PROTOCOL

FOR

CLEANING VALIDATION

PRODUCTION FORMULATION

TABLE OF CONTENTS

1. OVERVIEW:

1.1 Introduction:

The purpose of this protocol for assurance of cleaning methodology to detect previous product residue from equipment/equipments parts. To provide the necessary documentary evidence that the cleaning procedure can reduce the residual contamination of previous product below the established limit so that such residue do not affect the quality and safety of the subsequent product to be manufactured in the same equipment.

1.2 Objective:

The objective of the cleaning validation protocol is to establish & assure with documented evidence that the cleaning procedure for vial filling & stoppering machine parts are reproducibly remove residue of the previous product to levels below the established acceptance limits.

1.3 Scope:

The scope of this validation activity is limited to validate the cleaning process of vial filling machine parts in production formulation department.

Reason for revision: Periodic cleaning verification is included in revalidation criteria.

1.4 Responsibility:

To conduct the cleaning validation study team shall be formed. The team shall contain the members from the Quality Control, Engineering, Production and Quality Assurance Departments. The Validation team is described through the following responsibility:

Quality Assurance	To prepare the protocol & report To provide the training To execute & supervise the study
Quality Control, Engineering, Production and Quality Assurance	To review the protocol To conduct the study To collect and analyze samples
Reviewer-1 : Production In-Charge/Designee	To review validation protocol. To review validation report.
Reviewer-2: CQA-Validation	To review validation protocol. To review validation report.
Approver-1: Head Production /Designee	To approve validation protocol. To approve validation report.
Approver-2: Head-QA/Designee	To approve validation protocol. To approve validation report.

2. EXECUTION TEAM:

Following personnel shall be responsible for the execution of validation study:

Production	:	To conduct the validation study as per protocol.
Quality Assurance	:	To monitoring the activity and collect the sample for chemical analysis as per protocol.
Quality Control	:	To conduct the microbiology monitoring, analysis of samples and reporting of results.
Engineering	:	To provide utility and maintenance support.

3. TRAINING RECORD:

3.1 Purpose:

The purpose of the training is to familiarize the trainees with the purpose and procedure of cleaning validation activity.

3.2 Scope:

This training is applicable to the protocol for cleaning validation.

3.3 Topics:

The following topics shall be covered during training: Identifying the responsibility of involved person.

4.3.1 Purpose & procedure of cleaning validation.
4.3.2 Documentation practices to be followed.
4.3.3 General precautions / guidelines to be followed during validation.

4. REQUIREMENT FOR CLEANING VALIDATION:

4.1 Documental Requirements:

S.No.	Document No.	Title of SOP
1.		Procedure for operation of ultrasonic cleaner
2.		Procedure for calibration of high performance liquid chromatography.
3.		Procedure for operation of high performance liquid chromatography (Model-Shimadzu).
4.		Procedure for operation of high performance liquid chromatography (Model-Waters).
5.		Bacterial endotoxin test procedure.
6.		Particulate matter testing.
7.		Bio burden testing by filtration method.

4.2 Apparatus / Instrument Requirements:

Polypropylene shaft (TEXWIPE),10×10 cm^2 stainless steel coupon, Test tube (Glass bottle), WFI, Rinse Sample bottle.

5. SYSTEM/EQUIPMENT DESCRIPTION:

5.1 **API Solubility:**

5.1.1 **Imipenem**: Slightly soluble in water.

5.1.2 **Cilastatin Sodium**: Soluble in water.

5.1.3 **Meropenem**: Sparingly soluble in water.

5.1.4 **Doripenem:** Sparingly soluble in water.

