PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Sampling of Sterile Raw Material	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Sampling of Sterile Raw Material.

2.0 SCOPE:

This SOP is applicable for Sampling of Sterile Raw Material.
Haridwar.

3.0 RESPONSIBILITY:

Officer / Executive – QC Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

AR No.	Analytical Reference Number
GRN	Goods Receipt Note
HDPE	High Density Poly Ethylene
ML	Microbiology Laboratory
mm	Millimeter
No.	Number
QA	Quality Assurance
QC	Quality Control
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedure
SS	Stainless Steel
UV	Ultra Violet

6.0 PROCEDURE:

6.1 Warehouse Personnel shall intimate to Quality Control Department for sampling by providing "Requisition for Analysis of Raw Material.

6.2 After receipt of Requisition for Analysis of Raw Material from Store and arrange the sampling within 15 days, after sampling; enter the details of the sampled raw material into Annexure-II, Titled "Sterile Raw Material Sampling Record". If sampling is not done within specified time, then intimate to head QA.

6.3 Equipment / Accessories Required:

6.3.1 Laminar Airflow Unit

6.3.2 Electronic Balance

6.4 Sample Preparation (Sampling kit) :

6.4.1 Clean, dry, Sterilized /Depyrogenated Sampling rod, Spatula, Pipette etc.

6.4.2 Sterile Garments (Boiler suit, Head Gears, Bootees) Nose Mask, goggle and Hand Gloves.

6.4.3 Clean, Dry, Sterilized /Depyrogenated Seal Cutter or Scissor.

6.4.4 Sterile Sampling poly (Zip) bags.

6.4.5 Sterilized aluminium tape

6.4.6 Sterilized /Depyrogenated vials/bottles for Sample Collection

6.4.7 Sample for Analysis Labels as per Annexure-II, Titled “Sample for Analysis”.

6.4.8 Sample for Identification Labels as per Annexure-III, Titled “Sample for Identification test”.

6.4.9 Sample for through satellite sample as per annexure-IV.

6.5 Sampling Plan:

6.5.1 QC Microbiology Personnel along with “Requisition for Analysis of Raw Material” and sampling kit shall go for sampling in Store.

6.5.2 As per Sampling Plan, Select the number of containers to be sampled and get them arranged on the pallet.

6.5.3 Check and observe the containers physically inspection for seal intactness and damage. Fill the detail of physical inspection as per Format.

6.5.4 Check the containers for its labeled details for :

- GRN No.,
- Batch Number,
- Material Name,

- Manufacturer Name,
- Quantity,
- Pharmacopoeial Grade,
- Mfg. and Exp. Date

6.5.5 Sampling:

6.5.5.1 Sampling of Consignment without Satellite Sample:

6.5.5.1.1 Kept the sampling kit in pass box of Sterile Raw Material Sampling Area.

6.5.5.1.2 QC Microbiology personnel shall enter to the Sterile Raw Material Sampling Area through the Change Room as per SOP, Titled "Entry and Exit in Sterile RM Sampling Cum Dispensing Area".

6.5.5.1.3 QC Microbiology Personnel shall Check and ensure the Sterile Raw Material Sampling Area and RLAF for its cleanliness.

6.5.5.1.4 Check for the pressure differential of the, Sampling Booth and ensure the pressure differential for within its limit and fill the detail in its record.

6.5.5.1.5 All Sterile Raw Materials shall be sampled aseptically to avoid any kinds of contamination, cross contamination. Sampling of one batch at a time is permissible.

6.5.5.1.6 Clean external surface of the entire container and sanitize it by wiping with sporocidal disinfectant.

6.5.5.1.7 Allow it to stand for 10 minutes in the pass box under burning UV light for sterilization of its external surface.

6.5.5.1.8 Switch "**ON**" the RLAF for 30 minutes before start of activity as per SOP "Operation and Cleaning of Reverse Laminar Air Flow Unit".

6.5.5.1.9 During Sampling blower and tube light shall be kept switched "**ON**".

6.5.5.1.10 In Sampling, Only one container shall be taken inside the Sampling Booth from the consignment.

6.5.5.1.11 Open the container by breaking its seal under RLAF with the help of suitable sterilized/Depyrogenated devices & observe for any abnormality in appearance in raw

material i.e. colour variation, black particle or any other foreign matter. In case of doubt inform to QC Manager.

6.5.5.1.12 With the help of clean , dried, sterilized / depyrogenated sampling devices, collect the required qty. of sample from container in clean, sterilized / dehydrogenated vials under RLAF.

6.5.5.2 Sampling of Consignment with Satellite Sample:

6.5.5.2.1 It is a representative sample quantity received along with the consignment from the manufacturer which can be used as sample for analysis.

6.5.5.2.2 After receipt of Requisition for Analysis of Raw Material from Raw Material store, check it for details and complete information. If Requisition for Analysis of Raw Material details are satisfactory, then assign Quality Control Analytical Reference Number of raw material by entering all details in Raw Material Inward Record.

6.5.5.3 Sampling of Consignment during Production activities:

6.5.5.3.1 Personnel shall enter to the Aseptic Filling Room through the Change Room as per Entry and Exit SOP of respective area.

6.5.5.3.2 Personnel shall Check and ensure the Aseptic Filling Room and LAF for its cleanliness.

6.5.5.3.3 Ensure the area to be maintained for Temperature & RH, if not, inform to concerned person of Production/QA.

6.5.5.3.4 All Sterile Raw Materials shall be sampled aseptically to avoid any kinds of contamination, cross contamination. Sampling of one batch at a time is permissible.

