PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: SOP for List of List	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:** The purpose of this SOP is to describe the procedure for preparation and updation of 'list of list' and for traceability of all the lists which have direct or indirect effect on the SISPQ.

2. **Scope:** The SOP shall be applicable for maintaining all the lists prepared and utilizing by the user department. The lists which have direct or indirect effect on SISPQ and are not a part of any SOP's.

3. **References & Annexures:**
   - 3.1 **References:**
     - 3.1.1. In house
   - 3.2 **Annexures:**
     - 3.1.2. Annexure- 1: List of list.
     - 3.1.3. Annexure- 2: Format of list.
     - 3.1.4. Annexure- 3: Authorization of access.

4. **Responsibilities:**
   - 4.1 **Quality Assurance (QA) :**
     - 4.1.1. To prepare list of list.
     - 4.1.2. To update the list of list.
     - 4.1.3. To archive all the list prepared by user department in soft file.
     - 4.1.4. To ensure implementation of the SOP.
   - 4.2 **User Department:**
     - 4.2.1 To prepare the list of item which are not the part of any SOP.
     - 4.2.2 To provide soft file of all the list to QA.
     - 4.2.3 To initiate for updation of list of list, in case there is any change or updation or inclusion of any new list.
   - 4.3 **User Department Head:**
     - 4.3.1 To review and approve the SOP.
     - 4.3.2 To ensure implementation of the SOP.
   - 4.4 **Regulatory Affairs, Quality Head and Plant Head :**
     - 4.4.1 To review and approve the SOP.

5. **Distribution:**
   - 5.1 QA
   - 5.2 QC
   - 5.3 Production
   - 5.4 Packing
   - 5.5 Personnel & Administration.
   - 5.6 Warehouse
   - 5.7 EHS
6. **Abbreviations and Definition of Terms:**

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6.1 **Abbreviations :**

6.1.1 CC No.: Change Control number
6.1.2 NA: Not Applicable
6.1.3 QA: Quality Assurance
6.1.4 SOP: Standard Operating Procedure
6.1.5 SISPQ: Safety Identity Strength Purity Quality

6.2 **Definition of Terms :** NA

7. **Procedure:**

7.1 QA shall prepare and update the list of list as per Annexure-1.
7.2 List of list shall contain all the lists prepared and utilized by the user department, which are not the part of any SOP, but have direct or indirect impact on SISPQ.
7.3 The list of items to be maintained in list of list can be identify by QA or User department.
7.4 User department shall provide the details to QA about all the lists which are to be prepared and under utilization. For eg. List of authorized trainer, List of clock, List of computer etc.
7.5 If there are any changes or modification or preparation of any list, then the user department shall intimate regarding the changes to QA and list of list to be updated accordingly.
7.6 QA shall assign a number to all the lists prepared by user department. Numbering of list shall be like "AA-DC/ LIST-001/RN"
Where,
AA is Location code of plant
DC is the Department Code
LIST-001 is the serial number of the list, irrespective of all departments.
RN is the Revision Number.
For example first list of QA department shall be "AA-QA/LIST-001/00"
Department code shall be assigned by using the following code for each respective department code:

GR	Granulation	WH	Ware house
CM	Compression	MN	Maintenance
CO	Coating	PA	Personal & Administration
CP	Capsulation	IT	Information & Technology
PK	Packaging	ES	Environment, Health & Safety
QA	Quality Assurance	QC	Quality Control

7.7 User department shall prepare the list of all miscellaneous item as per the format given in Annexure- 2. Format can be customized as per requirement or item.
7.8 After preparation of list, user department shall inform QA to get an identical number.
7.9 All list shall be maintained in soft copy in "QA-K" drive with limited access.
7.10 List of authorized person for accessing of list of list to be maintained as per Annexure-3. Updated list of annexure- 3 shall be attached with the master copy of current version of SOP.

7.11 No print shall be allocate to the other department. In case of print requirement, QA shall print the updated list and put the control/ uncontrolled stamp as per requirement.

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Annexure 1
List of List

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S.No.	Title of list	User Department	List Number	Revision No.	Effective date	Assigned By	Revision History

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Annexure 2
Format of List

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Title of list:					
List Number:		**Effective date:**			
Department:		**Revision No.**			
*** ID nomenclature:**					
Sr. No	**Item details**	***ID Number**	**Make/ Model**	**Capacity**	**Location**

***** *Format of the list can be customized as per requirement/item.*

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Annexure 3
Authorization of Access

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S.No.	Name	Department	Designation	Authorized By	
				QA Head	Quality Head

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8. History

Revision No	Effective Date	Revision Details	CC No
00		New SOP	NA