5.2 **Solubility Matrix:**

DESCRIPTION	SOLUBILITY (1g in listed ml)	mg/ml
Very soluble (VS)	Less than 1	>1000
Freely soluble (FS)	From 1 to 10	100 to 1000
Soluble (S)	From 10 to 30	33.33 to 100
Sparingly soluble (SPS)	From 30 to 100	10 to 33.33
Slightly soluble (SLS)	From 100 to 1000	1 to 10
Very slightly soluble (VSLS)	From 1000 to 10 000	0.1 to 1
Practically insoluble (PI)	More than 10 000	<0.1

5.3 **Equipment Description:**

The list of vial filling machine parts is given below with their surface area-

S. No.	Equipment Name	Equipment No.	Surface Area (cm^2)
1.	Vial Filling & Rubber Stoppering Machine	PF/VFS-01	
	Contact Parts		
	Dosing Wheel		1349.16
	Powder Hopper		1647.35
	Butter Fly Valve		471.05
	Total Surface area: **(3467.6 cm^2)**		**3467.56 cm^2**
	Non-contact parts		
	Rubber Stopper Bowl		6470.31
	Rubber Stopper Chute		726.72
	Total Surface area: **7197.03 cm^2**		**(7197.0 cm^2)**

☞ *If different capacity of equipments used in product, higher contact surface area shall be considered for calculation.*

Equipment contact surface area calculation as per **Anenxure-01**.

6. CLEANING VALIDATION METHODOLOGY OR PROCEDURE:

6.1 **General Recording Instructions:**

6.1.1 Read the contents of the document thoroughly before proceeding for Execution of the activity (in case of doubts / contradictions / contact the approvers of the document for clarifications).

6.1.2 Recording of all the observations and data shall be done as per **SOP "Good Documentation Practices"**.

6.2 **Cleaning Methodology:**

6.2.1 Cleaning of Equipment is classified as follows:

6.2.2 Clean the vial filling machine parts as per **SOP** "**cleaning and wrapping of filling machine parts"**.

6.2.3 The cleaning validation study shall be performed for three consecutive / changes over batches taken for validation.

6.2.4 Collect the swab and rinse sample as per sampling procedure.

6.2.5 The swab sampling location is defined in **Annexure– 02** (Sampling locations of equipment).

6.3 **Worst case product selection:**

6.3.1 Worst case product shall be selected by following criteria-

6.3.1.1 Solubility
6.3.1.2 Hardest to clean
6.3.1.3 Therapeutic dose

6.3.2 **Product matrix:**

Table-1

S.No.	Name of product	API	Therapeutic Dose Minimum (TD) (mg)	Therapeutic Daily Dose Maximum (TDD)(mg)	Minimum Batch Size (kg)	Solubility (in water)
1.	Meropenem for Injection 500mg / vial	Meropenem	500	6000	3	Sparingly soluble
2.	Meropenem for Injection 1000mg / vial	Meropenem	1000	6000	3	Sparingly soluble
3.	Imipenem and Cilastatin Injection for 250 mg	Imipenem	250	4000	3	Slightly soluble
		Cilastatin Sodium	250			Soluble
4.	Imipenem and Cilastatin Injection for 500 mg	Imipenem	500	4000	3	Slightly soluble
		Cilastatin Sodium	500			Soluble in water
5.	Doripenem for Injection 250 mg / vial	Doripenem	250	1500	3.5	Sparingly soluble
6.	Doripenem for Injection 500 mg / vial	Doripenem	500	1500	3.5	Sparingly soluble

☞*From above products (Table-1), Hardest to clean product is Imipenem and Cilastatin for Injection.*

6.3.3 Maximum Allowable Residue (MAR) calculation:

6.3.4 **Dose Criteria:**

$$\mathbf{L1} = \frac{\text{Minimum therapeutic dose of product A} \times \text{Safety Factor (L0)}}{\text{Maximum daily therapeutic dose of product B}}$$

6.3.5 **10 ppm Criteria:** 10 mg of product A in kg of product B

☞ *Where A is the product for which cleaning is to be performed and B is the next proposed product to be processed.*

☞ *L0 is the safe amount of residue that can be administered to a person on a daily basis for a long time.*

☞ *Safety factor is 1/10000th (0.0001) shall be considered for dose criteria.*

6.3.6 Maximum allowable carryover limit of product A in to total batch size of the product B (L2) as given below:

L2 = **L1** x Minimum batch size of product B

6.3.7 Maximum allowable carryover limit of product A per square centimeter (Sq.cm or cm^2) of surface area (L3) as given below:

$$\mathbf{L3} = \frac{\mathbf{L2}}{\text{Total product contact surface area of the equipments}}$$