6.5.5.3.5 Switch “ON” the blower of LAF for 30 minutes in Respective area before start of activity.

6.5.5.3.6 During Sampling, blower and tube light shall be kept switched “ON”.

6.5.5.3.7 In Sampling, Only one container at a time shall be taken inside the LAF.

6.5.5.3.8 Open the container by breaking its seal under LAF with the help of suitable clean, sterilized /depyrogenated devices & observe for any abnormality in appearance in Raw material i.e. color variation, black particle or any other foreign matter. In case of doubt inform to QC Manager.

6.6 Sample Quantity and Instruction:

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6.6.1 Sample for sterility, BET, identification, chemical analysis shall be collected from one container of the consignment.

6.6.2 If Satellite sample is being received one composite/representative container; sterility, Bacterial endotoxin test and chemical tests shall be performed using composite/ representative sample.

6.6.3 If Satellite sample is being received more than one container.

6.6.3.1 Sterility, Bacterial endotoxin test and chemical test shall be performed using composite sample.

6.6.3.2 Identification test shall be performed using each container.

6.6.3.3 Prepare composite sample by taking equal quantity of material in clean, sterilized / depyrogenated vials under LAF from the individual satellite sample container with sterile/depyrogenated spoon/spatula and mix thoroughly to make the required sample quantity for Sterility, Bacterial endotoxin test and chemical test.

6.7 After collection of sample from a container, seal the inner bag with sterile aluminum tape and close the lid of container, seal the container with sterile Aluminum tape under LAF. Remove such closed container from area through DPB to the surrounding area.

6.8 Affix "**UNDER TEST**" Sticker Label as per the SOP "Status Labeling" SOP on Quarantine Label and nearby affix "**SAMPLED**" Sticker Label as per the SOP "**Status Labeling**" SOP.

6.9 In case of Satellite Sample Received with Consignment Affix "**UNDER TEST**" Sticker Label as per the SOP "Status Labeling" SOP on Quarantine Label and nearby affix "**SAMPLED THROUGH SATELLITE SAMPLE**" Sticker Label as per the **Annexure-V**.

6.10 After sampling, clean external surface of the entire container and sanitize it by wiping with sporocidal disinfectant.

6.11 After completion of sampling, switch "OFF" the Tube Light and Blower of LAF.

6.12 Clean the area inside LAF with Sterilized mopper and sanitize it by wiping with filtered 70% IPA.

6.13 Record the details of cleanliness in LAF Record.

6.14 Transfer the sampled containers to the Under Test Area.

6.15 Clean the Sampling Booth and record in the Sampling and Cleaning Record.

6.16 Enter the details in **Annexure-I**, Titled "Sterile Raw Material Sampling Record".

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6.17 QC Microbiology personnel after sampling activity shall submit the sample to raw material section for chemical analysis.

6.18 Used sampling tools shall be wrapped in polybag for cleaning, sanitization / De- pyrogenation & to be affixed with **"TO BE CLEANED"** Status Label.

6.19 Re –Sampling for Retest Material:

6.19.1 Carry out the sample for retesting of a material after completion on or after the date of retest assigned on its Analytical Report, to reconfirm the purity of material.

6.19.2 Store officer shall intimate QC department on every first week of the month about the material whose validity period is about to complete in that month. All the opened containers / bags to be re-sampled shall be transferred from "**APPROVED**" area to "**UNDER TEST**" area and on its "**APPROVED**" label "**UNDER TEST**" shall be affixed.

6.19.3 Sample shall be taken for retesting from all the container / bag followed by the same procedure mentioned above, and retest A.R. No. generated automatically from software.

6.19.4 "**SAMPLED**" label as per the "Status Labeling" in SOP shall be affixed on the container with all the appropriate information.

6.19.5 After completion of the respective testing, the container shall be labeled with "**APPROVED**" or "**REJECTED**" on the "**UNDER TEST**" label as per the "Status Labeling" in SOP based on the outcome of the test results.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Sterile Raw Material Sampling Record	
Annexure – II	Sample for Analysis	
Annexure – III	Sample for Identification Test	
Annexure – IV	Sample Through Satellite Sample	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy Quality Assurance

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9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE – I
STERILE RAW MATERIAL SAMPLING RECORD

S. No.	Date	Area Cleaning Status OK / Not Ok	GRN / MRN No.	Material Name	B. No.	A.R. No.	Balance Used ID No.	Sampling time		Container Sampled	Sampled Qty.	Sampled By Sign & Date	Checked By (QA) Sign & Date	Sample Received by Sign & Date
								From	To					

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ANNEXURE – II
SAMPLE FOR ANALYSIS

Product	**:**	_____
Batch No.	**:**	_____
Container No.	**:**	_____
Date of Sampling	**:**	_____
Sampled By (Sign & Date)	**:**	_____
Sample Qty.	**:**	_____
Storage Condition	**:**	_____

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ANNEXURE – III
SAMPLE FOR IDENTIFICATION TEST

Product	**:**	_____
AR. No.	**:**	_____
Signature	**:**	_____
Date of Sampling	**:**	_____

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ANNEXURE – IV
SAMPLE THROUGH SATELLITE SAMPLE

Sampled By:
Date of Sampling: