PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 1 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

BATCH MANUFACTURING RECORD (ENGINEERING TRIAL)

PRODUCT NAME	:	**Bacillus Clausii Spores Suspension**
GENERIC NAME	:	**Bacillus Clausii Spores Suspension**
LABEL CLAIM	:	**Each 5 ml contains:**
		Bacillus Clausii Spores……2 Billion Spores
		Water for Injection IP…….……q.s.
STRENGTH	:	**2 Billion Spores**
MANUFACTURING LICENSE No.	:	**……..**
STANDARD BATCH SIZE	:	**100 Liter**
ACTUAL BATCH SIZE	:	
PACK SIZE	:	**5 ml**
DATE OF MANUFACTURING	:	
DATE OF EXPIRY	:	
SHELF LIFE	:	**18 Months**
BLOCK / PRODUCTION LINE	:	**FFS Line**
MARKET	:	**NOT FOR SALE**
DATE OF COMMENCEMENT	:	
DATE OF COMPLETION	:	
BATCH YIELD (%)	:	
PRODUCT OF (Company Name)	:	
BMR ISSUED BY (QA)	:	
DATE	:	

	Prepared By Executive QA	Checked By Manager Production	Approved By Head QA	Authorized By Head Operations
Sign				
Date				
Name				

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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1.0 QUANTITATIVE FORMULA:

A) RAW MATERIAL:

Material Code	Material Name	Vendor Source	Specifi-cation	Label Claim	Overages	Unit	Qty. Required as per Standard Batch Size. (100 Ltr.)
	Bacillus Clausii (1.0 Lac Million Spores)	--	IH	2 Billion Spores	100%	Kg.	0.800*
--------	Water for Injections	--	IP	--	--	Ltr.	q.s.

***Assay considered on 100%w/w basis and LOD considered on 0%w/w basis.**

B) PRIMARY PACKAGING MATERIAL :

Material Code	Name of Material	Unit	Qty. Required as per Standard Batch Size (100 Ltr.)
	LDPE	Kg.	100

2.0 CALCULATIONS:

2.1 Calculation of Bacillus Clausii Required for Standard Batch Size 100 L.

Label Claim: 0.4%w/v, Overage: 100%,

Assay: 100%w/w, LOD/ Water Content: 0 %w/w

Standard Quantity of Raw Material Required:

$$= \frac{\text{Label Claim with Overages (\%w/v) X Batch Size (ltr.) X 100}}{\text{\% Assay (ODB) X (100 - \% LOD (Water + Other Contents))}}$$

$$= \frac{100 \text{ X } 0.8 \text{ X } 100}{100 \text{ X } (100 - 00)}$$

= **0.8 Kg. Standard Batch Size**.

2.2 The below calculation is to be used when the quantity of "Bacillus Clausii" required for Actual Batch Size is available from one A.R. No.

A.R. No.:_____

Assay of Raw Material = _____

Required Quantity of Raw Material:

$$= \frac{\text{Label Claim with Overages (\%w/v) X Batch Size (ltr.) X 100}}{\text{\% Assay (ODB) X (100 - \% LOD (Water + Other Contents))}}$$

= _____

Total Quantity of Bacillus Clausii = _____ Liter.

2.3 The below calculation is to be used when the quantity of "Bacillus Clausii" required for Actual Batch Size is available from more than one A.R. No.

Actual Quantity of "Bacillus Clausii" to be dispensed (A):_____

1. For First A.R. No. :

$$\textbf{Actual Quantity of "Bacillus Clausii"} = \frac{\text{Label Claim with Overages (\%w/v) X Batch Size (ltr.) X 100}}{\text{\% Assay (ODB) X (100 - \% LOD (Water + Other Contents))}}$$

$$\textbf{Batch Size In Liter (B)} = \frac{\text{Actual Qty. of "Bacillus Clausii"(A) X \% Assay (ODB) X (100 - \% LOD)}}{\text{Label Claim with Overages (\%w/v) X 100}}$$

X

$$= \text{----------}$$

= _____ Liter (B)

2. For Next A.R. No.:

Quantity to be dispensed of "Bacillus Clausii" for (C) = Actual Batch size – Batch size (B)

= _____ - _____

= _____ Liter (C)

Actual Quantity to be dispensed "Bacillus Clausii" (D)

$$= \frac{\text{Label Claim with Overages (\%w/v) X Batch Size (ltr.) X 100}}{\text{\% Assay (ODB) X (100 - \% LOD (Water + Other Contents))}}$$

= ----------

= _____ Liter (D)

Total qty. of "Bacillus Clausii" to be dispensed = (A) + (D) =_____ Liter.

2.4 Calculation for Actual Batch Size (In Terms of Number):

$$= \frac{\text{Actual Batch Size in Liters X1000}}{\text{Fill Volume (in ml)}}$$

= _____

= _____ Nos.

Calculation Done By (Production) (Sign & Date)	**Calculation Checked By (Production) (Sign & Date)**	**Calculation Verified By (QA) (Sign & Date)**

- Attach the Assay Report of Raw Material used for Batch Size calculation on the back side of this page.

3.0 PRE DISPENSING / MANUFACTURING INSTRUCTIONS:

- Follow the Manufacturing Instructions carefully and strictly, before proceeding for any Operation / Activity.
- Follow all the "current Good Manufacturing Practices" during entire procedure of Manufacturing.
- Ensure the equipment and area is clean.
- Ensure proper gowning of persons working in the area.
- All the activities that are related to Equipment Cleaning, Operations, Material Handling and Process Controls, shall be carried out strictly as per respective Standard Operating Procedure.
- Environmental Conditions like Temperature, Relative Humidity and Differential Pressure shall always be maintained within the specified limits before / during processing.
- Sterile Area Gowning shall be strictly followed throughout the Manufacturing Operations.
- Double Gloves must be worn at all the times while handling the equipments / during processes.
- Before starting any activity check and ensure the supply of required utilities.
- Line Clearance shall be taken by the concerned department Officer / Executive and given by QA Officer / Executive.
- Approved Water for Injection shall be used for Batch Manufacturing (If Applicable).
- Report of Purified Water / WFI should comply and shall be recorded in BMR.
- In case of Product Change, Samples of all the Critical Equipments shall be tested for Rinse Water / Swab and the report of same shall be attached at specified place in BMR.
- Ensure that Garments etc. are sterilized before start up of Aseptic Filtration and Filling.
- Attach the Steam Clox indicator on the Thermograph.
- Attach the signed Thermograph and Temperature Printout at specified page.
- Used Equipment (s) and any Spillage in the Area shall be cleaned thoroughly, effectively and immediately.

