REPORT FOR NEUTRALIZATION

OF

PENICILLIN (PIPERACILLIN & TAZOBACTAM)

&

CEPHALOSPORIN (CEFTRIAXONE)

DATE OF VALIDATION	
SUPERSEDED REPORT NO.	NIL

REPORT FOR NEUTRALIZATION OF PENICILLIN & CEPHALOSPORIN WITH SODIUM HYDROXIDE

REPORT CONTENTS

REPORT FOR NEUTRALIZATION OF PENICILLIN & CEPHALOSPORIN WITH SODIUM HYDROXIDE

1. REPORT APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
MANAGER (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

REPORT FOR NEUTRALIZATION OF PENICILLIN & CEPHALOSPORIN WITH SODIUM HYDROXIDE

2. OBJECTIVE:

To provide documentary evidence and prove that concentration of NaOH Solution required to neutralizing Penicillin (Piperacillin & Tazobactam) and Cephalosporin (Ceftriaxone) contamination.

3. SCOPE:

The validation report is applicable to determine the concentration of NaOH Solution required to neutralizing Penicillin (Piperacillin & Tazobactam) and Cephalosporin (Ceftriaxone) contamination.

4. RESPONSIBILITY:

The Validation Group, Comprising of a representative from each of the following departments shall be responsible for the overall compliance of this report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Pre Approval, Compilation and Post Approval of Neutralization Study Report. • Monitoring of Neutralization Study. • Verification of Tests & Results. • Review the executed Report to check the compliance and corrective action for discrepancies found. Also shall prepare the summary and conclusion of neutralization study.
Production	• Review & Pre Approval of Report. • To Co-ordinate and support for execution of Neutralization Study as per protocol. • Post Approval of Neutralization Study Report after Execution
Engineering	• Review & Pre Approval of Report. • Co-ordination, Execution and technical support during Neutralization Study. • Responsible for Trouble shooting (if occurs during execution). • Post Approval of Neutralization Study after Execution.
Quality Control	• Review & Pre Approval of Report. • Analytical Support (Testing / Analysis) • Post Approval of Neutralization Study after Execution

REPORT FOR NEUTRALIZATION OF PENICILLIN & CEPHALOSPORIN WITH SODIUM HYDROXIDE

5. EXHIBITS:

EXHIBIT-I

TRAINING DETAILS

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked By (Sign & Date) (QA)
1.				All personnel involved in execution of Report shall be trained in the required procedure and shall be documented		
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Name of Trainer:_____

Inference:_____

_____

_____

Reviewed By (Sign & Date)_____
(Manager-QA)

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EXHIBIT-II
STUDY OF PERCENTAGE CONCENTRATION OF SODIUM HYDROXIDE

S. No.	Raw Material		Concentration of Neutralizing Agent (NaOH) in 2 ml	Observation
	Name	Quantity		
1.	Piperacillin Tazobactam	1g	1%	
2.			2%	
3.			3%	
4.			4%	
5.			5%	
6.			10%	
7.	Ceftriaxone	1g	1%	
8.			2%	
9.			3%	
10.			4%	
11.			5%	
12.			10%	
Acceptance Criteria: After Neutralization with NaOH, Raw Material/Product of Penicillin (Piperacillin Tazobactam) & Cephalosporin (Ceftriaxone) should be completely dissolved to get Clear Solution.				

Complied By:_____
(QA)
Sign & Date:

Inference:_____

_____

Reviewed By (Sign & Date)_____
(Manager-QA)

REPORT FOR NEUTRALIZATION OF PENICILLIN & CEPHALOSPORIN WITH SODIUM HYDROXIDE

6. **DEVIATIONS (If Any):**

7. **CONCLUSION:**

8. **RECOMMENDATION:**

9. REPORT POST- APPROVAL:

Signing of this report indicates that neutralization study of Penicillin & Cephalosporin with Sodium Hydroxide has been completed as per Approved Protocol.

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

10. ABBREVIATIONS:

Ltd.	:	Limited
ID	:	Identification
SOP	:	Standard Operating Procedure
QC	:	Quality Control
%	:	Percentage