



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: List of Authorized Personnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Preparation of List of Authorized Personnel.

2.0 SCOPE:

This SOP is applicable to Personnel working in Critical Areas like Microbiology Lab., Sampling, Dispensing, Control Sample Area, Stability Room, Core Area, Sterile Area & Multi-Column Distillation Plant, Water System, Utility Area, Service Floor, other Critical Areas and Different Production area at

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Distribution (to Respective Department), Revision, Retrieval and Destruction of this SOP.

QA Manager : Review, Approval, Training and effective implementation of this SOP in all the applicable areas.

Respective Department: To display List of Authorized Personnel at the entry of Respective Area. Provide Request/Change Request to QA for Preparation/any change in list.

4.0 ACCOUNTABILITY:

Head QA: Approval of this SOP & ensure Training and effective Implementation of SOP.

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 To prevent entry of Unauthorized Personnel in Critical Areas & Various Production area, All Head of the Department shall give Area wise Name of Technical Staff, Technicians, Operator and Helper/Worker etc. to QA Department in format “**Requisition for List of Authorized Personnel**” as shown in **Annexure-I.**



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- 6.2** QA shall prepare a list of Authorized Personnel as recommended by Concerned Department Head in format “**List of Authorized Personnel**” as shown in **Annexure-II** with few additions in blank rows and respective department shall display the list of Authorized Personnel in concerned areas.
- 6.3** If there is any change in Technical Staff, Technicians, Operator and Helper/Worker either by Resign/ Left or Designation change, detail shall be written in Black Ink Ball Point Pen in remarks column by Concern In-charge with sign & date.
- 6.4** In case any new personnel authorization in area, Name, Designation & Department of personnel to be written in Black Ink Ball Point Pen in blank row by Concern In-charge with sign & date
- 6.5** Concerned Department Head, Head QA are authorized to Access in all Areas.
- 6.6** Vendors are allowed to enter in Critical Areas only, if they are accompanied with any of Authorized Person of Concerned Area.
- 6.7** Microbiologists are authorized to enter in all Critical Areas (Microbiology lab) for Environmental Monitoring & sampling of sterile sample.
- 6.8** Engineering Personnel are allowed to enter in Critical Areas for Maintenance work, if they are accompanied with any of Authorized Person of Concerned Area.
- 6.9** Name of the Personnel listed, shall be restricted to that Particular Area only, no movement shall be allowed other than the Restricted Area.
- 6.10** QA shall update the Authorized Personnel List on yearly basis through intimation given by Concerned Department to QA Department in format “**Change Request for List of Authorized Personnel**” as shown in **Annexure-III** to update the List of Authorized Personnel.

7.0 ABBREVIATIONS:

ETP	Effluent Treatment Plant
Lab	Laboratory
Ltd.	Limited
PSG	Pure Steam Generator
Pvt.	Private
QA	Quality Assurance
S. No.	Serial Number
SOP	Standard Operating Procedure



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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ANNEXURE –I

REQUISITION FOR LIST OF AUTHORIZED PERSONNEL

To : Quality Assurance Department

From : (Name of Department)

Following Personnel are authorized to enter in _____ (Area Name).

S.No.	Name of Employee	Designation	Employee Code	Department

Prepared By
Officer/Executive
Sign & Date

Checked By
Department Head
Sign & Date

Approved By
Head of the Department
Sign & Date



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ANNEXURE –II
LIST OF AUTHORIZED PERSONNEL

Location:

Effective From:

Area :

Following Personnel are authorized to enter into ----- (Area Name)

S.No.	Name	Designation	Employee Code	Department	Remarks
1.					
2.					
3.					

Note:

1. Concerned Department Head, Quality Head and Head CQA are authorized to access in all areas.
2. If there is any change in List (i.e. personnel Left or Designation change etc.), detail shall be written in Black Ink Ball Point Pen in remarks column by Concern In-charge with sign & date.
3. In case any new personnel authorization in area, Name, Designation & Department of personnel to be written in Black Ink Ball Point Pen in blank row by Concern In-charge with sign & date

Approved By
Head QA



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ANNEXURE –III

CHANGE REQUEST FOR LIST OF AUTHORIZED PERSONNEL

To : Quality Assurance Department

From : (Name of Department)

Kindly Change/Remove the Name of following Personnel from the list of Authorized Personnel due to reason mentioned below:

S.No.	Name of Employee	Designation	Employee Code	Department	Existing Area	New Area	Reason for Change

Prepared By
Officer/Executive
Sign & Date

Checked By
Head Department
Sign & Date

Approved By
Head of the Department
Sign & Date