4.0 DISPENSING OF RAW AND PRIMARY PACKAGING MATERIALS:

4.1 DISPENSING OF RAW MATERIALS:

4.1.1 LINE CLEARANCE (SOP No.: …….):

Previous Product : _____ **Date** : _____

Batch No. : _____ **Time** : _____

S.No.	Line Clearance Checks	OK / Not OK / NA	Checked By Warehouse Officer / Executive	Verified By QA Officer / Executive
NA	**Dispensing**			
1.	Check the "Status Board" of the Dispensing Area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BPCR of Present Batch to be processed.			
2.	Check the cleanliness of the Dispensing Room and ensure that it is free from the remains of the previous Batch / Product and check the availability of Cleaning & Sanitization Record.			
3.	Check the Calibration Status of the Balances to be used for Dispensing.			
4.	Check the Temperature & Relative Humidity (RH) in Dispensing Room. (It should be within specified range). **Temperature = NMT 25^{0}C, RH = NMT 55%**	____ ^{o}C ____ %		
5.	Check the approval status of Raw Materials.			
6.	Check the intactness of Raw Material containers.			
7.	Check and verify, the Item code No. & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip.			
8.	Check and ensure that LAF is clean, verify the log books and check the working of LAF.			
9.	Ensure entries in logbooks are online.			
10.	Check the Waste bins, it should be clean.			

Note: After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date_____**
(WH Officer / Executive) **(QA Officer / Executive)**

4.2 DISPENSING OF PRIMARY PACKING MATERIALS:

4.2.1 LINE CLEARANCE (SOP No.: …….):

Previous Product : _____ **Date** : _____

Batch No. : _____ **Time** : _____

S. No.	Line Clearance Checks	OK / Not OK / NA	Checked By Warehouse Officer / Executive	Verified By QA Officer / Executive
NA	**Dispensing**			
1.	Check the "Status Board" of the Dispensing Area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BPCR of Present Batch to be processed.			
2.	Check the cleanliness of the Dispensing Area and ensure that it is free from the remains of the previous Batch / Product and check the availability of Cleaning & Sanitization Record.			
3.	Check the Calibration Status of the Balances to be used for Dispensing.			
4.	Check the Temperature in Dispensing Room. (It should be within specified range). **Temperature = NMT 25^0C**	___ ^{o}C		
5.	Check the approval status of Primary Packing Materials.			
6.	Check the intactness of Primary Packing Materials. Shippers / Bags.			
7.	Check and verify, the Item code No. & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip.			
9.	Ensure entries in logbooks are online.			
10.	Check the Waste bins, it should be clean.			

Note: After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date**_____
(WH Officer / Executive) **(QA Officer / Executive)**

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Affix the Line Clearance Label For Dispensing of Raw And Primary Packing Materials

4.2.2 INSTRUCTIONS:

- During Dispensing of Raw Material & Primary Packing Materials. Check Environmental Conditions are within limits **(Temperature = NMT 25^{0}C, RH = NMT 55%)** and record in Environment Monitoring Record at the time of start of dispensing, after every Two Hours and after completion of dispensing.

4.2.3 ENVIRONMENTAL MONITORING:

Date _____

Time	Room No. / Name	Temperature (NMT 25^{0}C)	Relative Humidity (NMT 55%)	Checked By WH (Officer/ Executive)	Verified By QA (Officer/Executive)

4.3 DISPENSING OF RAW MATERIALS:

Balance ID. No.: _____ **Date: _____**

Material Code	Material Name	Specifi -cation	Std. Qty.	Required Qty.	Date of Dispensing	Dispensing		Issued Qty.	SAP material Batch No.	No. of Packs
						Started At	Completed At			
	Bacillus Clausii (1.0 Lac Million Spores)	IH	0.800*							
--------	Water for Injections	IP	q.s.							

Dispensed By (WH) **Received By (Production)** **Verified By (QA)**

Sign & Date ———————— **Sign & Date ————————** **Sign & Date ————————**

4.4 DISPENSING OF PRIMARY PACKING MATERIALS:

S. No.	Material Code	Material Name	Unit	Std. Qty.	Required Qty.	Issued Qty.	No. of Packs	SAP material Batch No.
1.		LDPE	Kg.	100				

@ Required Quantity is calculated considering 2% excess quantity of material to compensate processing loss.

Dispensed By (WH) **Received By (Production)** **Verified By (QA)**

Sign & Date ———————— **Sign & Date ————————** **Sign & Date ————————**

5.0 VERIFICATION OF DISPENSED MATERIALS (ON PRODUCTION FLOOR):

Balance ID. No.: _____ Date: _____

Calibration / Verification Status (Ok / Not Ok):_____

- Verify the dispensed Raw Material containers as per Material Requisition Slip after receiving on Production Floor.
- Verify the dispensed Primary Packing Materials as per Material Requisition Slip after receiving on Production Floor.

5.1 Verification of Dispensed Raw Materials:

S. No.	Material Code	Material Name	Specifi -cation	Issued Quantity	SAP material Batch No.	No. of Packs	Checked By Production (Officer / Executive)	Verified By QA (Officer / Executive)
1.		Bacillus Clausii (1.0 Lac Million Spores)	IH					
2.	--------	Water for Injections	IP					

5.2 Verification of Dispensed Primary Packaging Materials:

S. No.	Material Code	Material Name	Unit	Issued Quantity	SAP Material Batch No.	No. of Packs	Checked By Production (Officer / Executive)	Verified By QA (Officer/ Executive)
1.		LDPE	Kg.					

