PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of Finished Products, Semi-finished and In-process Samples	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for handling of finished products, semi-finished & in process samples.

2.0 SCOPE:

This procedure is applicable to handling of finished products, semi-finished & inprocess samples in Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 After receipt of samples along with sample slip from IPQA, QC personnel shall enter the details in finished product sample register and semi-finished product & In-process register as per Annexure-I and Annexure-II.

5.2 QC Incharge shall allocate the samples along with analytical test data sheets to the respective persons for analysis.

5.3 QC Officer/Executive shall perform the analysis as per respective standard test procedures and specification.

5.4 QC Officer/Executive shall maintain all print outs with the analytical test data sheets along with signature.

5.5 After completion of analysis, QC Officer/Executive shall submit the report along with all supporting documents to QC Incharge for review.

5.6 QC Incharge shall review each of the test and supporting data according to respective standard test procedure and specification of the products for compliance.

5.7 During analysis of the finished products, semi-finished products and inprocess sample if results are out of specifications, Inform immediately to the respective supervisor for investigation as per Out of Specification results SOP.

5.8 QC Incharge shall prepare COA as per respective specifications.

5.9 After completion of all the record at each stage, QC Incharge shall handover the complete batch analysis report at each stage along with supporting data to QA department for storage.

6.0 ABBREVIATION(S):

QCD - Quality Control Department

COA - Certificate of Analysis

OOS - Out of Specification

QA - Quality Assurance

QC - Quality Control

SOP - Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure I: Finished product Inward Record.

Annexure II: In-process & Semi-finished Inward Record.

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9.0 REVISION CARD:

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

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ANNEXURE I

FINISHED PRODUCT INWARD RECORD

S.No.	Date of Intimation	Name of Finish product	B. No.	Mfg. Date	Exp. Date	Batch Size	Received by	AR No.	Date of analysis	Date of Release	Remarks	Analyzed By

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INPROCESS & SEMIFINISHED INWARD RECORD

S.No.	Date of Intimation	Name of In-process & Semi-finish	B. No.	Mfg. Date	Exp. Date	Batch size/ Quantity	Received by	A.R. No.	Date of analysis	Date of Release	Remarks	Analyzed By