



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	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

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	2 of 4	

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



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	4 of 4	

ANNEXURE-II

INTIMATION FOR DISCARDING OF DEACTIVATED BACILLUS CLAUSII SOLUTION IN ETP

Block:

Section:

Date:

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