BATCH MANUFACTURING RECORD

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Affix the Raw Material & Primary Packing Material Dispensing Labels

Product Code:	**BMR No.:**	
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6.0 LIST OF EQUIPMENTS / MACHINES TO BE USED FOR MANUFACTURING:

S.No.	Name of Equipment / Machine	Equipment / Machine Identification No.	Make
1.	Manufacturing Tank		
2.	Manufacturing Tank		
3.	Holding Tank		
4.	CIP/SIP Module		
5.	FFS Machine		
6.	Dynamic Pass Box		
7.	Dynamic Pass Box		
8.	Dynamic Pass Box		
9.	Dynamic Pass Box		
10.	Dynamic Pass Box		
11.	Dynamic Pass Box		
12.	Dynamic Garment Cabinet		
13.	Dynamic Garment Cabinet		
14.	Dynamic Garment Cabinet		
15.	Vertical Laminar Air Flow		
16.	Vertical Laminar Air Flow		
17.	Vertical Laminar Air Flow		
18.	Vertical Laminar Air Flow		
19.	Vertical Laminar Air Flow		
20.	Autoclave Steam Sterilizer		
21.	Vacuum Leak Tester		
22.	Garment Washing Machine		
23.	Granule Loader		
24.	Granule Loader		
25.	Granule Tank		

6.1 LIST OF COMPONENTS TO BE USED FOR MANUFACTURING:

S.No.	Name of Component	Equipment Identification No.	Make
1.	0.22 Filter Housing with filter		
2.	Nitrogen Gas Filter		
3.	Air Assembly Filter		
4.	pH Meter		
5.	Filter Integrity Tester (BPT)		
6.	Weighing Balance (Mixing Room)		
7.	Weighing Balance (Holding Room)		
8.	Weighing Balance (Filling Room)		

7.0 PREPARATION OF GARMENTS:

7.1 LINE CLEARANCE (SOP No.: …….):

Previous Product : _____ **Date** : _____

Batch No. : _____ **Time** : _____

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Washing and Sterilization of Garments**			
1.	Check the "Status Board" of the Unit Preparation Area.			
2.	Check the cleanliness of the Unit Preparation Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check the cleanliness of the Garment Washing Machine and ensure that it is clean.			
4.	Check the Temperature of Unit Preparation Area. It should be within specified range. **Temperature: NMT 25^{0}C, RH: NMT 55%**	____^{0}C ____%		
5.	Check the Differential Pressure of Unit Preparation Area w.r.t. External Corridor. It Should be within specified range.			
6.	Check the cleanliness of Autoclave and ensure that it is free from the remains of the previous Batch / Product.			
7.	Check the "Status Label" of "Autoclave".			
8.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

BATCH MANUFACTURING RECORD

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Affix the Line Clearance Label for Garment Washing and Sterilization

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Batch No.:	**Batch Size:**	**Supersedes No.:**

7.2 INSTRUCTIONS:

- Wash the garments as per **SOP…….**
- Sterilize the washed garments in Autoclave as per **SOP……..**
- Collect the washed garments, and record following details:
  - Garment Washing Machine ID No. : _____
  - Washing Cycle Time. : _____
  - Date of Garment Washing : _____
  - No. of Garments Washed : _____
  - Checked By Production Officer / Executive (Sign.& Date) : _____

7.3 STERILIZATION OF GARMENTS:

Load Pattern No.: _____ **Sterilization Temperature:** 121.4^{0}C

Sterilization Time: 30 Minutes

Date	Run No.	Sterilization Cycle					Qty.	Done By (Operator)	Checked By Production (Officer/Executive)
		Cycle Started At	Temp. Attained At	Temp. Attained Till	Total Sterilization Time	Cycle Completed At			

7.4 BMR REVIEW UP-TO STERILIZATION OF GARMENTS STAGE:

	Checked By Production Officer / Executive	Reviewed By QA Officer / Executive
Name		
Sign & Date		
Emp. Code		

BATCH MANUFACTURING RECORD

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Attach the Thermograph and Print out of Autoclave Cycle For Washed Garments

8 CLEANING IN PLACE (CIP) AND STERILIZATION IN PLACE (SIP) DETAILS OF VESSELS (COMPOUNDING & HOLDING) & FFS MACHINE:

8.1 COMPOUNDING VESSEL CLEANING AND STERILIZATION DETAILS:

8.1.1 LINE CLEARANCE (SOP No.: ……):

Previous Product : _____ **Date : _____**

Batch No. : _____ **Time : _____**

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Compounding Vessel Cleaning & Sterilization**			
1.	Check the "Status Board" of the Manufacturing Area.			
2.	Check the cleanliness of the Manufacturing Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check the Temperature of Manufacturing Area. It should be within specified range. **Temperature Limit: NMT 25ºC,** **RH Limit: NMT 55%**	____^{0}C ____%		
4.	Check the Differential Pressure of Manufacturing Area w.r.t. Manufacturing Area Corridor.It Should be within specified range.			
5.	Check the cleanliness of CIP & SIP Module.			
6.	Check the "Status Label" of "CIP & SIP Module".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

8.2 HOLDING VESSEL CLEANING AND STERILIZATION DETAILS:

8.2.1 LINE CLEARANCE (SOP No.: ……..):

Previous Product : _____ **Date : _____**

Batch No. : _____ **Time : _____**

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Holding Vessel Cleaning & Sterilization**			
1.	Check the "Status Board" of the Holding Area.			
2.	Check the cleanliness of the Holding Area and ensure that it is free from the remains of the previous Batch / Product.			
	Check the availability of cleaned Dedicated Silicon tubing on machine			
3.	Check the Temperature of Holding Area. It should be within specified range. **Temperature Limit: NMT 25ºC, RH: NMT 55%.**	___^{0}C ____%		
4.	Check the Differential Pressure of Holding Area w.r.t. Aseptic Area Corridor. It Should be within specified range.			
5.	Check the cleanliness of CIP & SIP Module.			
6.	Check the "Status Label" of "CIP & SIP Module".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date_____**
(Production Officer / Executive) **(QA Officer / Executive)**

