VAL-230 Procedure for Cleaning Validation Coverage Testing

Appendix A: Cleaning Validation Coverage Testing – using Riboflavin Solution

1. Equipment Details

Activity	Result	Verified by/Date
Vessel ID #		
Previous batch manufactured	Batch ID/Date:	
Previous Clean completed and type of clean	Date/Type:	

2. Riboflavin Preparation

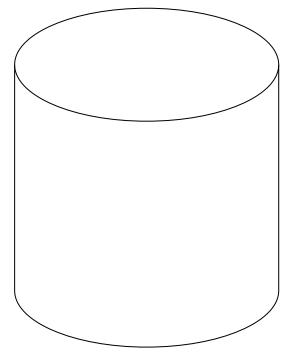
Riboflavin Solution Batch Number: _____ Riboflavin Solution Expiry Date: _____

Activity	By / Date	Verified by/Date
Riboflavin Solution prepared		
Riboflavin Solution applied by		

3. Tank Assessment

Tank:_____

Illustrate the hard to clean locations in the below diagram



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4. Visual Inspection prior to Riboflavin application

Product contact surfaces:	Absence / Presence of Fluorescence prior to <i>Riboflavin</i> application	Absence / Presence of Fluorescence after <i>Riboflavin</i> application	Comments

Performed by / Date:

Verified by / Date:

5. Water Rinse Cycle

Water Rinse cycle start	Time/date:	Verified by / Date
Water Rinse cycle end	Time/date	Verified by / Date:

Comments:

Coverage test (Pass / Fail):

Validation Approval:

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Appendix B: Cleaning Validation Coverage Testing – using Methylene Blue

1. Equipment Details

Activity	Result	Verified by/date
Vessel ID #		
Previous batch manufactured	Batch ID#/date:	
Previous Clean completed and type of clean	Date/Type:	

2. Methylene Blue Preparation and rinse cycle

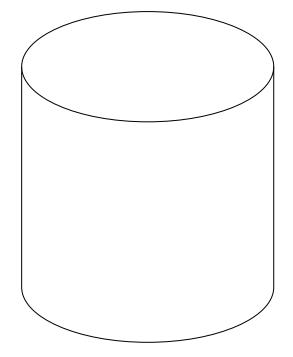
Methylene Blue Solution	Methylene Blue Solution
Batch Number:	Expiry Date:

Activity	By / Date	Verified by/date
Methylene Blue solution prepared		
Methylene Blue Rinse Cycle start		
Methylene Blue Rinse Cycle end		

3. Tank Assessment

Tank: _____

Illustrate the hard to clean locations in the below diagram



4. Visual Inspection after the Methylene Blue application

Product contact surfaces	Presence/Absence of blue after Methylene Blue application	Comments

Coverage test (Pass / Fail):

Performed by / Date:

Verified by / Date:

5. Water Rinse Cycle

Water Rinse cycles start	Time/date:	Verified by / Date
Water Rinse cycles end	Time/date	Verified by / Date:

The tank is visually free of dye: □Yes	No
Comments:	
Performed by / Date:	
Validation Approval:	