



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Bio Burden of Primary Packing Material	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down the procedure for bio burden of packing material.

### 2.0 SCOPE:

The SOP is applicable to check the bio burden of the Primary packing material such as PVC film, PVDC film, Aluminium foil and LDPE bags.

### 3.0 RESPONSIBILITY:

Microbiologist-Quality Control

Head-Quality Control

### 4.0 PROCEDURE:

#### 4.1 APPARATUS

4.1.1 LAF

4.1.2 Colony counter

4.1.3 Incubators of temperature range: 20°C - 25°C & 30°C - 35°C.

4.1.4 Preincubated SCDA contact plates

4.1.5 Sterilize beakers, Scissor, forceps, conical flasks

**4.2 Sampling Procedure:** For PVC, PVDC film, Aluminium foil, Polybag (LDPE bag) and triple laminated pouches follow the method of contact plate mention below:

4.2.1 Prepare the RODAC plates as per reference SOP and Perform growth promotion test for Soyabean casein digest agar as per reference SOP.

4.2.2 Sampling Of Primary Packing shall be done in the respective Sampling booth.

4.2.3 Switch ON the RLAF for 15 Minutes before the sampling of Primary packing Material.

4.2.4 Prepare sterile 70% v/v IPA as per reference SOP.

4.2.5 Mop the RLAF bench and outer body with 70% IPA.

4.2.6 For Aluminium foil, PVC film, PVDC film, discard first one meter Roll and sample another one meter as a sample of the film / Foil under RLAF and for LDPE bags, one bag from each bundle.

4.2.7 Keep the Sampled Primary Packing Material in Sterile Polybag and transfer the sample to



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microbiology testing area for checking the Bioburden.

- 4.2.8 Prepare the RODAC plates as per reference SOP and Perform growth promotion test for SCDA as per reference SOP. Determine the bio burden of the packaging material with the help of contact (RODAC) plate having sterile Soyabean casein digest agar.
- 4.2.9 Determine the bio burden of the packaging material with the help of contact (RODAC) plate having sterile Soyabean casein digest agar.
- 4.2.10 Aseptically open the RODAC plates under LAF and take the impression of respective sample of packing material and close the plates.
- 4.2.11 Incubate the RODAC plates at 20-25<sup>0</sup>C for 3 days and at 30-35<sup>0</sup>C for two days.
- 4.2.12 Count the number of colonies observed on the RODAC plate containing Soyabean casein digest agar and report the total bacterial and Total fungal count as CFU/30cm<sup>2</sup> in case of contact plate method as per Annexure – I.

### **4.3 Precautions :**

- 4.3.1 Perform all the activity under LAF.
- 4.3.2 Ensure the cleaning of testing area and LAF module.
- 4.3.3 Ensure the differential pressure of room and LAF module
- 4.3.4 Properly disinfect each and every article used for sampling and analysis.
- 4.3.5 During sampling or filtration under LAF, in case media plate/Forceps / Scissor touch on any part than do not use this Scissor / Forceps.
- 4.3.6 During sampling and testing, if sterile hand gloves found ruptured than immediately replace it with new sterile hand gloves.
- 4.3.7 During sampling and testing, frequently disinfect the hand gloves by spraying sterile 70% v/v IPA and LAF bench with sterile mopping pad with sterile 70% v/v IPA.
- 4.4.8 Always use pre incubated plates for analysis.

### **4.5 Frequency:**

#### **4.5.1 Schedule for Sampling of Packing Materials for Bioburden Test**



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S.No.	Name of Material	Frequency
1.	PVC	Monthly
2.	PVDC Film	Monthly
3.	Aluminium Foil	Monthly
4.	Polybag(LDPE Bag)	Monthly

#### 4.6 Limits:

4.6.1 Bacterial count: NMT 20 CFU/30 cm<sup>2</sup>

4.6.2 Fungal count: NMT 2 CFU/30 cm<sup>2</sup>

4.6.3 **Note:** The diameter of RODAC plate is 55 mm.

#### 5.0 ANNEXURE (S):

Annexure – I: Bio burden of packing material report.

#### 6.0 REFERENCE (S):

SOP: Preparation of Disinfectant and cleaning of Microbiology Laboratory

SOP: Procedure for Growth Promotion Test

SOP: Procedure for Preparation of Media

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

#### 7.0 ABBREVIATION (S) / DEFINITION (S):

LAF : Laminar Air Flow

CFU: Colony Forming unit.

RODAC : Replicating of detecting and Counting

PVC: Poly Vinyl Chloride

PVDC: Poly Vinyl Di Chloride



**PHARMA DEVILS**  
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**REVISION CARD**

<b>S.No.</b>	<b>REVISION No.</b>	<b>REVISION DATE</b>	<b>DETAILS OF REVISION</b>	<b>REASON (S) FOR REVISION</b>	<b>REFERENCE CHANGE CONTROL No.</b>
1	00	-----	----	New SOP	----



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**Annexure 1**

**BIOBURDEN OF PACKING MATERIAL REPORT**

<b>Name of Sample</b>	:		
<b>A. R. No.</b>	:	<b>Date of Sampling</b>	:
<b>Batch Number</b>	:	<b>Date of Testing</b>	:
<b>Batch Size</b>	:	<b>Sample Quantity</b>	:
<b>Report No.</b>	:	<b>Sampled By</b>	:
<b>Test Method</b>	:	Contact Plate Method	

<b>Media Details</b>	<b>Incubation Temperature</b>	<b>Incubation Time</b>	<b>Incubator ID. No.</b>	<b>Sign &amp; Date</b>
Soyabean Casein Digest Agar	20 – 25°C	03 days		
Lot No.:	30 – 35°C	02 days		

<b>Sample preparation</b>			
<b>Contact Plate Method</b>	<b>Cfu / 30 cm<sup>2</sup></b>		
	<b>Bacteria</b>	<b>Fungi</b>	
Take an impression of respective Sample on RODAC plate.			
<b>Tested By (Sign &amp; Date) :</b>			
<b>Medium</b>	<b>Negative Control</b>	<b>Positive Control</b>	
SCDA			

	<b>Results</b>	<b>Limit (Cfu / 30cm<sup>2</sup>)</b>	<b>Date of observation</b>	<b>Signature</b>
<b>Bacteria</b>		20 CFU/30 cm <sup>2</sup>		
<b>Fungi</b>		2 CFU/30 cm <sup>2</sup>		

**CONCLUSION:** The above Sample Complies / Does not Comply.

<b>Observed By (Sign. &amp;Date)</b>	<b>Date of Report</b>	<b>Checked By (Sign. &amp; Date)</b>