PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for handling of samples received in Quality Control Department.

2.0 SCOPE:

This SOP is applicable for all samples (Except Packing Material) received for analysis in the

Quality Control Laboratory.

3.0 RESPONSIBILITY – Execution - Executive QC.
Checking - Assistant Manager QC .

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 After receiving the samples for analysis , the concerned person enter the details in their respective inward registers as per mentioned in Table – I.

5.1.1 For purified water, Potable water, WFI & Pure steam, the annexure no. is same.

5.1.2 Separate registers shall be maintained for all types of water as mentioned above. Label the registers separately.

TABLE – I

S.No.	Type of Sample	Annexure
1	Raw Material	Annexure- I
2	Packing Material	Annexure- II
3	Finished Products	Annexure- III
4	In process	Annexure -IV
5	Purified Water / Potable Water / WFI / Pure Steam	Annexure - V
6	Validation	Annexure - VI
7	Cleaning	Annexure – VII
8	Miscellaneous	Annexure – VIII

5.2 Allot the AR No. to the sample received in Quality Control.

5.2.1 The AR No. shall be in 9 digit alphanumeric as mentioned under

Type of sample	1st Character	2nd &3rd Characters	4th & 5th Characters	6th ,7th ,8th & 9th Characters
Raw Material	A	RM	XX	NNNN
Packing Material	A	PM	XX	NNNN
In Process (Product)	A	IP	XX	NNNN
Finished Products	A	FP	XX	NNNN
Validation (Product)	A	VD	XX	NNNN

Potable Water	A	PO	XX	NNNN
Purified Water	A	PW	XX	NNNN
WFI	A	WF	XX	NNNN
Pure Steam	A	PS	XX	NNNN
Miscellaneous	A	MS	XX	NNNN
Cleaning	A	CL	XX	NNNN

Where:

A = Analytical Report
RM = Raw Material
PM = Packing Material
IP = In Process
FP = Finished Products
VD = Validation Products
PO = Potable Water
PW = Purified Water
WF = WFI
PS = Pure Steam
MS = Miscellaneous
CL = Cleaning
XX = Last two digits of the year
NNNN = Serial No. starting from 0001every calendar year

For Example : First AR No. for Raw Material in 2007 shall be ARM070001 & 2008 shall be ARM080001.
First AR No. for Finished Product in 2007 shall be AFP070001 & 2008 shall be AFP080001.
(Miscellaneous samples other than above category)

5.3 Respective section in charge or designee should issue the sample to concerned person for analysis along with respective data sheets & STP's.

5.4 During distribution the concerned person fill the distribution details of sample in the respective inward registers.

5.5 The concerned persons shall analyse the sample as per respective STPs & fill the observations accordingly into the datasheets.

5.6 After analysis the concerned person shall submit the filled raw data sheet along with STP & remaining sample to their respective section In charge

5.7 The respective section In charge shall review the raw data as per current version of "SOP Review of the rawdata of the analysis" &submit the file to QC Manager or his designee for their approval / rejection.

5.8 After making the comments for approval / rejection QC Manager shall send the file to the concerned person.

5.9 The concerned persons shall make entry in their respective inward registers & put the APPROVED or REJECTED .

5.9.1 In case of Raw Material & Packing Material concerned persons shall affix the label (APPROVED or REJECTED) in to the respective material.

5.9.2 Hand over the release slip to store in charge (as per Annexure –IX).

5.10 The concerned persons shall record the file in respective place for Raw Material & Packing Material and send the file to QA un case of Finished Products, In process samples & Validation samples.

5.11 The concerned persons shall dispose "off" the remaining sample as per current version of ` "SOP Destruction of samples after testing:.

6.0 SAFETY & PRECAUTIONS

Not Applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

SOP Review of the raw data of the analysis
SOP Destruction of samples after testing

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

QA : Quality Assurance

No. : Number

QC : Quality Control

A.R. N : Analytical report number

FP : Finished Product

RM : Raw Material

SFG : Semi-finished goods.

Annexure-I: Raw Material Inward Register

Annexure-II: Packing Material Inward Register

Annexure-III: Finished Product Inward Register

Annexure-IV: In Process Inward Register

Annexure-V: Inward Register For Purified Water, Potable water, WFI & Pure Steam.

Annexure-VI: Validation Sample Inward Register

Annexure-VII: Miscellaneous Inward Register

Annexure-VIII: Cleaning Inward Register

Annexure-IX : Quality Control Laboratory Release Slip

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I

RAW MATERIAL INWARD REGISTER

S.No.	AR No.	B.No.	Name of Raw Material	Mfg by	Supplied by	Mfg. Date	Exp. Date	Batch Size	Date of Receipt	Date of Release	Remarks	Sample Destruction		Name of Analyst	Sample Destruction
												date	sign		

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-II

PACKING MATERIAL INWARD REGISTER

S.No.	AR No.	B.No.	Name of Packing Material	Mfg by	Supplied by	Mfg. Date	Exp. Date	Batch Size	Date of Receipt	Date of Release	Remarks	Sample Destruction		Name of Analyst	Sample Destruction
												date	sign		

ANNEXURE-III

FINISH PRODUCT INWARD REGISTER

S.No.	A.R. No	B. No.	Name of Product	Date of Receipt	Date of Release	Analyzed by	Remarks	Sample Destruction		Name of Analyst
								Date	Sign	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-IV
IN PROCESS SAMPLE INWARD REGISTER

S.No.	A.R. No	Batch No.	Name of Sample	Mfg. Date	Exp. Date	Date of Receipt	Batch Size	Analyzed by & Date	Sample Destruction		Remarks
									Date	Sign	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-V

INWARD REGISTER FOR PURIFIED WATER, POTABLE WATER, WFI & PURE STEAM

Date	AR No.	Sampling/ Usage point	Analyzed by		Checked by	Released on	Remarks
			Chemical	Micro			

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VI
VALIDATION SAMPLE INWARD REGISTER

S.No.	A.R. No.	Batch No.	Name Of the Sample	Stage	Date Of Receipt	Test	Analysed By & Date	Sample Destruction		Remarks
								Date	Sign	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VII
CLEANING INWARD REGISTER

S.No.	A.R. No.	Batch No.	Name Of The Sample	Stage	Date Of Receipt	Test	Analysed By & Date	Sample Destruction		Remarks
								Date	Sign	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VIII
MISCELLANEOUS INWARD REGISTER

S.No.	A.R. No.	Batch No.	Name of the Sample	Stage	Date of Receipt	Test	Analysed By & Date	Sample Destruction		Remarks
								Date	Sign	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of samples received in QC department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-IX
QUALITY CONTROL LABORATORY RELEASE SLIP

A.R.No._____

Name of Product / Material : _____

Batch No. : _____

Q.C. Release Date : _____

Incase of Raw Materials, mentioned the following details also,

Assay % : _____

%LOD/Water : _____

Remarks **: Complies / Does not Complies**

QC Incharge
(Sign & Date)