Cleaning Validation Report Template

(Ref. SOP _____)

Project Name		**Project Number**	
Equipment		**Serial Number**	
Manufacturer		**Model Number**	
Process Line/Location		**Protocol number**	

	WRITTEN BY:	REVIEWED BY:
Name:		
Position:		
Signature:		
Date:		

VALIDATION STATUS:
As per [insert guidance reference] cleaning validation for miscellaneous equipment has been completed successfully.

	APPROVED:		
Name:			
Position:			
Signature:			
Date:			

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6.3 Microbial Removal.

Following cleaning and sanitizing, swab samples were taken and tested for microbial levels. All results were recorded in laboratory work book [Insert workbook # and page nos] and are summarised in section 7.3

6.4 Clean and Dirty Holding Time

Clean and dirty hold times have been recorded for each run [Insert workbook # and page nos] and are summarised in section 7.4.

6.5 Campaign Manufacture

[If campaign cleaning or campaign manufacture is required, detail what was done here e.g. number of runs]

7 ACCEPTANCE CRITERIA

- On inspection, all surfaces must be visually clean i.e. must be free of product and detergent residues, foaming and accumulation of water when dry.
- The Maximum allowed carry-over for product residue swabs must be less than [Insert limit]
- The pH and Conductivity of the rinse water samples tested for detergent must meet the BP specification for purified water. This specification is not more than 4.3 μS/cm-1 at 20°C and between 5.0 and 7.0 pH units.
- All equipment must have microbial contamination at acceptable levels as follows for swabs:

TPC:	≤ 1 c.f.u / cm2
Yeast & Mould count:	≤ 1 c.f.u / cm2
ObjPseudomonas spp.:	Not Detected/ swab
Coliforms:	Not Detected/ swab
E.coli:	Not Detected/ swab
Salmonella spp	Not Detected/ swab

- The cleaning cycles will be considered validated on completion of three consecutive successful evaluations.
- All Cleaning Procedure SOP's must be current and in place. All identified training must be completed and documented.
- All analytical methods and recovery procedures must be validated. All equipment must be validated and instrumentation used for testing must be within calibration
- No unexplained intervening failures may occur. When there is a deviation from one of the replicate runs, it may be removed from the sequence if the deviation is unrelated to the cleaning procedure, Corrective action may be necessary. A failure to meet acceptance criteria necessitates a review of the cleaning procedure and the residual limits to which the procedure was required to clean, followed by three successful runs.

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9 DEVIATIONS

[Insert brief description of deviation and resolution. Reference deviation number if applicable. Only include this section if there are deviations]

10 DISCUSSION

[Discuss results obtained and what it means to the validity of the study. Include deviations. If all acceptance criteria were met then this section should be brief. Any unusual events recorded in your lab work book should also be documented here]

11 CONCLUSION

[The conclusion should be a brief statement on the disposition of the study. It should briefly discuss deviations if any occurred. The conclusion should give a definitive indication of the validation state e.g. Therefore the cleaning procedure [Insert SOP and title] is validated for cleaning of the [Insert equipment name.]

[if applicable]

Dirty Hold Time is:

Clean Hold Time is:

Changes to the qualified procedure can only be made in accordance with in-house change control procedure. Re-qualification shall be performed as necessary, in accordance with the recommendations made on the change control documentation. The Validation status must be re-evaluated for any significant change in processing, cleaning procedure or cleaning agent.

12 AMENDMENT LIST

Version Number	Date	Section Reference	Page	Amendment Details	Authorised