BATCH MANUFACTURING RECORD

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Affix the Line Clearance Label for Cleaning & Sterilization of Vessels (Compounding & Holding)

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Batch No.:	**Batch Size:**	**Supersedes No.:**

8.3 INSTRUCTIONS:

- Follow SOP No. ------ for Cleaning of Vessel using CIP Module.
- Visually check cleanliness of each washed vessel (Compounding & Holding).
- Send the Rinse Water / Swab sample for analysis and attach the Release Report prior to Sterilization (if applicable).
- Report of Purified Water Complies / does not Comply.
  A.R. No.: _____Checked By (QA) / Date : _____.
- Report of Water for Injection Complies / does not Comply.
  A.R. No.: _____Checked By (QA) / Date : _____.
- Follow SOP No. -------- for Sterilization of Compounding, Holding Vessel & FFS Machine using SIP Module.

8.4 CLEANING & STERILIZATION:

Sterilization Temperature: 121.4^{0}C **Sterilization Pressure:** 1.1 to 1.5 Bar
Sterilization Time (hrs): 30 Minutes **Date:** _____

Date	Equipment Name	Equipment ID No.	Sterilization Cycle						Done By (Operator)	Checked By Production (Officer/ Executive)
			Started At	Temp. Attained At	Temp. Attained Till	Total Sterilization Time (hrs)	Sterilization Pressure	Completed At		
	Mixing vessel cleaning									
	Mixing vessel sterilization									
	Holding vessel cleaning									
	Holding vessel sterilization									
	FFS machine cleaning									
	FFS machine sterilization									
	FFS Machine Follow – up air									

- **Attach Rinse Water /Swab Sample Release Report (Compounding & Holding) on the back side of this page.**

9.0 BATCH MANUFACTURING:

9.1 LINE CLEARANCE (SOP No.: …….):

Previous Product : _____ **Date : _____**

Batch No. : _____ **Time : _____**

S.No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Batch Manufacturing**			
1.	Check the "Status Board" of the Manufacturing Area.			
2.	Check the cleanliness of the Manufacturing Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check & ensure that Temperature & RH in Manufacturing Area is with in specified limit. **(Temperature Limit = NMT 25°C, RH Limit = NMT 55%).**	____^{0}C ____%		
4.	Check & ensure that Differential Pressure of Manufacturing Area is with in specified limit.			
5.	Check & ensure that the Compounding Vessel and Accessories are cleaned & sterilized.			
6.	Check the "Status Label (Name of Product, Batch No., Date, Stage)" of "Compounding Vessel".			
7.	Check & ensure the Availability of Approved Raw Material in the Manufacturing Area.			
8.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date_____**
(Production Officer / Executive) **(QA Officer / Executive)**

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Affix the Line Clearance Label for Batch Manufacturing

9.2 BEFORE MANUFACTURING PRECAUTIONS:

- **Carry out all the Manufacturing operations at not only specified aseptic area but also at the specified temperature & humidity.**
- **Positive pressure is maintained at processing area.**
- **Use only sterile & dry utensil.**
- **Use Nitrogen gas during manufacturing & filling process OR when ever applicable.**
- **All the process should be carried out in 'Aseptic Area' only.**

9.3 MANUFACTURING PROCESS:

Date: _____

Batch Manufacturing Start Time: _____ **Batch Manufacturing End Time: _____**

S. No.	Manufacturing Procedure	Qty. of Material	Observation	Time		Done By Production (Sign / Date)	Checked By QA (Sign / Date)
				From	To		
1.	**Verification of Dispensed Raw Material:** Verify the weight of dispensed raw material against the quantity mentioned in the bill of raw materials. Verify the A.R. No. of dispensed raw materials as mentioned in the bill of raw materials.						
	Preparation of microbial suspension:						
2.	Take 0.22 filtered water for injection (WFI) 90 Ltr. in manufacturing tank and allow in to come at temperature below 20°C.		**Temp.:_____**				
3.	Now added 0.800Kg. of Bacillus Clausii Spores and stirred for 120 minutes at 500 RPM.		**Speed: _____RPM**				
4.	Now make up the volume up to 100 Ltr. With WFI (below 20°C) under constant stirring at 500 RPM for 10 minutes.		**Speed: _____RPM**				

Bulk pH Limit: 6.00 to 8.00

Collection of Bulk Sample:

- After receiving intimation from Production, QA personnel shall withdraw the sample from Bulk Solution.

Sampled Quantity: _____ ml

Bulk Sample Collected by (QA): _____ Sign / Date: _____

9.4 BMR REVIEW UP-TO BATCH MANUFACTURING STAGE:

	Checked By **Production Officer / Executive**	**Reviewed By** **QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

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Attach the Bulk Solution Release Report

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10.0 BATCH FILTRATION:

10.1 LINE CLEARANCE (SOP No.: ……):

Previous Product : _____ **Date : _____**

Batch No. : _____ **Time : _____**

S.No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Batch Filtration**			
1.	Check the "Status Board" of Filtration Area.			
2.	Check the cleanliness of Filtration Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check & ensure that Temperature & RH in Filtration Area is with in specified limit. **(Temperature Limit = NMT 25°C, RH Limit = NMT 55%).**	____^{0}C ____%		
4.	Check the Differential Pressure of Filtration Area w.r.t. Aseptic Area Corridor. It Should be within specified range.			
5.	Check & ensure that the Holding Vessel, Filters and Accessories are cleaned & sterilized.			
6.	Check the "Status Label (Name of Product, Batch No., Date, Stage)" of "Holding Vessel".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Affix the Line Clearance Label for Batch Filtration

10.2 FILTRATION:

- Filter the Bulk Solution from Compounding Vessel to Holding Pressure Vessel through the Sterilized 100 Mesh Nylon Clothe and also filter the Solution through Online 200 Mesh Nylon Clothe from Holding Vessel to the FFS Machine.

