DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Site Master File	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To define Standard Operating Procedure for Site Master File.

2.0 SCOPE:

This standard operating procedure is applicable for preparation, review and approval of Site Master File of ……..

3.0 RESPONSIBILITY:

Executive/Designee-QA shall be responsible for Preparation of Site Master File.

Head-Quality Control/ Designee, Head-Engineering/ Designee, Head-Production/Designee, Manager QA/ Designee shall be responsible for review of Site Master File.

Head Quality Assurance shall be responsible for Approval of Site Master File.

Head Quality shall be responsible for Authorization of Site Master File.

4.0 ACCOUNTABILITY:

Head Quality Assurance shall be accountable for compliance of this Standard Operating Procedure.

5.0 DEFINITION:

A site master file is a document prepared by the manufacturer containing specific and Factual GMP information about the production and/or control of pharmaceutical manufacturing Operations carried out at the named site and any closely integrated operations at adjacent and nearby Buildings. If only part of a pharmaceutical operation is carried out on the site, the site masters file need describe only those operations,

6.0 PROCEDURE:

6.1 Site Master File provides information on the manufacturer's operations and procedures to customer and authorities for the purpose of information or efficient planning and undertaking a GMP inspection.

6.2 Site Mater File shall be prepared by Executive/Designee-QA & Reviewed by Head-Quality Control/Designee, Head-Engineering/Designee, Head-Production/Designee, Manager Quality

Assurance/Designee

6.3 Site Mater File shall be approved by Head-Quality Assurance/Designee and Authorized by Head Quality.

6.4 Frequency of review of Site Master File is two years from date of preparation. Site Master File can also be reviewed & revised before the due date of review if required through change control system.

6.5 Site Master File shall be a concise document containing brief information about the Manufacturer operations and procedures.

6.6 Site Master File shall be printed on A4 size white paper.

6.7 SMF shall be prepared as per PICs/WHO GMP/EU GMP requirement.

6.8 Annexure-I for site master file preparation.

6.9 The Header part of SMF shall contains following details:

6.9.1 Company Logo, Title as “SITE MASTER FILE”, Company Name with address, Document No., Effective Date, Review Date, and Revision No.

6.10 Site Master File shall contain the following content:

6.10.1 Approval Sheet

6.10.2 General Information

6.10.3 Quality Management System

6.10.4 Personnel

6.10.5 Premises and Equipments

6.10.6 Documentation

6.10.7 Production

6.10.8 Quality control

6.10.9 Distribution, complaints, product defect & recalls

6.10.10 Self inspection

6.10.11 Annexures

6.10.12 Abbreviations

6.10.13 Reference

6.10.14 Revision History

Note: The above mentioned content are specimen, it can be customized based on the requirement.

6.11 All the Annexure shall be attached with the SITE MASTER FILE as per requirement. Cover page,

Abbreviation sheet, List of Annexure and History Sheet shall be maintained separately from the main text part of SMF.

6.12 Text part of SMF shall be revised through change control procedure but Annexure of SMF can be updated as per requirement with out taking change control. A separate history sheet shall be maintained for all Annexure of SMF.

6.13 **Intimation to Drug Department (State Licensing Authority) for Change in Approved Technical Staff**

6.13.1 For change in approved technical staff list at the site Drug Department (State Licensing Authority) shall be informed through intimation or as per prescribed Format presented in Annexure-II.

6.13.2 After receiving the acknowledgement from Drug Department (State Licensing Authority) with name of approved persons, List of Approved Technical Staff (presented in Annexure-III) shall be updated.

6.13.3 List of Approved Technical Staff shall be prepared by Officer/Executive QA and Approved by Head QA/Designee.

6.13.4 Any updation in List of Approved Technical Staff (Annexure-III) shall be tracked through revision history of Annexure, no change control is required.

6.13.5 Numbering System for Annexures to be presented in Site Master File:

6.13.6 Format No. shall be mentioned in font size 10, Normal and Capital letters in the bottom left hand side corner of the page after Footer and outside the page border.

6.13.7 Each Format shall be assigned unique Format Number for identification and control. Once a Number is allocated to any Format; the same number shall not be repeated to any other format.

6.13.8 Each Format No. shall consist of Sixteen Alphanumeric Characters (Six Alphabets, Three Slash Separator and Six Numerical characters (e.g. SMF/QA/01/F01-00) and one dash separator.

For Example: First format No. for SMF shall be numbered as

SMF/QA/01/F01-00

Where,

First Three characters indicate Site Master File.

4th character is Slash/for Separator.

5^{th} & 6^{th} character indicates Quality Assurance Department.

7th character is Slash/for Separator.

