



## STANDARD OPERATING PROCEDURE

**Title:** Decontamination and Destruction of Bacillus Clausii Solution in Form, Fill Seal Section

<b>SOP No.:</b>		<b>Department:</b>	Production	
		<b>Effective Date:</b>		
<b>Revision No.:</b>	00	<b>Revision Date:</b>		
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 4	

### 1.0 OBJECTIVE:

To lay down a procedure for Decontamination & Destruction of Bacillus Clausii Solution in FFS section.

### 2.0 SCOPE:

This SOP is applicable for Decontamination & Destruction of Bacillus Clausii Solution in FFS section.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head - Production

### 5.0 ABBREVIATIONS:

ETP	Effluent treatment plant
FFS	Form, Fill Seal
Kg	Kilogramm
Ltr.	Liter
ml	Milliliter
pH	Power of Hydrogen
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

- 6.1 Prepare 40% w/v Sodium Hydroxide Solution as per requirement in water for Injections in dedicated vessel & record the same in **Annexure-I**.
- 6.2 Discard the rejected respoules /solution of Bacillus Clausii in dedicated vessel containing 10 Ltr. of 40% Sodium Hydroxide decontamination solution.
- 6.3 Hold the decontaminated solution for minimum period of 4 hours for decontamination of Bacillus Clausii spore.
- 6.4 Send it to ETP for destruction with Intimation for discarding of deactivated Bacillus Clausii Solution in ETP in **Annexure-II**.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Preparation & Decontamination Record of Bacillus Clausii Solution	
Annexure-II	Intimation for discarding of deactivated Bacillus Clausii Solution in ETP	

**ENCLOSURES:** SOP Training Record.



# PHARMA DEVILS

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### 8.0 DISTRIBUTION:

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

### 9.0 REFERENCES:

Literature provided from **Anthem Biosciences**.

### 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-II

#### INTIMATION FOR DISCARDING OF DEACTIVATED BACILLUS CLAUSII SOLUTION IN ETP

**Block:**

**Section:**

**Date:**

<b>Product Name:</b>		<b>Mfg. Date</b>	
<b>Batch No.:</b>		<b>Exp. Date</b>	
<b>Qty. in Ltr.</b>		<b>Remark</b>	
<b>Intimated By (Prod.) Sign &amp; Date</b>	<b>Checked By (QA) Sign &amp; Date</b>		<b>Receive By (ETP) Sign &amp; Date</b>