10.2.1 PRODUCT FILTER DETAILS :

- Filter the above suspension through #200 mesh nylon clothe online sterilized.

Date: _____

Filtration Started At: _____ **Filtration Completed At_____**

S. No.	Procedure	Equipment Number	Time (hrs.)		Observation	Done By Production (Sign & Date)	Checked By QA (Sign & Date)
			From	To	Pass/Fail		
1.	Start the filtration from mixing vessel to holding vessel by 100 mesh Nylon Clothe.						
2.	Now allow the suspension to hold for 24 hrs. at 7-12^{0}C temperature.						
3.	Start the filtration from holding vessel to FFS machine through 200 mesh Nylon Clothe.						
4.	0.22 micron filter Integrity before & after filtration.						

***** Write Pass/Fail after performing the filter Integrity Test and also attach the Filter Integrity Report.

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Attach Filter Integrity Report

11.0 RECONCILIATION OF BULK SOLUTION:

Date	
Standard Batch Size	

S.No.	Stage	Qty. in Liters	Done By (Production)	Checked By (QA)
1.	Actual Batch Size			
2.	**Rejections / Losses**			
2A	Loss During Batch Manufacturing			
	Total Rejection / Loss			
3.	**Samples**			
3A	**Production Sample**			
	• Clarity Sample			
	• Sample for pH adjustment			
	QA Sample			
	• Clarity Sample			
	• Bulk Sample for Analysis			
3B	Validation Samples			
3C	Other Samples (If Any)			
	Total Samples			
4.	Total Solution Filtered			

% Batch Yield (Limit: NLT 99 %)

$$= \frac{\text{Total Quantity of Solution Filtered + Total Sample}}{\text{Actual Batch Size}} \times 100$$

$$= \_\_\_\_\_ \times 100$$

$$= \_\_\_\_\_ \%$$

Note: In case of High / Low Yield, Fill Yield Deviation Note.

Reason for deviation (if any): _____

_____

11.1 Batch Review Up-To Manufactured & Filtration Stage:

	Checked by Production officer/ executive	Reviewed By QA Officer / Executive
Name		
Sign & Date		
Emp. Code		

12.0 RESPULE FILLING AND SEALING:

12.1 LINE CLEARANCE (SOP No.: ……..):

Previous Product : _____ **Date :_____**

Batch No. : _____ **Time (hrs): _____**

S.No.	Line Clearance Checks	OK / Not OK/ NA	Done by Production Officer/Executive	Checked By QA Officer/Executive
NA	**Respule Filling And Sealing**			
1.	Check the "Status Board" out side the Filling and Sealing Room and match with the BPCR for following details: Product Name, B. No, Mfg. Date, Exp. Date, Batch Size etc.			
2.	Check Filling and Sealing Room is duly cleaned and free from remains of the previous Batch.			
3.	Check Filling and Sealing Machine is duly cleaned and free from remains of the previous Batch.			
4.	Check the Temperature and Relative Humidity (RH) of Filling and Sealing Room (It should be within specified range). **(Temperature Limit = NMT 25°C,** **RH Limit = NMT 55%).**	___ °C ___ %		
5.	Check the Differential Pressure of the Aseptic Filling Area. (It should be within specified range).			
6.	Check the Release / Approval status of the filtered solution to be used for Aseptic Filling.			
7.	Check the Sterilization Cycles (Machine Parts, and other aids used in Aseptic Filling) details from the print out / record, and ensure Sterilization is done as per the Pre - defined Cycle.			
8.	Check and ensure whether the Media Settle Plates are available for exposing in area to monitor Viable Count.			
9.	Ensure that the Non – Viable Particle Count has been performed before line set up and the results are within Acceptance Criteria.			
10.	Ensure Calibrated Measuring Cylinder, and balance has been used			

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S.No.	Line Clearance Checks	OK / Not OK/ NA	Done by Production Officer/Executive	Checked By QA Officer/Executive
11.	Ensure logbooks of the area are online			

Note: 1. After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

2. After completion of Filling and Sealing, Affix the Line Clearance Label at the specified page in the BPCR.

3. Attach the Swab Release Report for Area & Equipment.

Checked By
(Production Officer / Executive)

Sign/Date_____

Line Clearance Given By
(QA Officer / Executive)

Sign/Date_____

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Affix the Line Clearance Label for Respule Filling & Sealing by FFS Machine

12.2 INSTRUCTIONS:

- Follow proper Gowning Procedure as per SOP ……..
- Follow Aseptic Area Practices as per SOP No.----------.
- Follow SOP No. --------- for Fill Volume Adjustment.
- Discard & destroy the Respules filled during Adjustment of Fill Volume or Rejected during Filling and Sealing.
- **Check Volume Variation of Filled RESPULES from each filling Head at initially and after One Hour Interval by Production and QA, record the observations in the In - Process Table.**
- **Sanitize the Hands during whole Operation with 70%v/v IPA Solution as and when required.**
- **Keep the suspension under continuous stirring while filling is going on.**

12.3 FILLING PARAMETERS SETTING & OPERATION:

- Cover the Entire Filling time for Microbiological Environmental monitoring by settle plate Method.
- Set the Machine as Per **SOP No.** ----------
- Check The Granules For Foreign Particles And Other Contaminants Before Feeding To Machine.
- **Adjust following Parameter for Respule Filling and Sealing Machine:(for 5 ml)**
    - Standard / Target Fill Volume **:** **5.2 ml**
    - Upper Limit of Individual Volume **:** **5.3 ml**
    - Lower Limit of Individual Volume **:** **5.1 ml**
- Filling & Sealing M/c ID No.: _____
- Filling Started at : Date : _____ Time : _____
  Filling Completed at : Date: _____ Time: _____
- Run the Respule Filling and Sealing Machine as per **SOP No.** ---------- and adjust the Fill Volume and sealing. Record the Observations in table below.