8th and 9th Numerical characters 01 indicate Serial Number of Site Master File.

10th character is Slash/for Separator.

11th, 12th and 13th character Indicates Format No. of the Annexure of Site Master File.

14th - is Dash

15th and 16th Numerical characters indicate Revision Number of that particular format which starts with 00 and there shall be increment of One Digit after every revision.

6.13.9 Revision history of every Annexure of Site Master File shall be tracked in the Annexure itself no change control is required. For specimen of Annexures to be presented in Site Master File refer Annexure-IV.

6.13.10 Similarly revision history of Annexure-V shall also be tracked in the Annexure itself.

6.13.11 If there is any change in the contents of Annexures presented in this SOP then SOP shall be revised through change control system.

6.13.12 If there is change in content of SOP, having no impact in the format then revision number of SOP shall be change and revision number of format shall remains the same.

6.13.13 In case, addition of new Annexure/Format, same shall be numbered sequentially.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
SMF	Site Master File
F	Format
PIC/S	Pharmaceutical Inspection Convention Scheme
WHO	World Health Organization

8.0 ANNEXURES

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure -I	Preparation for Site Master File (Specimen Copy)	
Annexure –II	Intimation to Drug Department for Change in Approved Technical Staff by Endorsement Letter	
Annexure -III	List of Approved Technical Staff	
Annexure -IV	Specimen for Annexure of Site Master File	
Annexure -V	List of Annexure of Site Master File	

9.0 DISTRIBUTION:

Master Copy	Quality Assurance Department
Controlled Copy No. 01	Quality Assurance Department.
Controlled Copy No. 02	Production Department
Controlled Copy No. 03	Engineering Department

10.0 REFERENCES:

- Eudralex, The Rules Governing Medicinal Products in the European Union, Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Explanatory Notes on the preparation of a Site Master File.
- PIC/S Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File (PE 008-4, 1 Annex, 1 January 2011).
- WHO Technical Report Series, No. 961, 2011, Annex 14, WHO guidelines for drafting a site master file.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I
PREPARATION FOR SITE MASTER FILE

PREPARED BY:

NAME	DESIGNATION	SIGN & DATE

REVIEWED BY:

NAME	DESIGNATION	SIGN & DATE

APPROVED BY:

NAME	DESIGNATION	SIGN & DATE

AUTHORIZED BY:

NAME	DESIGNATION	SIGN & DATE

ANNEXURE-II
INTIMATION TO DRUG DEPARTMENT FOR CHANGE IN APPROVED TECHNICAL STAFF BY ENDORSEMENT LETTER

To,
The Drugs Controller Licensing Authority,
Directorate of General Medical Health Family Welfare,

Sub: Additional name of Approved Chemist on Mfg. Lic.

Dear Sir,

We are submitting the following documents for addition of name of Approved chemist in……section on our Drugs manufacturing License No. **…….Form 28.**

S.No.	Name of Approved Chemist	Section	Certificate No.

We request you to do the needful.

Thanks with regards
For Decodinpharma

(Authorized Signatory)
Enclosed: 1. Approval Letter
2. Affidavit
3. 2 Photo

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ANNEXURE-III
LIST OF APPROVED TECHNICAL STAFF

EFFECTIVE DATE: **REVISION No.:**

S.No.	Name of Approved Person	Department	Designation	Qualification	Experience

REVISION HISTORY OF ANNEXURE:

Revision no. of Annexure	Details of changes	Justification of changes	Done by

Prepared By:
Sign & Date
Officer/Executive-QA

Approved By:
Sign & Date
Head QA

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ANNEXURE-IV

SPECIMEN FOR ANNEXURE OF SITE MASTER FILE

	ANNEXURE No.
TITLE OF ANNEXURE	

EFFECTIVE DATE: **REVISION No.:**

HEADING OF ANNEXURE

REVISION HISTORY OF ANNEXURE:

REVISION No. OF ANNEXURE	DETAILS OF CHANGES	JUSTIFICATION OF CHANGES	DONE BY

Prepared By:
Sign & Date
Officer/Executive-QA

Approved By:
Sign & Date
Head QA

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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ANNEXURE-V
LIST OF ANNEXURES OF SITE MASTER FILE

EFFECTIVE DATE: **REVISION No.:**

ANNEXURE NUMBER	TITLE OF ANNEXURE	FORMAT No.

REVISION HISTORY OF ANNEXURE:

REVISION No. OF ANNEXURE	DETAILS OF CHANGES	JUSTIFICATION OF CHANGES	DONE BY

Prepared By:
Sign & Date
Officer/Executive-QA

Approved By:
Sign & Date
Head QA