as ASMF."	• "A Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be 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." Or • "This is the document which contains the information about CMC of component of drug product, submitted to the FDA &permit the FDA to review this information in support of a third party submission."
3.	**Types**	No types	There are four types: ➢ **Type II** - Drug Substance, Drug Substance Intermediate and Material Used in their Preparation or Drug Product ➢ **Type III** – Packaging Material ➢ **Type IV** - Excipient, Colorant, Flavor, Essence, or Material Used in their Preparation ➢ **Type V** - FDA Accepted Reference Information • Type-I were eliminated in

			2000 but numbering was kept the same. (Type I – Manufacturing Site, Facilities, Operating Procedures, and Personnel)
4.	**No. of agencies**	• Multiple	• One
5.	**Regulatory agencies**	• EMA ➢ CHMP ➢ CVMP ➢ COMP ➢ HMPC ➢ PDCO ➢ CAT • HMA ➢ CMDh ➢ CMDv • EDQM • NCA	• FDA ➢ DHHS ✓ CDER ✓ CBER
6.	**Registration process**	• Multiple ➢ CP ➢ DCP ➢ MRP ➢ National	• NA
7.	**Variation types**	• Type IAIN • Type IA • Type IB • Type II	• Annual report
8.	**Fees**	➢ **CEP:** ➢ **For New Application** ➢ Simple chemical certificate: 5000 € ➢ Simple TSE or herbal certificate: 3000 €	• (FY) 2016 : $ 42,170 • Type II API DMF's holder. Nly onetim pay a fees as describe under GDUFA Amendments of 2012. • DMF fees only applies for type II DMF for drug substance use to support ANDAs, NDA & IND. • No fees required for any other type of DMF.
9.	**No. of copies**	• One copy	• Two copies of DMF in CTD module ➢ One copy in red colour (3316) ➢ Second copy in Blue colour (3316a)
10.	**Paper size**	• A4 size of paper	• 8-1/2 by 11 inches • Letter size paper
11.	**Division & office for**	• CEP: Certification of Substances Division (DCEP)	• **DMF review only for Administrative purposes:**

	handling of DMFs:	• ASMF: Working Group of EMA: ➢ CHMP ➢ CVMP, ➢ CMDh, ➢ CMDv, ➢ EDQM	By OBI staff within CDER. • **Completeness Assessment:** By OGD/DMF Review Staff
12.	**Delivery of Paper Application:**	• **CEP:** ➢ EDQM and Healthcare Council of Europe Division certification of substances 7, allee kastner, CS 30026, F-67081, Strasbourg, France. • **ASMF:** ➢ European Medicines Agency CPMP, 7 westferry circus, Canary wharf, London, E 14, 4 HB, U.K.	• Food and drug administration, Centre for drug evaluation and research, Central document room, 5901-B Ammendale road, Beltsville MD 20705-1266
13.	**Validity**	• CEP: Valid for 5 years from the date of first issue and valid indefinitely following the 5-year renewal.	NA
14.	**Language**	• One of the two official languages of the Council of Europe: English or French (preferably in English)	English
15.	**eCTD**	• Mandatory • But in some countries paper submission is also required.	• Mandatory • From the 5th May 2017 DMF submission must be in eCTD format.
16.	**Electronic portal**	• CESP	• FDA ESG
Module: 1 Administrative information & prescribing Information			
17.	**Cover letter**	• Applicable	• Applicable(section: 1.2) (transmittal letter)
18.	**Statement of commitment**	• NA	• Applicable
19.	**Application form**	• Applicable • CEP: Application form is available on EDQM website • ASMF: Some countries require • e.g. France	• NA
20.	**GDUFA cover sheet**	• NA	• Applicable
21.	**Debartment certification**	• NA	• Applicable

22.	**Administrative information**	• Applicable ➢ ASMF reference number ➢ ASMF holder's version ➢ Active substance name ➢ Active Substance Manufacturer's internal API code (if applicable)	• Applicable (section : 1.3) ➢ 1.3.1.1 : Change of address or corporate name ➢ 1.3.1.2 : Change in contact/agent
		➢ Additional information (as applicable, e.g. different route of synthesis, grade) ➢ Name & address of ASMF holder ➢ Name & address of Active Substance Manufacturer Manufacturing site(s)	
23.	**LOA**	• **Letter of Access** The ASMF holder should give permission to the competent authorities/EMA to assess the data in the ASMF in relation to a specific MAA/MAV in the form of a Letter of Access. ➢ Only for ASMF(ANNEX 2) ➢ Not require for CEP	• **1.4.1 : Letter of authorization** A written statement by the holder or designated agent or representative permitting FDA to refer to information in the DMF in support of another person's submission.
24.	**Statement of right of reference**	• NA	• Applicable (section: 1.4.2)
25.	**TSE-BSE certificate**	• Applicable	• NA
26.	**Environmental assessment**	• NA	• Not compulsory • It can be include
27.	**Submission Letter**	• Applicable for ASMF (ANNEX 3)	• NA
Module 2 QOS		•	•
28.	**QOS**	• QOS required • Template form • (available on EDQM website)	• QbR required • Question answer form
Module 3 Quality		•	•
29.	**Applicant part (Open Part)**	• Technical documentation accordance with the CTD format. • Applicant part: ASMF holder consider this part as non-confidential. • It Contain summary of	• Require one Continuous document embracing the CTD format without distinction of an AP & RP. • All significant steps are describe in only one part about manufacturing &

		module 3 with section 2.3.S.1 to 2.3.S.7.	control of the drug intermediate or substance.
30.	**Restricted Part (Closed Part)**	• This part contains confidential information about manufacturing Process of drug substance. • Only section 3.2.S.2 (Manufacture part) provided in this part.	
31.	**Regional information**	• NA	• Applicable
32.	**Closure of DMF**	• Where the active substance is no longer supplied to the MA Holder or the corresponding ASMF is replaced by a Ph.Eur. Certificate Of Suitability (CEP), The ASMF Holder should provide a withdrawal of access letter to the NCA/EMA.	• A holder who wishes to close a DMF should submit a request to the Drug Master File Staff stating the reason for the closure. • The Agency may close a DMF that does not contain an annual update of persons authorized to incorporate information in the DMF by reference and a list of changes made since the previous annual report. The holder will be notified of FDA's intent to close the DMF.

CONCLUSION

The global pharmaceutical industry is growing immensely in rapidly developing and changing environment of the health care sector. In this growing era of pharmaceutical industry the framework of medicinal products mainly depends on the core active pharmaceutical ingredient & excipients. These two constituents are the major element in pharmaceutical products. APIs have a main role to provide pharmacological activity for treatment, mitigation, cure, prevention, of disease it is essential that their proper quality is maintained. API is not only the heart & mind of medicinal product but these substances have a critical submission requirements to the regulatory filing success of the drug application as these are the ones which will lead to better healthcare in future. Drug master file contains the confidential data as an applicant part & restricted part which is prepared by pharmaceutical manufacture. The main objective of the DMF is to support regulatory requirements of a medicinal product to prove its quality, safety and efficacy. Although firm actions are been taken to develop a uniform DMF submission, yet variations do occur. This thesis concludes the specific requirements to establish an accurate DMF submission to Europe and a brief

comparison with USFDA which resulted in understanding the specific differences between the requirements of world's one of the most stringent regulatory authorities. Deficiencies in the DMF can result in the delay of approval process of drug product application so it is important that the DMF be filed in a timely manner according to the determined legislation and guidelines so that the standards used to compete it are of the same quality as that of the actual drug application.

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