☞ *While calculating the equipment surface area, +5% of the obtained values may be taken to prevent error due to manual measurements*

6.3.8 Maximum allowable carryover limit of product A per swab area (L4a) is as given below:

L4a = **L3** x Swab area (sq. cm)

6.3.9 Concentration of residue in extracted swab sample (**L4b**) is given as below**:**

$$\mathbf{L4b} = \frac{\text{L3} \times \text{(area swabbed)}}{\text{Amount of desorbing solvent}}$$

6.3.10 Rinse concentration (**L4c**) of the active in any rinse solution is as given below;

$$\mathbf{L4c} = \frac{\text{L3} \times \text{(area rinsed)}}{\text{Amount of rinsing solvent}}$$

☞ *In case of swab sampling the calculation for chemical residue shall be performed by using 100 cm^2 surface area and 10ml as swab desorbing solvent (Water for injection).*

☞ *In case of rinse sampling the calculation for chemical residue shall be performed by using 100ml rinsing solvent (Water for Injection).*

6.4 **Maximum Allowable carryover (MACO) or Maximum Allowable Residue (MAR) determination:**

6.4.1 The minimum value obtained from 10ppm and therapeutic dose criteria shall be considered for acceptance limit of MAR in cleaning validation.

6.4.2 Worst case product is Imipenem and Cilastatin for Injection w.r.t. solubility (Slightly soluble in water) and hardest to clean (Imipenem).

6.4.3 Establishment of Acceptance Limits of Maximum Allowable Residue (MAR) calculation is as per **Annexure – 04** (Establishment of Acceptance Limits).

6.4.4 Worst case product is selected based on the least solubility of API in water. If the two or more products had the same solubility, the minimum therapeutic dose among those is considered as worst case product.

☞ *If the worst case product is not covered in all equipments, select next product as a worst case product based on worst case selection.*

☞ *For the products containing multi active ingredients, the active ingredient which has minimum therapeutic dose is considered for MAR calculation.*

☞ *Cleaning validation may considerthe next worst product, in case the actual worst product has not been manufactured since a long time.*

6.5 **Sampling Procedure and Test Methodology:**

6.5.1 **Physical verification:**

6.5.1.1 After completion of cleaning Production and QA personnel shall physically verify the equipment for cleanliness. It should be visually clean then only further activity shall be performed.

6.5.2 **Rinse Sample:**

6.5.2.1 Place the dosing wheel, powder hopper, rubber bowl, rubber stopper chute and butter fly valve etc. one by one in Ultrasonicator as per SOP "**Operation of ultra sonic cleaner**" and then machine parts transfer to part final wash room.

6.5.2.2 In part final wash room clean the machine parts as per the "**Procedure for Cleaning & Wrapping of Filling Machine Parts**". Then rinse the equipment parts by WFI. After completion of final rinsing collect the samples.

6.5.2.3 Send all the samples along with blank sample to QC department for analysis of following test:

- Visual particles
- Sub visual particles
- Residue of previous product
- BET
- Bio burden

6.5.2.4 Depyrogenated container shall be used for BET sample collection.

6.5.2.5 Use the pre validated analytical method for analysis.

☞*If samples are not analyzed immediately then samples are stores at 2 to 8°C and Samples shall be analyzed within 24 hours for chemical analysis.*

☞*If samples are not analyzed immediately then samples are stores at 2 to 8°C and Samples shall be analyzed within 12 hours for microbial analysis.*

☞*For bio burden sample use autoclaved bottle.*

6.5.3 **Swab Sample:**

6.5.3.1 Place the dosing wheel, powder hopper, rubber bowl, rubber stopper chute and butter fly valve etc. one by one in Ultrasonicator as per SOP "O**peration of ultra sonic cleaner**" and then machine parts transfer to part final wash room.

