DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Review, Approval and Control of Master Documents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for the review, approval and control of master documents.

2.0 SCOPE:

This SOP is applicable to all master documents in the ……..

3.0 RESPONSIBILITY:

Officer/Executive/Manager – Quality Assurance

Head Of Department- QA

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Master documents are those which are the primary document of a particular process/ procedure/work instructions/formats.

5.2 All the master documents shall be in the custody and controlled by QA.

5.3 The following master documents need to be reviewed and or approved by QA.

a) Batch Manufacturing Record/Batch Packing Record
b) Standard Operating Procedures.
c) Specifications, Standard Test Procedures, General Test Procedures, Dissolution profiles, Stability Protocols and artworks etc.
d) Standardization/Validation Protocols, Equipment qualification /Re qualification Protocols
e) Formats for recording of data/information.
f) Engineering drawings
g) Validation Master Plan
h) Site Master File
i) Validation Policy
j) Any other related quality documents

5.4 Whenever a master document is prepared or received, the same needs to be reviewed and or approved by QA.

5.5 QA personnel will review the document for its accuracy and adequacy, before giving formal approval.

5.6 Head- QA or his designee shall review and approval of the master documents. (Refer Annexure-I)

5.7 Training shall be provided to these persons for the exercise based on their qualification, experience, technical knowledge, skill, understanding of GMP/GLP concepts and expertise.

5.8 In case, the document is found inadequate/inaccurate, it shall be sent back to the originating department for corrections.

5.9 Once reviewed and approved, the document shall become the property of QA department.

5.10 Copies for the use of the document shall be issued as per SOP for document control.

5.11 In case, a master document undergoes a revision, the change shall be effected through change control procedure approved by QA after assessing its accuracy, adequacy and impact of the change on the quality of the products and processes or GMP/GLP regulations.

5.12 Once the new document is made, it will follow the same review and approval procedures as described above in 5.4 to 5.7

5.13 Once the new master document is approved, previous master shall be stamped as ‘obsolete’ and control copies shall be destroyed. Copies of the new master document to be issued as per SOP.

5.14 The master documents (current and obsolete) shall be retained indefinitely in order to maintain the traceability and account for the history of changes.

5.15 Formats are revised and approved as per SOP. Approved blank formats for regular recording of data shall be issued in the form of registers/spirally bounded form.

5.16 Once the new format is generated, after its revision and approval (refer SOP on form numbering and control) the previous ‘QA approved’ format shall be withdrawn. The new format shall then be issued.

6.0 ABBREVIATION(S):

GMP : Good manufacturing Practices

GLP : Good Laboratory Practices

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I: List of authorized persons for the review and approval of Master Documents.

9.0 REVISION CARD:

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

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ANNEXURE I

List of authorized persons in QA for review and approval of master documents.

S.No.	Document	Name of Reviewer	Name of Approver
1.	BMR/BPR		
a)	Solid Dosage forms		
2.	SOP's		
a)	QA		
b)	Production		
c)	Engineering & Maintenance		
d)	QC		
e)	Microbiology		
f)	Stores		
g)	Administration		
3.	Specifications / STPs/GTPs etc.		
4.	Artworks		
5.	Formats		
6.	Engineering Drawings		
7.	Validation Master Plan		
8.	Quality Policy		
9.	Other documents		