Cleaning Validation Interim Report template

(Ref. SOP _____)

	WRITTEN BY:	REVIEWED BY:
Name:	insert name	insert name
Position:	insert position title	insert position title
Signature:		
Date:		

VALIDATION STATUS:
The cleaning validation run in/ on the equipment/ module after the manufacture of product batch insert batch number and prior to product batch insert batch number was completed successfully as per protocol [insert protocol no]. Validation remains ongoing insert details of validation status. Once complete, a separate final report will be created to summarise and to close out the cleaning validation study.

	APPROVED:		
Name:	insert name	insert name	insert name
Position:	insert position title	insert position title	insert position title
Signature:			
Date:			

1.0 OBJECTIVE

The objective of this interim report is to summarise cleaning validation run insert run number carried out in/ onthe equipment/ module in the manufacturing/ packaging Area [insert site name] on was performed as per cleaning validation protocol [insert protocol no].

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Successful completion of the cleaning validation run insert run number provides 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 predetermined levels for product contact equipment prior to use.

2.0 SCOPE

The scope of the cleaning validation covers all aspects of the cleaning procedure used to clean equipment/ module only and all products that are processed in this equipment. Equipment cleaning validation was based on a worst-case product as outlined in cleaning validation plan COR/CV001P v 2.

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5.0 DEVIATIONS

There were no deviations raised in relation to cleaning validation run X post product batch XXXXX.

X deviations were raised in relation to . Refer to Appendix X of protocol [insert protocol no].

5.1 Deviation X

Deviation X was raised .

This is a critical/ non critical deviation insert product/validation impact status.

6.0 DISCUSSION

All acceptance criteria for this cleaning validation run in/on the equipment/module in the manufacturing/packaging area were met as per the specified criteria in protocol [insert protocol no].

There were X non critical deviations generated. The deviations has/ have been documented and closed out successfully.

7.0 CONCLUSION

Cleaning validation run post product batch XXXXX was executed as per cleaning validation protocol [insert protocol no].

All acceptance criteria were met as per the specified criteria in protocol [insert protocol no].

There were X non critical/criticaldeviations which were documented and closed out successfully.

Table X summaries the status of execution of protocol [insert protocol no] to date.

Table X Summary of Cleaning Validation Status

Run #	CV post		DHT	CHT	Result	Report
	Product	Batch				
X						
X						
X						
Current Status						

A final report will be required to close the cleaning validation for equipment/ module protocol [insert protocol no].

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