6.5.3.2 In part final wash room clean the machine parts as per the "**Procedure for Cleaning & Wrapping of Filling Machine Parts**". Then rinse the machine parts by WFI. After completion of final rinsing collect the samples.

6.5.3.3 Sampling locations (points) are selected based on the worst case criteria:

- Hard to clean area
- Inaccessible area

The sampling locations are defined in **Annexure – 02**.

6.5.3.4 Take the clean swab made up of Polyurethane foam having Polypropylene shaft (TEXWIPE) and put it in the test tube containing diluents and squeeze the swab along with the sides of test tube to remove the excess diluents from it.

6.5.3.5 Take out the wet swab from the test tube without touching the tip of swab.

6.5.3.6 Place the one side tip of swab at the identified location and apply it on the 10 x 10 cm^2 areas of the equipment/equipments parts (locations as defined in **Annexure – 02**). Swab samples are taken as shown in the **Figure – 01**.

☞ *In case of non-regular shape (e.g. cylindrical piping) simulate to the possible accessible area. Use appropriate swab holding devices to get the proper access of sampling points as described in the swab location.*

6.5.3.7 Put the swab stick into the test tube without touching the tip.

6.5.3.8 Label the test tube with the information of Swab sample, equipment part name, Sampling location, product name, batch no., sampled by and date.

6.5.3.9 Send the test tube to the QC department for analysis of following test:

- Residue of previous product
- BET
- Bio burden

6.5.3.10 Use the pre validated analytical method for analysis.

☞*If samples are not analyzed immediately then samples are stores at 2 to 8°C and Samples shall be analyzed within 24 hours for chemical analysis.*

☞*If samples are not analyzed immediately then samples are stores at 2 to 8°C and Samples shall be analyzed within 12 hours for microbial analysis.*

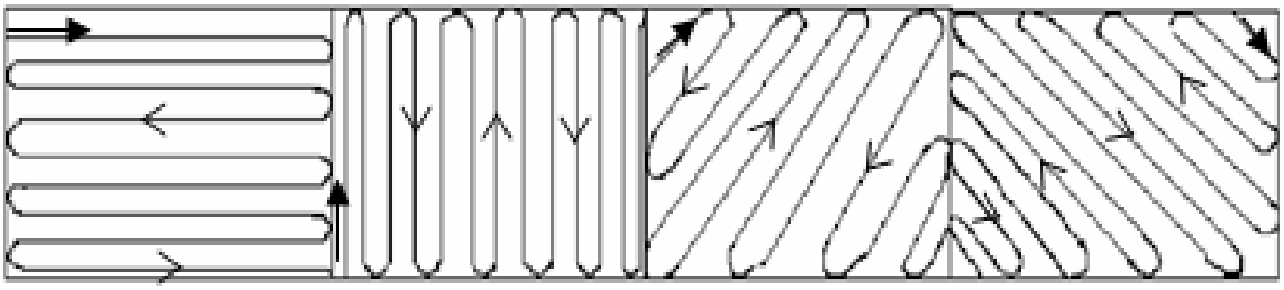


Figure – 01

6.6 **Recovery, LOQ and LOD Study:**

Recovery study, LOQ and LOD study is performed as per the analytical cleaning method validation protocol as follows -.

6.6.1 Analytical Method Validation protocol for Imipenem and Cilastatinfor Injection by HPLC.

6.6.2 Analytical Method Validation protocol for Doripenemfor Injection by HPLC.

6.6.3 Analytical Method Validation protocol for Meropenemfor Injection by HPLC.

6.6.4 **Testing Plan:**

6.6.4.1 **Rinse sample:** Visually inspect to particulate matter and analyze the rinse sample by suitable HPLC method for residue of previous product in the sample. BET shall be analyzed as per GTP and bio burden shall be analyzed as per GTP. Use the pre validated analytical method for analysis.

6.6.4.2 **Swab sample:** Analyze the swab sample by suitable HPLC method for residue of previous product in the sample. BET shall be analyzed as per GTP and bio burden shall be analyzed as per GTP. Use the pre validated analytical method for analysis.