BATCH MANUFACTURING RECORD

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FFS MACHINE PARAMETER CHECKS:

Frequency: Once in a Shift

Date	Time (hrs)	Extruder Temperature (°C)								Hydraulic Oil			Chilled Water		Air Press.	Checked by Production
		1.	2.	3.	4.	5.	6.	7.	8.	Level (80 - 90%)	Temp. (Limit 40^{0}C to 50^{0}C)	Press. (Limit 70 to 90 Bar)	Temp. (Limit 9^{0}C to 12^{0}C)	Press. (Limit 2.0 to 3.0 Bar)	(Limit 6.5 to 7.5 Bar)	

- Run the Filling Machine as per **SOP No. -------** and check the Empty Respule Weight of Individual Respule from the individual Parison:
- Standard Weight of Good Empty Respule **: 2.2 gm**
- Allowable Variation **: 0.1 gm**
- Upper Weight Range for Good Empty Respule **: 2.3 gm**
- Lower Weight Range for Good Empty Respule **: 2.1 gm**

Record the initial weight of Good Empty Respules in the table below

Checked By
(Production Officer / Executive)

Sign/Date_____

Line Clearance Given By
(QA Officer / Executive)

Sign/Date_____

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

EMPTY RESPULE WEIGHT CHECK RECORD:

Date: _____ **Time (Hrs):_____**

Cavity No.	Weight in gm.	Cavity No.	Weight in gm.	Cavity No.	Weight in gm.	Cavity No.	Weight in gm.	Cavity No.	Weight in gm.
1.		33.		65.		97.		129.	
2.		34.		66.		98.		130.	
3.		35.		67.		99.		131.	
4.		36.		68.		100.		132.	
5.		37.		69.		101.		133.	
6.		38.		70.		102.		134.	
7.		39.		71.		103.		135.	
8.		4.		72.		104.		136.	
9.		41.		73.		105.		137.	
10.		42.		74.		106.		138.	
11.		43.		75.		107.		139.	
12.		44.		76.		108.		140.	
13.		45.		77.		109.		141.	
14.		46.		78.		110.		142.	
15.		47.		79.		111.		143.	
16.		48.		80.		112.		144.	
17.		49.		81.		113.		145.	
18.		50.		82.		114.		146.	
19.		51.		83.		115.		147.	
20.		52.		84.		116.		148.	
21.		53.		85.		117.		149.	
22.		54.		86.		118.		150.	
23.		55.		87.		119.		151.	
24.		56.		88.		120.		152.	
25.		57.		89.		121.		153.	
26.		58.		90.		122.		154.	
27.		59.		91.		123.		155.	
28.		60.		92.		124.		156.	
29.		61.		93.		125.		157.	
30.		62.		94.		126.		158.	
31.		63.		95.		127.		159.	
32.		64.		96.		128.		160.	

Checked by: Production
(Officer/Executive)
Sign/date: _____

Verified by: QA
(Officer/Executive)
Sign/date: _____

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

- Run the Respule Filling and Sealing Machine as per **SOP No. _____** and adjust the Fill Volume / Sealing. Record the Observations in table below.
- Once Machine Setting done, Inform QA person to take Volume for another set of Respules from each Filling Head. After confirmation of the result (Fill Volume, and Sealing) from QA, start Operation of Respule filling and Sealing Machine as per **SOP No. _____**

INITIAL VOLUME ADJUSTMENT RECORD (By Weighing Method): (for 5 ml)

- Collect Individual Respules from all the Filling Head. Check the Fill volume as below:

Target Volume: 5.2 ml **Limit: 5.1 to 5.3 ml.**

Specific Gravity: 1.0656 gm per ml at 25^0C

For 5.0 ml volume:

Weight in gm. = _____ ml X Specific Gravity + Empty Weight

= _____ gm

Limit for Good Empty Respule **: 2.1 gm to 2.3 gm**

Limit for Filled Respule **: 7.5 gm to 8.0 gm**

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Date: _____ **Time (Hrs):**_____

Date:_____ **Time (Hrs):**_____

Cavity No.	Filled Weight (gm)	Cavity No.	Filled Weight (gm)	Cavity No.	Filled Weight (gm)	Cavity No.	Filled Weight (gm)	Cavity No.	Filled Weight (gm)
1.		33.		65.		97.		129.	
2.		34.		66.		98.		130.	
3.		35.		67.		99.		131.	
4.		36.		68.		100.		132.	
5.		37.		69.		101.		133.	
6.		38.		70.		102.		134.	
7.		39.		71.		103.		135.	
8.		4.		72.		104.		136.	
9.		41.		73.		105.		137.	
10.		42.		74.		106.		138.	
11.		43.		75.		107.		139.	
12.		44.		76.		108.		140.	
13.		45.		77.		109.		141.	
14.		46.		78.		110.		142.	
15.		47.		79.		111.		143.	
16.		48.		80.		112.		144.	
17.		49.		81.		113.		145.	
18.		50.		82.		114.		146.	
19.		51.		83.		115.		147.	
20.		52.		84.		116.		148.	
21.		53.		85.		117.		149.	
22.		54.		86.		118.		150.	
23.		55.		87.		119.		151.	
24.		56.		88.		120.		152.	
25.		57.		89.		121.		153.	
26.		58.		90.		122.		154.	
27.		59.		91.		123.		155.	
28.		60.		92.		124.		156.	
29.		61.		93.		125.		157.	
30.		62.		94.		126.		158.	
31.		63.		95.		127.		159.	
32.		64.		96.		128.		160.	

Checked by: Production
(Officer/Executive)
Sign/date: _____

Verified by: QA
(Officer/Executive)
Sign/date: _____

12.4 ASEPTIC AREA ENVIRONMENT MONITORING RECORD:

Frequency: Initially & after every One Hour by Production & QA alternatively.

