



STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 Objective:

The objective of this SOP is to lay down a procedure for writing of job description of an employee.

2.0 Glossary:

SOP	Standard operating procedure
cGMP	Current good manufacturing practices
JD	Job Description
No.	Number
Q.A	Quality Assurance
EMP.	Employee

3.0 Scope:

This SOP is applicable for all the employees working in the Production, Engineering, Warehouse, Quality Control, Quality Assurance, process development laboratory, Human Resource Department Information Technology of

4.0 Responsibility:

- 4.1** Department Head/Department Designee Prepares the job description for the different level.
- 4.2** Head of department Approves the job description and completing competency mapping of the new employee.



STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.0 Accountability:

Head of Department.

6.0 Procedure:

6.1 Each person employed inwhich is engaged in the manufacturing, packing, testing or holding of a drug product must have education, training and experience or any combination thereof to enable that person to perform the assigned functions.

6.2 After the successful completion of induction program, the executive of department shall prepare the job description and take the signature of the employee in coordination with the Head of department based on the job requirements in the department in the prescribed format. Refer Annexure-I “JOB DESCRIPTION”.

6.3 Each Job Description shall bear a unique alpha numeric no. as mentioned below

Job description No.: JD/EMP. No.-Version No.

Where JD Stands for Job Description

EMP. No. Stands for Employee code

Version No. Stands for the revision no. of the JD starting from 00, 01, 02

For Example: JD No. of Mr. will be JD/.....-00 for the JD prepared for the first time, in case any revision the JD no. will change to JD/..... and reason for revision to be documented.

6.4 The head of Department shall prepare the list of activities and define the expertise of the personnel in accordance with the previous job experience.

6.5 The Head of department shall define the reporting responsibilities of the personnel as mentioned below:

6.5.1 Daily reporting to the immediate supervisor

6.5.2 Reporting to the next level supervisor in the absence of immediate supervisor.



STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.5.3 In the absence of personnel, deputize personnel to report to the supervisor.

6.5.4 Organogram shall be attached to the job description to state the reporting system.

6.6 On completion of departmental training (SOP and On job training), Head of Department shall evaluate the competence part as mentioned below:

6.5.1 List of activities can be done under the supervision of the supervisor

6.5.2 List of activities in which the personnel is proficient.

6.5.3 List of activities in which the personnel can train others.

6.7 After the final signature of JD along with competency chart, of employee can start the job as per assignment.

6.8 The original copy of the signed job description shall be maintained by the Head of the department.

6.9 Photocopy of the signed job description shall be provided to personnel and administration department to maintain in the individual file.

6.10 The job description must be revised within one month in case of any change in the current designation of the personnel or any change/updation in the current job responsibilities.

6.11 The job description shall be filled in archive file once an employee resigns from the employment of

7.0 Training:

Trainer -- Head – Quality Assurance

Trainees -- All Departmental/Sectional Heads

8.0 Distribution:

Certified Copy No. 1 : Head of Department – Cephalosporin Block



STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- Certified Copy No. 1 : Head of Department – General Block
- Certified Copy No. 2 : Head of Department – Engineering
- Certified Copy No. 3 : Head of Department – Warehouse
- Certified Copy No. 4 : Head of Department – Personnel and HRD
- Certified Copy No. 5 : Head of Department – Quality Control
- Certified Copy No. 6 : Head Operations
- Certified Copy No. 7 : In charge PM QC
- Certified Copy No. 8 : Head of Department – Warehouse
- Certified Copy No. 9 : In charge IT Department
- Certified Copy No. 10: Head of Department – Microbiology Lab
- Original Copy : Head – Quality Assurance

9.0 Annexure:

Annexure – I : Format for Job Description

10.0 References:

In- house.



STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

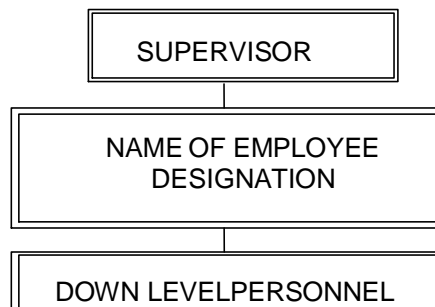
ANNEXURE – I

.....	JOB DESCRIPTION		
Name		Employee no	
Department		Date of Joining	
Designation/Level		Reporting to	
Education		Total experience	
Job description No.	JD/EMP. No.- Version No.	Page No.	
Reason For Revision			

To fulfill the cGMP requirement Job description of _____ who has been employed by engaged in the manufacture, processing, packing, or holding of drug product must have the education, training, and experience, or any combination thereof to enable _____ to perform the assigned functions.

JOB RESPONSIBILITIES:

REPORTING RESPONSIBILITIES OF Mr./Mrs. _____



Brief Description on Reporting Responsibilities:

1. Mr./Mrs. -----reports to his/her supervisor -----
2. In the absence of Mr./Mrs. -----on communication from supervisor, Mr./Mrs. _____ can be deputize for department activity but for a period notified in the notice.



PHARMA DEVILS

PERSONNEL AND ADMINISTRATION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Personnel and Administration	SOP No.:
Title: Writing of Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

(Note:-In case of level-1,section head/Designee can deputize any competent person for assigned job)

Job Responsibilities:

1. Authorization to sign on documents (as prepared By/checked By/Approved By):
2. Authorization to procurement of departmental items.(if any)
3. Responsible for ensuring Safety in Operation
4. Responsible for practicing Good Documentation practice in department
5. Responsible for carry out activities /allot work to others

.....	JOB DESCRIPTION		
Name		Employee no	
Department		Date of Joining	
Designation / Level		Reporting to	
Education		Total experience	
Job description No.	JD/EMP. No.- Version No.	Page No.	
Reason For Revision			

Competency chart:

Job Title	Can do under Supervision	Proficient	Can train Others

Note: Put tick (√) or cross mark (×) appropriately



PHARMA DEVILS

PERSONNEL AND ADMINISTRATION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Personnel and Administration

SOP No.:

Title: Writing of Job Description

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Name of employee		Name of Department Head	
Sign		Sign	
Date		Date	

Format No.:.....