6.6.4.3 **During Product Change over Testing**: Visual checking, particulate matter, residue of previous product, BET and Bio burden.

6.6.4.4 **During Change over Testing:** Visual checking, particulate matter and BET.

- ☞ *Particulate matters to be check firstly, if it is complying then proceed for next analysis.*
- ☞ *For sampling and dispensing different accessories to be used for each different product.*

7. ACCEPTANCE CRITERIA:

7.1 Should be visually clean.

7.2 Should be free from visible particle and sub visible particle ≥ 10µ: NMT 25/ml
≥ 25µ: NMT 3/ml

7.3 For the product contact surfaces, the least MAR in the product grouping obtained shall be considered as acceptance chemical residue limit (as per **Annexure – 04:** Establishment of Acceptance Limits).

7.4 For the product non-contact surfaces such as external surface of equipment etc., an acceptance chemical residue limit of 100 PPM per swab shall be considered.

7.5 The acceptance limit for microbial load is as follows:

- Bacterial Endotoxin Test shall be < 0.125 EU/ml.
- Bioburden shall be less than <10 CFU / 100ml.

8. REVALIDATION CRITERIA:

Process to be revalidated in any of the following case:

8.1 Equipment change with different design specification.

8.2 Major modifications / changes to the equipments.

8.3 Change in the cleaning procedure.

8.4 Change in the manufacturing process.

8.5 Addition of new molecule.

8.6 MACO value decreased

8.7 **Periodic verification:**

8.7.1 Periodic verification shall be done once in a year (± 30 days) with product, precisely the worst case product to cover all the equipments for those equipment on which worst case product is not taken, consider the worst case product from the group of products sharing that equipment.

☞ *Periodic verification may consider the next worst product, in case the actual worst case has not been planned during the review period.*

☞ *Periodic verification shall be carried out as per approved protocol.*

9. OBSERVED NON-CONFORMANCE (IF ANY):

All the deviation discrepancy shall be addressed as per SOP “Reporting and Monitoring of Process Non-Conformance in the Automated Quality Management System Software”.

10. VALIDATION REPORT:

On completion of the cleaning validation, evaluation of the test results shall be carried out for achievement of the acceptance criteria. A summary report shall be prepared clearly stating the outcome of the cleaning validation against the predetermined acceptance criteria.

11. ABBREVIATIONS:

11.1	MACO	:	Maximum Allowable Carry Over
11.2	MAR	:	Maximum Allowable Residue
11.3	HPLC	:	High Performance Liquid Chromatography
11.4	NMT	:	Not More Than
11.5	BET	:	Bacterial Endotoxin Test
11.6	TDD	:	Therapeutic Daily Dose
11.7	MBS	:	Minimum Batch Size
11.8	SF	:	Safety Factor
11.9	cm^2	:	Centimeter Square
11.10	CFU	:	Colony Forming Unit
11.11	EU	:	Endotoxin Unit

11.12 PPM : Parts Per Million
11.13 LOQ : Limit of Quantitation
11.14 LOD : Limit of Detection
11.15 WFI : Water for Injection
11.16 API : Active Pharmaceutical Ingredient

12. LIST OF ANNEXURE:

Annexure No.	Annexure Title
01	Equipment product contact surface area calculation
02	Sampling location of equipment
03	Visual inspection for cleaning validation / verification
04	Establishment of Acceptance Limits
05	Equipment / equipment parts cleaning record

13. REFERENCE DOCUMENT (IF ANY):

13.1 Management of Validation/Qualification documents in DMS.
13.2 Quality Policy.
13.3 Cleaning Validation Programme.
13.4 Preparation of Validation and Qualification Protocol and its Control.