Date	Time (hrs)	Temp. (°C) (Limit NMT 25°C)			% RH (Limit NMT 55%)			Pressure Differential (mm of water)			Checked By Production/ QA
		Mixing Room	Holding Room	FFS Room	Mixing Room	Holding Room	FFS Room	Mixing Room	Holding Room	FFS Room	

BATCH MANUFACTURING RECORD

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12.5 INPROCESS CHECKS DURING RESPULE FILLING & SEALING:

Frequency: Initially, middle & end, after every Two Hour by Production & QA Alternatively.

Filling & Sealing M/c ID No.: _____ Date:_____

Filling Technician's Name : (1) (2) (3)

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

39.							**119.**							
40.							**120.**							
41.							**121.**							
42.							**122.**							
43.							**123.**							
44.							**124.**							
45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA) :_____

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 47 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

44.							**124.**							
45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						
44.							**124.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 49 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 50 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 51 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

44.							**124.**							
45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 52 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						
44.							**124.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 53 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 54 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						
44.							**124.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 55 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 56 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

Date													
Time (hrs)													
Cavity No.	**Shape**	**Clarity**	**Fill Wt.**	**Empty Wt.**	**Net wt.**	**Net Volume**	**Cavity No.**	**Shape**	**Clarity**	**Fill wt**	**Empty wt**	**Net wt.**	**Net Volume**
1.							**81.**						
2.							**82.**						
3.							**83.**						
4.							**84.**						
5.							**85.**						
6.							**86.**						
7.							**87.**						
8.							**88.**						
9.							**89.**						
10.							**90.**						
11.							**91.**						
12.							**92.**						
13.							**93.**						
14.							**94.**						
15.							**95.**						
16.							**96.**						
17.							**97.**						
18.							**98.**						
19.							**99.**						
20.							**100.**						
21.							**101.**						
22.							**102.**						
23.							**103.**						
24.							**104.**						
25.							**105.**						
26.							**106.**						
27.							**107.**						
28.							**108.**						
29.							**109.**						
30.							**110.**						
31.							**111.**						
32.							**112.**						
33.							**113.**						
34.							**114.**						
35.							**115.**						
36.							**116.**						
37.							**117.**						
38.							**118.**						
39.							**119.**						
40.							**120.**						
41.							**121.**						
42.							**122.**						
43.							**123.**						
44.							**124.**						

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 57 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

45.							**125.**							
46.							**126.**							
47.							**127.**							
48.							**128.**							
49.							**129.**							
50.							**130.**							
51.							**131.**							
52.							**132.**							
53.							**133.**							
54.							**134.**							
55.							**135.**							
56.							**136.**							
57.							**137.**							
58.							**138.**							
59.							**139.**							
60.							**140.**							
61.							**141.**							
62.							**142.**							
63.							**143.**							
64.							**144.**							
65.							**145.**							
66.							**146.**							
67.							**147.**							
68.							**148.**							
69.							**149.**							
70.							**150.**							
71.							**151.**							
72.							**152.**							
73.							**153.**							
74.							**154.**							
75.							**155.**							
76.							**156.**							
77.							**157.**							
78.							**158.**							
79.							**159.**							
80.							**160.**							

Checked By (Sign/Date)
(Production/QA):_____

13.0 RECONCILIATION OF FILLED RESPULES AFTER FILLING:

Date of Filling	Fill Volume	No. of Respules Filled	Filling Rejection	Filling Loss	IPQA Samples	Other Samples (if any)	Checked by Production	Verified By QA

Total No. of Respules sent for Deflesher (For 5 ml) _____

$$\text{\% Batch Yield (Limit: NLT 98 \%)} = \frac{\text{Total No. of Respules sent for Deflesher}}{\text{Actual Batch Size}} \times 100$$

Note: In case of High / Low Yield, Fill Yield Deviation Note.

Reason for deviation (if any):

_____

_____

_____

Reconciliation Done By
Production
(Officer / Executive)

Reconciliation Checked By
QA
(Officer / Executive)

13.1 Batch Review Up-To filling & Sealing stage:-

	Checked By Production Officer/Executive	Reviewed By QA Officer/Executive
Name		
Sign & Date		
Emp. Code		

14.0 SUMMARY OF MACHINE BREAKDOWN (If Any):

- Record the details of Machine Breakdown during any stage of Batch Manufacturing in table below:

S.No.	Date	Time(hrs)	Stage	Type of Break Down*	Break Down		Total Down Time(hrs)	Recorded By (Production)	Verified By (QA)
					From	To			

*** Machine Down Time (hrs) Codes:**

A. Machine Cleaning
B. Machine Break Down
C. Lunch / Dinner / Tea
D. Material Problem
E. Machine Setting
F. Other

15.0 DEFLESHING OF RESPULES: (As per SOP No.:_____)

- Record the observations in the table given below:

Total No of Respules for Defleshing: _____

Date	Time (hrs.)		Operator	Total quantity input for Defleshing	*Rejection during Defleshing	Good quantity send for Leak Test	Checked by Production	Verified By QA
	From	To						
Total Rejection								

Quantity of good Respules after Defleshing: _____Respules

% Yield after Defleshing: _____ %

Checked By
(Sign/Date):_____
(Production)

Verified By
(Sign/date):_____
(QA)

* Rejected Respules shall be sent for Destruction.

16.0 LEAK TEST:

- Load the Respules in trays and place the trays inside the leak-testing m/c chamber and apply vacuum of about 700 to 720 mm of Hg for 30 minutes as per **SOP No. _____**.
- Record the observations in the table given below:

Total No of Respules for Leak Test: _____

Date	Lot No.	Operator	Vacuum pressure applied	Time(hrs)		Nos. of Respules tested	*Rejection	Nos. of Good Respules
				From	To			
	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
	9							
	10							
	11							
	12							
	13							
	14							
	15							
	16							
	17							
	18							
	19							
	20							
	21							
	22							
	23							
	24							
	25							
			Total Rejection					

Quantity of good Respules after leak testing: _____Respules

% Yield after Leak testing: _____ %

Checked By
(Sign/Date):_____
(Production)

Verified By
(Sign/date):_____
(QA)

* Rejected Respules shall be sent for Destruction.

