DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Issue and control of Formats and Registers/Books	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Issue and control of formats and registers/books.

2.0 SCOPE:

This SOP is applicable to all the formats, registers, books, logbooks used in the stores, production, QC, QA, engineering utilities & maintenance, personnel departments for ……

3.0 RESPONSIBILITY:

Officer/Executive – Quality Assurance

Executive/In charge –Quality Control

Head – QA

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 The master copy of approved formats of the all departments shall be available in QA department.

5.2 The copies of the approved formats shall be taken from the master, and the same shall be issued to individual departments. However, the copies of the same will be sent to other department like, Regulatory Affairs, whenever any requisition is received.

5.3 Each format shall be uniquely identified with reference to Annexure of SOP No.

Annexure:

SOP No.:

5.4 The master copy shall be stamped “Approved” (in red) on the top left hand side of each page.

5.5 The copies of the approved format shall be taken from the master copy.

5.6 The “Controlled copy” (in Red) seal shall be stamped at the bottom center on all the pages of the approved format by QA.

5.7 The department code shall be written by QA on all pages.

5.8 All pages of the controlled copies of formats shall be signed and dated by QA.

5.9 QC related documents such as analytical raw data, calculation sheets and COA shall be issued by QC Incharge.

5.10 The master copy of analytical raw data, calculation sheets shall be stamped with '' MASTER COPY'' (in red) on the top right hand side of each page.

5.11 The photocopies of master copy are taken and ''ISSUED BY (QC)/ DATE '' stamp shall be put (in blue) on the bottom right hand side of each page and issue shall be maintained as per Annexure –II and Annexure –III.

5.12 All formats, registers, books, logbooks used in the plant shall be considered as ''controlled'' documents.

5.13 The QA department issues these to the respective departments for recording of raw data or information/observation regarding functioning of equipment or processes.

5.14 The respective department shall check availability of the format, register/book in the department and inform to QA department as per requirement basis.

5.15 Request for a new register shall be made by the department if not available.

5.16 A label (Annexure-I) shall be affixed on the front of the book/register containing the following information

a) Subject: What is the use or subject title of the book.

b) Book No: Each book shall have a unique identification number as described as per point 5.22.

c) Identification: Each book shall have information in a tabulated format or sequence, which is described as per point no. 5.3.

d) Date of issue

e) Issue by QA with date and signature: by QA.

5.17 The first book for that subject is numbered as '01' and all pages shall be serially numbered.

5.18 Upon completion of the book, the respective department shall return the book to QA department.

5.19 The next book with serial no. '02' shall then be issued.

5.20 The old register shall be reviewed and all corrections shall be rectified immediately and the register sent for archival in the document.

5.21 In case of a change in format, the same shall be approved by QA.

5.22 Book numbering pattern:

The books shall have the following coding:

……/XXX/BOOK/001/01

Where,

…… = Company Name

XXX = 3 alphabetical prefix to indicate the department name

001 = Serial number of book starting from 001 for a specific function Process

01 = Number of the same book starting from '01' serially.

5.23 The department prefix are as follows:

DEPARTMENT	DEPARTMENT CODE
Quality Assurance	QAD
Quality Control	QCD
Microbiology (QC)	QCM
Production Tablet/Capsule	PRD
Production soft gelatin	PRS
RM / PM / FG Stores	STR
Utility	UTI
Personnel and Administration	PAD

5.24 The approved format can under go change or revision as per the various internal or external requirements.

5.25 Whenever this takes place, QA department shall ensure that the new format is having the current version number.

5.26 It shall be ensured that the revised format is complete in all respects before it is approved.

5.27 Simultaneously, the existing document is removed and marked as 'Obsolete' in Red stamp.

5.28 The new format shall be copied and marked/stamped as required and described above.

5.29 During the distribution to the various departments, the QA department shall communicate to the various departments that the particular format has under gone a revision and the new format is now being issued and that the existing old format be returned to the QA department.

5.30 After all the copies are received, the QA shall retain only the obsolete master copy for history purpose and destroy all the other copies.

5.31 The entire obsolete master copies shall be stored as per SOP.

6.0 ABBREVIATION(S):

FG : Finished Goods

PM : Packing Material

RM :Raw Material

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

ANNEXURE- I : Label for books/registers

ANNEXURE-II : Analytical data sheet and report issue record

ANNEXURE -III: Calculation sheet and COA issue record

ANNEXURE -IV: Format Issue register

ANNEXURE –V: Book/register issue register

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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Annexure I

Label for Log book/Register

Subject :
Book No. :
Identification :
Date of Issue :
Issued by QA : **(Sign/Date)**

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Annexure II

ANALYTICAL DATA SHEET & REPORT ISSUE RECORD

S.No.	Name of data sheet & report	A.R. No/Batch No.	Issued by/Date	Issued to	Remarks

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Annexure III

CALCULATION SHEET & COA ISSUE RECORD					
S.No.	**Name of Calculation sheet & COA**	**Batch No.**	**Issued by/Date**	**Issued to**	**Remarks**

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Annexure IV

FORMAT ISSUE REGISTER

Title:

Identification:

Date of issue	No. of copies issued	Issued By/Date	Received By/Date

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Annexure V

BOOK/REGISTER ISSUE REGISTER

Book Details:

Identification:

Date of issue	No. of book (s) issued	Book No.	Issued By/Date	Received By/ Date