STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Sampling of Finished Product of Sterile Bulk API	**Effective Date:**
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1.0 OBJECTIVE

1.1 To lay down the procedure for sampling of finished product of sterile bulk API.

2.0 SCOPE

2.1 This procedure is applicable for Microbiology Laboratory.

3.0 RESPONSIBILITY

3.1 Microbiologist is responsible for sampling of finished product of sterile bulk API.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 NA

6.0 PROCEDURE

6.1 **Materials required:**

6.1.1 Clean dry and depyrogenated small S.S. sampling container with lid, long handle S.S. spoon and depyrogenated clear glass vials of suitable size for collection of sample with sterilized rubber bungs and aluminum seals.

6.2 **Sampling formula**

6.2.1 Sample should be collected from each container.

6.2.2 20 vials containing approximately 06 gm sample collected from each batch.

6.2.3 For sterility test, following container shall be sampled:

6.2.3.1 If batch contain up to 4 container - Each container sampling

6.2.3.2 If batch contain more than 4 containers, but not more than 50 containers - 20% or 4 containers, whichever is greater.

6.2.3.3 If batch contain more than 50 containers - 2% or 10container, whichever is greater.

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6.3 **Sampling Procedure**

6.3.1 Production / IPQA will inform to Microbiologist for sampling.

6.3.2 On receipt of intimation of sampling from the production department, microbiologist will go for sampling.

6.3.3 Microbiologist with IPQA person will enter into aseptic area for sampling as per SOP of entry and exit of sterile area.

6.3.4 Sampling should be done under Mobile LAF; switched on 20 minutes before sampling.

6.3.5 Identify the unsealed containers of the batch and shift all the containers of the batch to container sealing LAF.

6.3.6 In a depyrogenated SS tray take depyrogenated S.S. sampling container, S.S. Spoon, clear glass vials, sterilized rubber bungs and aluminum seals.

6.3.7 Shake all the containers to be sampled so as to homogenize the material inside the container.

6.3.8 Transfer the container inside the Mobile LAF in container sealing room.

6.3.9 Aseptically open the lid of the container and take a sample (20 gram approximately) from the side walls at the middle position with the help of a spoon with long handle.

6.3.10 Transfer the sample into the pre sterilized small S.S. container and close it.

6.3.11 Close the lid of the container properly.

6.3.12 Similar way, sample all the containers and collect the sample in same small S.S. container.

6.3.13 Aseptically homogenize the sample in the small S.S. container by shaking.

6.3.14 Fill 20 clear glass vials from the material approximately 06 gram per vial.

6.3.15 For sterility testing, take 3 vials from the containers to be sampled.

6.3.16 In special cases for export, sample 03 different locations from each container. Collect 02 vials from each location and mark the container number and location.

6.3.17 Close the vials with the help of rubber bungs.

6.3.18 Seal the vials with aluminum seal using a sealer.

6.3.19 Mark the batch no. on the vials with a marker pen for identification.

6.3.20 Discard the rest sample in the small S.S.Container.

6.3.21 Transfer the sampling tool used through the pass box to washing area for cleaning.

6.3.22 Transfer the samples through the Pass box to microbiology department.

6.3.23 Label the vials with a label indicating name of the material, Batch No.

6.3.24 All sampled container should be sealed and transferred to quarantine area through Pass box.

6.3.25 After sampling, put "Under Test & Sampled" Label on all the containers of the batch by microbiologist.

6.3.26 Always sample in presence of IPQA person.

6.3.27 Always use a single set of sampling tools for a batch.

6.3.28 Use dedicated sampling tools for different products.

7.0 DEFINITIONS AND ABBREVIATIONS

7.1 IPQA - In process quality assurance

7.2 LAF - Laminar air flow

8.0 REFERENCE

8.1 USP monograph <71> Sterility testing

9.0 ANNEXURES

9.1 Annexure I : Finished product sampling log book

9.2 Annexure II : Label for finished product

10.0 DISTRIBUTION DETAILS

10.1 Controlled copy of this SOP shall be distributed to Quality Assurance, Production and Microbiology.

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11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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ANNEXURE I
FINISHED PRODUCT SAMPLING RECORD OF STERILE BULK API

S.No.	Date of Sampling	Name of Product	Batch No.	Mfg Date	Expiry Date	Batch Quantity	Packing Size	Total No. of Container	Done By	Remarks

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ANNEXURE II
LABEL OF FINISHED PRODUCT SAMPLING

UNDER TEST & SAMPLED
Sign Date