PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Distribution control, Revision and Destruction of Standard Operating Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for preparation, approval, distribution control, revision and destruction of all SOP's.

2.0 SCOPE:

This SOP is applicable for the preparation, approval, distribution, control, revision and destruction of all Standard Operating Procedures for ……..

.

3.0 RESPONSIBILITY:

Officer/Executive/Head Concern department for preparation and review of SOP's.

Manager –QA: To approve and ensure the compliance all SOP's.

4.0 DEFINITION(S):

It is defined as an authorized written procedure giving instructions for performing operations.

5.0 PROCEDURE:

5.1 Preparation procedure:

5.1.1 The format for the SOP structure is provided in Annexure - I.

5.1.2 Use A4 size (Width: 8.27" and Height: 11.69" approximately) white paper.

5.1.3 Format SOPs with the following margins. Top : 1.0", Bottom: 0.5", Left: 1.0", Right: 0.7", Header: 0.7" and Footer: 0.7" approximately.

5.1.4 Prepare SOPs "Arial" font with font size "12" but in special cases font size "15" can be used e.g. **Decodingpharma** approximately.

5.1.5 Prepare SOP's in a unambiguous, easy to understand language. Prepare SOP in draft form as required & print with ''DRAFT'' only .The draft copy is circulated for checking and should be retained upto approval.

5.1.6 Included list of the abbreviations used in SOP.

5.1.7 Only checked and approved SOP's can be issued.

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5.1.8 All SOP's shall follow the following sequential sub headings. They will be in Bold and sub – subheadings shall also be in bold and follow the sequence as described below -

1.0 Objective:

2.0 Scope:

3.0 Responsibility:

4.0 Definition:

5.0 Procedure:

6.0 Abbreviation(s):

7.0 Reference(s):

8.0 Annexure(s):

9.0 Revision Card:

The subheading and its subheadings shall follow the format Numbering as per the following example-

5.0 Procedure:

5.1 Preparation of solution:

5.1.1 -------

5.1.2 -------

5.2 Cleaning of Vessels:

5.1.9 The following details are given under each of the above mentioned (Step No.: 5.1.8) subheadings.

5.1.9.1 **OBJECTIVE:**

State the reason for writing the SOP. Restrict the reason to one sentence or maximum two sentence statement, starting with the word "To".

5.1.9.2 **SCOPE:**

State the scope to which SOP is applicable for. The scope shall be applicable for processes / equipment/policies/ particular section/site.

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5.1.9.3 **RESPONSIBILITY:**

State the designation of the person who is competent enough/operating person responsible for performing the job as described in SOP. Care must be taken to ensure that preferably one to two persons are responsible for compliance of SOP.

5.1.9.4 **DEFINITION:** State the definition of Important terms incorporated in SOP if it is not applicable then type NA.

5.1.9.5 **PROCEDURE:**

Give in short, unambiguous sentences of the operating procedure, all checks to be done, record to be maintained, frequency of various operations, etc. Give special precautions, if any. SOP must not have long paragraphs but in short, a few sentences paragraphs. Special instructions may be given as 'Note', 'Precautions' etc.

5.1.9.6 **ABBREVIATION (S):**

State the Abbreviation(s) used in SOP.

5.1.9.7 **REFERENCE(S):**

State the Reference(s) used in SOP.

5.1.9.8 **ANNEXURE (S):**

Give the Annexure (s) used in SOP.

5.1.9.9 **REVISION CARD:**

State serial no., revision no., revision date, details of revision and reason(s) for revision. The revision card shall note the history of revision and be part of the master copy to be circulated as per requirement.

5.1.10 Each SOP incorporates header and footer with the following details.

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5.1.10.1 **ITEM – I:**

Header of the all pages will have the word **Restricted Circulation** on the top right hand side corner, above the header. The title **Restricted Circulation** shall be in Bold letters.

5.1.10.2 **ITEM – II:**

The title of **Company, Department** and **logo** shall be in Bold letters. And address of the site of the company shall also mention with The title of **Company & Department** in Normal letters.

5.1.10.3 **ITEM – III:**

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5.1.10.4 **ITEM – IV:**

Mention the title of the SOP for which it is being prepared in **BOLD letters.**

5.1.10.5 **ITEM- V: Supersedes**, Mention previous revision number. Write "Nil", if the new SOP is written.The title supersedes shall be in Bold letters.

5.1.10.6 **ITEM- VI: SOP No.**, Mention a unique number to each SOP. First seven characters shall be considered as SOP number and last three characters (8^{th}, 9^{th} & 10^{th}) shall be consider as sop version number or revision number, broken down as follows:

XXX	/	XXX	-	XX
First three characters	4^{th} Character	5^{th}, to 7^{th} character	8^{th} Character	9^{th} & 10^{th} character
Department Code*	Forward Slash	Serial No.	Hyphen	Revision No.

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('**X**' In capital alphabetic letters)

The First (1st) three characters are letters of the alphabet denoting the "Department Code" for which SOP is being written for. e.g. The code of each department is given below.

- 4th character denotes"/" (Forward Slash).

5th, 6th and 7th character denotes "serial number of SOP" (A three-digit number starting serially from 001). The title SOP No. shall be in Bold letters.

DEPARTMENT	DEPARTMENT CODE
Quality Assurance	QAD
Quality Control	QCD
Microbiology (QC) Section	QCM
Production of Tablets/Capsule	PRD
Production of Soft gelatin	PRS
RM/PM/FG Stores	STR
Utility	UTI
Personnel & Administration	PAD

5.1.10.7 **ITEM – VII: Page No.** Mention the running page number followed by the total page number (CURRENT PAGE of TOTAL NUMBER OF PAGES).For example page no. 4 of 5 , 5 of 5. The title **Page No.** shall be in Bold letters.

5.1.10.8 **ITEM – VIII: Issue Date**, Mention day, month & year in dd/mm/yy format when this SOP is issued to the respective department. The title **Issue Date** shall be in Bold letters.

5.1.10.9 **ITEM-IX: Effective Date**, Mention date, month & year when this SOP is scheduled to be effective and the SOP should be made effective after training of this SOP. The title **Effective Date** shall be in Bold letters.

5.1.10.10 **ITEM-X: Review Date**, Mention day, month & year for review of SOP's. (Two years from the date of issue date), SOP's to be reviewed on mentioned

date. However any change in SOP, can be brought on need basis. It will require a revision and re-issuance of the same as and when the change is implemented. The title **Review Date** shall be in Bold letters.

5.1.10.11 **ITEM – XI:**

Each SOP footer shall have following details:

- **Prepared by:** Will be signed by a person responsible for Preparing the SOP. The title **Prepared by** shall be in bold letters.
- **Checked by:** Will be signed by Head of Department or his designee. The title **Checked by** shall be in bold letters.
- **Approved by:** Will be signed by QA Head. The title **Approved by** shall be in bold letters.
- **Designation** shall be in bold letters and the corresponding Authorities shall be in Normal letters.
- **Signature and Date** shall also in bold letters.
- **Name** shall be in bold letters and Name of persons shall be in Normal letters.

NOTE- Each signatory will sign in blue permanent ink ball point pen and put the signature and date.

5.1.10.11 Mention designation of the person, signature, date & name of the signatory for each signature column.

5.2 Distribution and Control Procedure :

5.2.1 Quality Assurance department will keep all approved SOP's (Master Copy in safe custody).

5.2.2 The Quality Assurance department stamp will the SOP's as described below using the standard stamps as given in Annexure – II.

5.2.3 Stamp as "MASTER COPY" in red ink on the front top right hand side corner of all the pages on Original copy

5.2.4 Quality Assurance department will take photocopy of the "MASTER COPY" and stamp it as "CONTROLLED COPY/DEPT. CODE No." in

red ink on the front centre bottom side of all the pages and signed by Quality Assurance person controlling the SOPs or nominated person and allot a specific code to each department. Department code No. is allotted to various departments is as follow.