17.0 SAMPLING OF ASEPTIC FILLED PRODUCTS:

Location- Date of Sampling:

No. of Trays / crates per batch:

Tray No.	Qty. of Sample
Initial : Crate No.: 01 – 5 06 – 10 11 – 15 16 - 20	
Middle Crate No.: 21 – 25 26 - 30 31 - 35 36 - 40	
Final Crate No.: 41 – 45 46 - 50 51 - 55 56 – 60	
Total	

No. of samples sent to Q.C. Lab:

Sampling Done by: 1) _____ Q.A.

18.0 MATERIAL RETURN DETAILS (If Any)

- Record the Material Return details (If Any) in table below:

S. No.	Name of Material	A. R. No.	Quantity	Reason for Return

Material Returned By (Production)	Sign Date: _____
Returned Material Verified By (QA)	Sign Date: _____
Material Received By (Ware House)	Sign Date: _____

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 64 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

19.0 IN – PROCESS OBSERVATIONS (To be Filled by QA only)

S. No.	Date / Time	Observations	Informed To Production (Officer/Executive)	Observed By IPQA (Officer / Executive)	Action taken by Production (Officer/Executive)	Verified By QA (Officer/Executive)

20.0 SCRAP TRANSFER RECORD:

- **Before Transferring the Scrap, check and ensure that:**
  - Empty Respules are kept in double layered Polyethylene bags with labeled.
  - Discarded Respules during Filling and Sealing are kept in separate double layered Polyethylene bags with labeled.
- **Details of all the Scrap sent to Scrap Yard shall be mentioned in the Scrap Transfer Form and recorded in table below:**

S. No.	Type of Scrap	No. of Containers / Bags	Weight in Kg (Approx.)	Scrap Transferred By Production (Officer /Executive)	Verified By QA (Officer / Executive)
1	LDPE Scrap during filling				
2	Discarded Respules during Filling and Sealing				
3	Respules used for IPQA Observations				
	Rejected Gloves				
1.	**Other Scrap (If Any)**				
A.					
B.					
C.					

NOTE: Attached Scrap Transfer Form.

21.0 QUALITY CONTROL SAMPLING

- Send the Intimation Slip to QA Dept. to withdraw the samples 56 Nos. of Filled Respules for complete Analysis.

Sampling, Analysis and Batch Release Details

Intimated By (Production) Sign, Time & Date	Intimation Received By (QA) Sign, Time & Date	Sampled By (QA) Sign, Time & Date	Qty. Sampled

- After receiving the Analysis Report from QC, fill the A.R. No: _____

QA Officer / Executive Sign: _____ Date: _____ Time: _____

22.0 RECONCILIATION:

22.1 RECONCILIATION OF LDPE GRANULES:

Quantity of Granules Issued (Kg.) (A)	Extra Quantity of Granules Issued (Kg.) (B)	Total Quantity of Granules Issued (Kg.) (C = A+B)	Quantity of Granules Used for Good Respules (D)	Quantity of Granules sent for Scrap (E)	Total Quantity of Granules Used (Kg.) (F=D+E)	Quantity of Granules Returned to Store (G=C-F)

Reconciliation Done By
Production
(Officer / Executive)

Reconciliation Checked By
QA
(Officer / Executive)

22.2 BATCH RECONCILIATION:

DATE: _____

S.No.	Stage	No. Of Respules	Done By (Production)	Checked By (QA)
1.	Actual Batch Size			
2.	No. of Good Respules transferred for Packing			
3.				
3A	Loss During Volume / Machine Adjustment			
	Loss during filling & sealing			
	Deflesher & Leak Test Rejection			
	Less Volume Rejection during Weighing			
NA	**Total Rejection / Loss**			
4.	**Samples**			
4A.	**QA Samples**			
	• Volume Variation Sample (IPQA Sample)			
	• Leak Test Sample			
	Production Sample			
	• Volume Variation Sample (IPQC Sample)			
	• Leak Test Sample			
	Other Samples (If Any)			
4B.	Validation Samples			
4C.	Other Samples (If Any)			
	Total Samples			
5.	Total No. of Respules Filled (2+4)			
6.	Total Solution Loss (3)			
7.	Variance [NMT 1%] [1-(5+6)] / 1*100			

$$\text{\% Batch Yield (Limit: NLT 97 \%)} = \frac{\text{No. of Good Respules transferred for Packing}}{\text{Actual Batch Size}} \times 100$$

Note: In case of High / Low Yield, Fill Yield Deviation Note.

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Bacillus Clausii Spores Suspension	
Document No.:	**Effective Date:**	**Page No.:** 69 of 70
Batch No.:	**Batch Size:**	**Supersedes No.:**

Reason for Deviation (If Any):

_____

_____

_____

Reconciliation Done By
Production
(Officer / Executive)

Reconciliation Checked By
QA
(Officer / Executive)

The Batch Released / Not Released for Packing: _____ on Date: _____.

22.3 Batch Review Manufactured Stage, Documents / Data & Records

	Checked By Production Officer/Executive	Reviewed By QA Officer/Executive
Name		
Sign & Date		
Emp. Code		

22.4 Certificate for Batch Manufacturing:

I, the undersigned, approved technical staff having prescribed qualification & experience, hereby confirm that the above batch is manufactured under my direction & supervision. All process relating to the selection, weighing and measuring of raw material & processing during various stages are performed by trained personnel. All statutory requirements prescribed for manufacturing under the Drugs and Cosmetics Act, 1940 & cGMP standards are duly followed.

Competent Technical staff for Mfg (Name): ----------

(Sign) ----------

(Emp. Id) ----------

The Batch Released / Not Released for Packing: _____ on Date: _____.

Checked By Sign / Date Head - Production	Reviewed By Sign / Date Head - QA

23.0 REVISION HISTORY:

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New Document	Introducing of New Document		