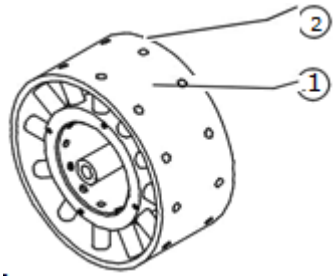
14. REVISION HISTORY:

Superseded Protocol		S. No.	Step No.	Changes made
Protocol No. / Version No.	Effective Date			

Annexure – 01: Equipment product contact surface area calculation

Equipment Name:	Vial Filling Machine	**ID No.:**	

POWDER WHEEL:



1.

DIA-231.8mm Base surface area= $2x3.14x115.9^2$
L-110mm = 84,400 sq mm

2.

DIA-10mm Base surface area = 2x3.14x5
L-62mm = 157.07 sq mm
Qty.-24 Lateral surface area=2x3.14x5x62
=1947.78 sq mm
Total surface area =2104.85 X24
=50,516.64

TOTAL CONTACT SURFACE AREA OF POWDER WHEEL-1,34,916.64 Sq.mm equal to **1349.16 Sq. cm**.

Done by (Sign/Date)	Checked by (Sign/Date)

Equipment Name:	Vial Filling Machine	**ID No.:**	

BUTTERFLY VALVE:

1.

DIA-98mm Base surface area= 2 x 3.14 x 49^2

L-104mm = 15,085.92 sq mm

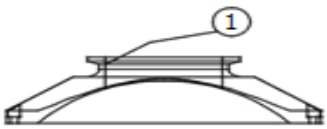
Lateral surface area=2 x 3.14 x 49 x 104

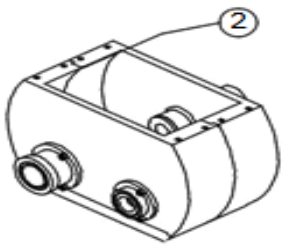
=32,019.11 sq mm

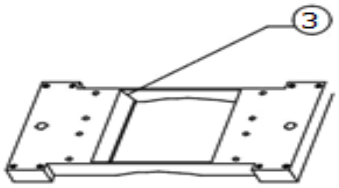
Total surface area =47,105.04sq mm

TOTAL CONTACT SURFACE AREA OF BUTTERFLY VALVE- 47105.04 Sq.mm equal to **471.05Sq. cm.**

HOPPER:







1.

DIA-70mm Base surface area = 2 x 3.14 x 35^2

L-24mm = 7669.9 sq mm

Lateral surface area = 2 x 3.14 x 35 x 24

= 5277.87 sq mm

Total surface area = 12,974.77sq mm

2.

DIA-200mm Base surface area = 2 x 3.14 x 100^2

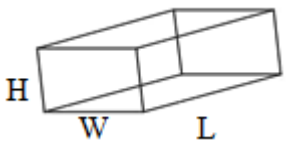
L-97mm = 62,831.85 sq mm

Lateral surface area = 2 x 3.14 x 100 x 97

= 60,976.89 sq mm

Total surface area = 1,23,778.75 sq mm

3.



L-103mm Surface area = 2x(103X97+103X20+97X20)

W-97mm = 27,982 sq mm

H- 20mm

TOTAL CONTACT SURFACE AREA OF HOPPER-1,64,735 Sq.mm equal to **1647.35Sq. cm.**

RUBBER STOPPER BOWL:

1.

