PROTOCOL
FOR

DIRTY EQUIPMENT HOLD TIME

(DEHT)

STUDY

PROTOCOL FOR DIRTY EQUIPMENT HOLD TIME STUDY

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1.0 PRE-APPROVAL

The Author signature indicates that this document has been prepared in accordance with existing cGMP standards and adequately reflects the tasks and deliverables necessary for validation of dirty equipment hold time.

Prepared By/Function	Designation	Signature	Date
Quality Assurance			

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the adequately tasks and deliverables necessary for validation of dirty equipment hold time and that the documentation and information included complies with current Good Manufacturing Practices.

Reviewed By/Function	Designation	Signature	Date
Operations			

The Approver's signature indicates that, this documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements and current good Manufacturing practices.

Approved By/Function	Designation	Signature	Date
Quality Assurance			

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2.0 OVERVIEW:

2.1 Objective:

The objective of this Protocol is to provide an outline for performing DEHT study, after type A cleaning, by estimating the microbial load and chemical residue after performing type C

2.2 Scope:

This protocol is applicable for conducting a DEHT study and its associated activities to over view outcome of study .This study shall be performed after completion of first validation campaign and elaborative studies shall be performed on consecutive products with focus on more sampling points and intervals.

3.0 RESPONSIBILITIES:

4.0 REFERENCE OF RELATED DOCUMENT

SR.	DOCUMENT NAME	DOCUMENT NO
1		
2		
3		
4		
5		

Reviewed By: _____ Date: _____

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5.0 VALIDATION STUDY PLAN

6.0 SELECTION CRITERIA AND SAMPLING DETAILS:

7.0 PROCEDURE FOR VALIDATION STUDY:

8.0 ACCEPTANCE CRITERIA

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9.0 FINAL REPORT

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Summarized By: _____ Date: _____

Reviewed By : _____ Date: _____

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10.0 ABBREVIATIONS

S.No	Abbreviations	Description

Reviewed By : _____ Date: _____

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11.0 ATTACHMENTS

S.No.	Description

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12.0 REVISION HISTORY