POLICY ON SITE MASTER FILE

INTRODUCTION:

This document provides a policy for preparation of Site Master File.

SCOPE:

This policy is applicable to all the site master files prepared at ……..

POLICY DETAILS:

- ✧ There shall be written procedure for preparation and updation of site master file. Preparation of site master file shall be managed by respective location.

- ✧ Site master file shall be prepared and maintained separately for API and formulation sites.

- ✧ Site master file shall provide clear information on cGMP related activities carried out at respective sites. Each site master file shall have a unique identification and version control.

- ✧ **Site master file shall contain the following at the minimum:**

a. Contact information
b. Authorised pharmaceutical manufacturing activities or any other manufacturing activities carried out on the site.
c. Copy of valid GMP licence.
d. Valid manufacturing authorisation.
e. Brief description of quality management system.
f. Release procedure of finished products.
g. List of suppliers and contract manufacturers/laboratories with addresses and contact information.
h. Quality risk management.
i. Brief descriptions of methodologies used in product quality reviews.
j. Information on personnel employed.
k. Organisation charts
l. Details of the premises i.e. short description of plant, layout and flow charts of production areas, water system, HVAC and other relevant utilities such as steam, compressed air, nitrogen etc.
m. Details of major production and laboratory equipment, computerised systems including equipment cleaning and sanitisation procedures of product contact surfaces.
n. Description of GMP critical computerised systems.
o. Description of documentation system (i.e. electronic or manual)
p. Types of products manufactured.
q. Process validation/assessment study.
r. Material management and warehousing.
s. Details of the quality control activities.
t. Distribution, complaints, product defects and recalls.
u. Self-inspection system and other documents as appendices with proper references.

The review and updation of site master files shall be carried out at a pre-defined frequency or earlier through a change request procedure.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable

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Site Master File:

The site master file is prepared by the pharmaceutical manufacturer and should contain specific information about the quality management policies and activities of the site, the production and/or quality control of pharmaceutical manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings.

ABBREVIATIONS:

API	: Active pharmaceutical ingredients
cGMP	: Current good manufacturing practice
HVAC	: Heating, ventilation and air conditioning systems
PIC/S	: Pharmaceutical inspection co-operation scheme
TRS	: Technical report series
WHO	: World health organization

REFERENCES:

PIC/S: Explanatory notes for pharmaceutical manufacturers on the preparation of a site master file, 2011
Rules and guidance for pharmaceutical manufacturers and distributors 2014 - the 'Orange Guide' Part III: Site Master File- Explanatory notes on the preparation of a site master file.
WHO TRS 961, 2011 Annex 14: WHO guideline for drafting a site master file.