

Cleaning Validation Campaign Length Increase Protocol

(Ref. SOP QMS-030)

TEM-255: CLEANING VALIDATION CAMPAIGN LENGTH INCREASE PROTOCOL				
[Equipment/Room] Plant Number	Previous Protocol		Validated Campaign Length	

Objective
<p>The objective of this protocol is to define the procedure used and the acceptance criteria for the campaign length cleaning validation for the Equipment/Room & Plant Number, Equipment/Room in the Manufacturing/Packaging Area at the site [Insert site name].</p> <p>Successful completion of the qualification study will provide a high degree of assurance and documented evidence that the cleaning process is effective in removing residues of drug product, cleaning agent and microbial contamination to below a predetermined level for product contact equipment.</p>

Procedures	
Conduct the following tests and attach details/results to the relevant Appendices as per SOP [insert SOP no]	
Appendix	Test
	Sampling Plan
	Cleaning Validation Summary and Visual Inspection
	Microbiological Test
	Product Removal
	Deviation Log and Report

Approval for Execution	Print/Type Name	Signature	Date
Written By (Validation Engineer)			
Approved By (Technical Services)			
Approved By (Quality Operations)			
Approved By (System Owner)			
Approved By (Quality Assurance)			

Appendix 1 – Sampling Plan

Procedures
Attach the sampling plan from the previous validated protocol.

The following section is left intentionally blank.

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Appendix 3 – MICROBIOLOGICAL TEST RESULTS SUMMARY						
Procedure						
Swab and test for microbial contamination as per SOP [insert SOP no] at sites identified in Appendix 1.						
Swab #	Location	Sampled By/ Date/ Time	Laboratory receipt By / Date	Result (c.f.u/cm ²)	Result Conclusion (Please circle)	Initial & Date
					Pass Fail	
					Pass Fail	
					Pass Fail	
					Pass Fail	
Supplemental Data for Swab Samples						
Swab	Lot #		Expiry			
Media	Lot #		Expiry			
Incubation Details	Incubator Number	Calibration Status	Date & Time	Performed By		
TSA Incubation Start (25°C) 5-7 Day						
TSA Incubation Transfer (30°C) 2-4 Days						
TSA Incubation End						
Acceptance Criteria	TPC: ≤ 1 c.f.u / cm ²					
Results Approved By	Name	Signature	Date			
Comments						
Page	X	of	X			Initial & Date
All Acceptance Criteria Met (Circle Yes/No)			Yes	No Deviation <input checked="" type="checkbox"/>		
Reviewed By						

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APPENDIX 5 – DEVIATION LOG AND REPORT

The following log sheet is to be filled out in the event that any deviations occurred in this protocol.

For each deviation enter the Test Number where the deviation was found, a description of that deviation and

whether it was critical or non-critical (C or N respectively).

Dev. #	Test Number	Deviation	C or N	Initials/Date