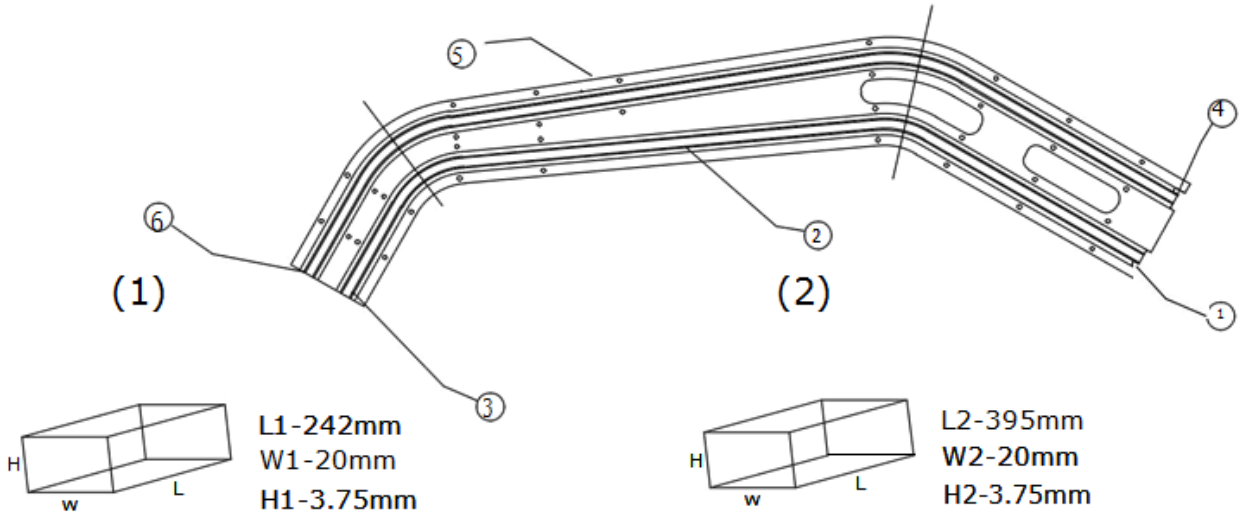
DIA1-287.89mm End surface area = 3.14 x (143^2 +288^2)
DIA2-579.00mm = 3,25,629.87 sq mm
L-188.600mm Lateral surface area = 3.14 x (143.9 +288) x $(143.9 -288)^2$+ $188)^{1/2}$
= 3,21,402.02 sq mm

TOTAL CONTACT SURFACE AREA OF RUBBER STOPPER BOWL- 6,47,031.94 Sq.mm equal to **6470.31Sq. cm.**

Done by (Sign/Date)	Checked by (Sign/Date)

Equipment Name:	Vial Filling Machine	ID No.:	

RUBBER STOPPER CHUTE:



Surface area
= 2x(242X20+242X3.75+20X3.75)
= 11,645 sq mm

Surface area
= 2x(395X20+395X3.75+20X3.75)
= 18,912.5 sq mm

Surface area
= 2x(100X20+100X3.75+20X3.75)
= 4900 sq mm

Surface area
= 2x(275X20+275X3.75+20X3.75)
= 13,212.5 sq mm

Surface area
= 2x(399X20+399X3.75+20X3.75)
= 19,102.5 sq mm

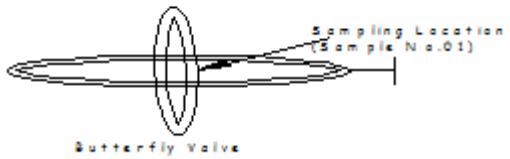
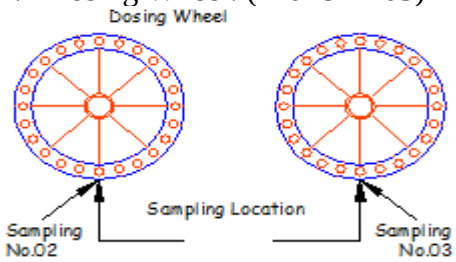
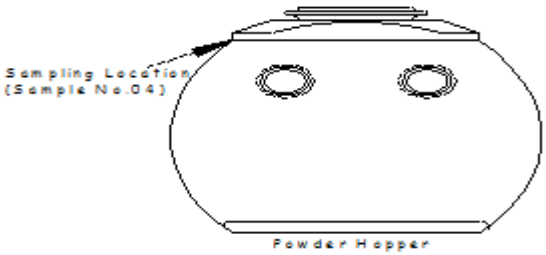
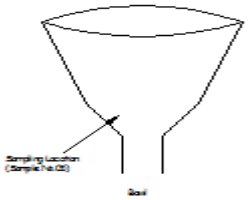
Surface area
= 2x(100X20+100X3.75+20X3.75)
= 4900 sq mm

TOTAL CONTACT SURFACE AREA OF RUBBER STOPPER CHUTE-72,672.5 Sq.mm equal to **726.72 Sq. cm**.