DEPARTMENT	DEPARTMENT CODE NUMBER
Quality Assurance	QAD
Quality Control	QCD
Microbiology (QC)	QCM
Production of Tablet/Capsule	PRD
Production of Soft Gel	PRS
RM/PM/FG Stores	STR
Utility	UTI
Personnel & Administration	PAD

5.2.5 Quality Assurance department controls distribution of all SOP's by entering details of distribution in "SOP DISTRIBUTION RECORD" (Annexure – III).

5.2.6 For displaying on the site, photocopy of "MASTER COPY'' shall be taken and stamped as "REFERENCE COPY/DEPT. CODE No." in green ink on the bottom right hand side corner of all the pages and issued.

5.2.7 Any photocopy of SOP(s) required by external agencies other than regulatory/ statuary/legal authorities shall be issued based on request and shall be approved by Head – QA. Quality Assurance Department will issue a photocopy of "MASTER COPY'' stamped as "UNCONTROLLED COPY" in black ink at the bottom right hand side corner on all the pages.

5.3 Revision Procedure:

5.3.1 Revision of SOP shall be done at any time on need basis. It shall be reviewed at the end of two years from the date of issue. The SOP's change shall follow the steps as detailed in the SOP for change control system.

5.3.2 SOP to be reviewed shall be returned to Quality Assurance department, which will be entered in the "SOP DISTRIBUTION RECORD" (Annexure-III).

5.3.3 Quality Assurance Department shall ensure reconciliation and destroy the controlled and reference copies received from different departments and enter in the "SOP DISTRIBUTION RECORD".

5.3.4 The old "MASTER COPY" maintained in the Quality Assurance department shall be stamped "OBSOLETE" in red ink in the centre of all pages and stored / archived for history purpose.

5.3.5 Serial No., revision No., revision date, details of revision and reason of revision of SOP shall be clearly mentioned in the last item of the SOP. i.e. revision card.

5.3.6 If there is no change in text of SOP, stamp "REVIEWED BY/DATE'' and ''NEXT REVIEW DATE" in red ink at the bottom left hand side corner of all the pages of "MASTER COPY" shall be put.

5.3.7 The revised SOP's shall once again go through the same procedure of approval, authorization and distribution control as mentioned earlier.

5.4 Destruction procedure:

5.4.1 Retrieved copies of SOP shall be destroyed by following method.

1. Shredding

Quality Assurance department shall supervise this activity.

6.0 ABBREVIATION(S):

Dept. : Department

FG : Finished Goods

PM : Packing Material

QA : Quality Assurance

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QC : Quality Control

RM : Raw Material

SOP : Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

ANNEXURE – I : SOP formats

ANNEXURE – II : Stamp impressions

ANNEXURE – III : SOP distribution record

9.0 REVISION CARD:

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

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ANNEXURE I

STANDARD OPERATING PROCEDURE	
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1.0 OBJECTIVE:

2.0 SCOPE:

3.0 RESPONSIBILITY:

4.0 DEFINITION(S):

5.0 PROCEDURE :

6.0 ABBREVIATION(S):

7.0 REFERENCE(S):

8.0 ANNEXURE(S):

9.0 REVISION CARD:

	Prepared By	Checked By	Approved By
Designation			
Sign and Date			
Name			

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ANNEXURE II

Stamp Impressions

TEXT	STAMP IMPRESSIONS
MASTER COPY (To be stamped in Red color)	
CONTROLLED COPY **Dept. Code No.:** **Sign. :** **Date:** (To be stamped in Red color)	
REFERENCE COPY **Dept. Code No.:** **Sign:** **Date:** (To be stamped in Green color)	
UNCONTROLLED COPY (To be stamped in black color)	
OBSOLETE (To be stamped in red color)	
REVIEWED BY/DATE: **NEXT REVEW DATE:** (To be stamped in red color)	

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ANNEXURE III

SOP Distribution Record

Title of SOP:

SOP No.:

S.No.	Issued to (Dept. Code No.)	No. of Copies Issued	Issued By/ Date (QA)	Reason for Issuance	Received By/Date	Retrieved By (QA)/Date (Obsolete Copies)