Done by (Sign/Date)	Checked by (Sign/Date)

Annexure – 02: Sampling location of equipments

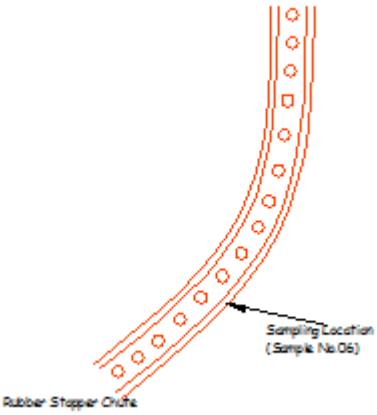
Equipment Name:	Vial Filling Machine	**ID No.:**	

Location Photo	**Location Identification & rational for selection**
1. Butterfly Valve: (L-01)  2. Dosing Wheel: (L-02& L-03)  3. Powder Hooper: (L-04)  4. Rubber Stopper Bowl: (L-05) 	L-01: Hard to clean area and physical verification is not feasible. L-02: Hard to clean area, maximum change of product deposition at dosing port and physical verification is not feasible. L-03: Hard to clean area, maximum change of product deposition at dosing port and physical verification is not feasible. L-04: Hard to clean area, physical verification is not feasible and maximum contact of product. L-05: Maximum time contact of rubber stopper

Done by (Sign/Date)	**Checked by (Sign/Date)**

Equipment Name:	Vial Filling Machine	**ID No.:**	

Location Photo	**Location Identification & rational for selection**

5. Rubber Stopper Chute: (L-06)  	L-06: Hard to clean area and physical verification is not feasible.

Done by (Sign/Date)	Checked by (Sign/Date)

Annexure – 03: Visual inspection for cleaning validation / verification

S.No.	Product Name/ Batch No.	Equipment Name	Equipment ID No.	Part Inspected	Visually clean (Yes/No)	Checked by Sign/Date

Annexure – 04: Establishment of Acceptance Limits

Product B →			Min Dose (mg)	Meropenem for Injection 500mg	Meropenem for Injection 1000mg	Imipenem & Cilastatin for Injection 250 mg	Imipenem & Cilastatin for Injection 500 mg	Doripenem for Injection 250 mg	Doripenem for Injection 500 mg	Worst Case Mar Value	Remarks
↓ Product A				**DOSE**	**DOSE**	**DOSE**	**DOSE**	**DOSE**	**DOSE**		
		Max. Dose (gm)		6000	6000	4000	4000	1500	1500		
		Batch Size (kg)		3	3	3	3	3.5	3.5		
	1	Meropenem for Injection 500mg	Surface Area			3467.6	3467.6	3467.6	3467.6		
			500			1.081	1.081	3.365	3.365	1.081	
	2	Meropenem for Injection 1000mg	Surface Area			3467.6	3467.6	3467.6	3467.6		
			500			1.081	1.081	3.365	3.365	1.081	
	3	Imipenem & Cilastatin fo Injection 25 mg	Surface Area	3467.6	3467.6			3467.6	3467.6		
			250	0.360	0.360			1.682	1.682	0.360	
	4	Imipenem & Cilastatin for Injection 500 mg	Surface Area	3467.6	3467.6			3467.6	3467.6		
			250	0.360	0.360			1.682	1.682	0.360	
	5	Doripenem Injection for 250 mg	Surface Area	3467.6	3467.6	3467.6	3467.6				
			250	0.360	0.360	0.541	0.541			0.360	
	6	Doripenem Injection for 500 mg	Surface Area	3467.6	3467.6	3467.6	3467.6				
			250	0.360	0.360	0.541	0.541			0.360	
		Minimum Value								**0.360 mg/swab**	

Annexure – 05: Equipment / equipment parts cleaning record

S.No.	Product Name/ Batch No.	Equipment /equipment part name	Equipment ID No.	WFI loop pressure	Cleaning		Cleaning done by (Sign/Date)	Checked by Sign/Date
					From	To		