PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL WASHING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Washing & Sterilizing Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL WASHING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL WASHING MACHINE	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Vial Washing Machine,** installed in the Washing and Sterilizing Room.
- This Protocol will define the methods and documentation used to qualify the Vial Washing Machine for PQ.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol. • Analytical Support (Microbiological Testing/Analysis).
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Washing Machine
Equipment	……..
Manufacturer's Name	Ambica Pharma Machines Pvt. Ltd
Model	……..
Supplier's Name	Ambica Pharma Machines Pvt. Ltd
Location of Installation	Washing & Sterilization Room

6.0 SYSTEM DESCRIPTION:

The Automatic High Speed linear External Vial Washing Machine is located in the Washing Room with restricted access.

INFEED TURN TABLE

Supporting Frame made out of rigid SS rectangle pipe structure having two compartments, one for all mechanical drives and other for infeed conveyor.

All drive gear boxes & pumps are securely mounted on frame for vibration free, balanced and rigid machine. Supporting frame designed to have complete balanced machine hence it does not call for any foundation. Load the Vials directly on Infeed Conveyor Belt.

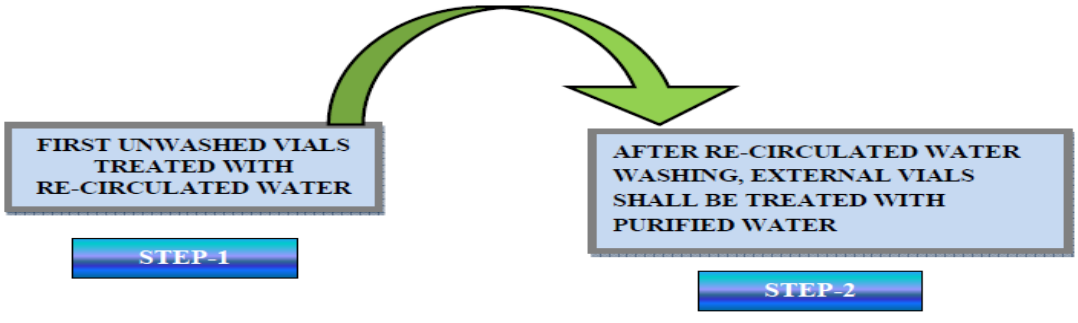
Infeed conveyor is in fine stainless steel wire mesh, move the Vials to the overturning drum, through Poly-pic Guides. An oscillating lever system known as wedge breaker assembly assists the Vials in entering the Vial Holders. System consists of two stainless steel link chains carrying the channels on which the Vial holders are mounted.

Shafts and sprockets imparting the inching movement to the chains in the washing area are also made of Stainless Steel and are supporting by the two anti-corodal shoulders. The chains are supporting by Poly-pic guide which does not need any lubrication. At the turning point of the chains at the unloading sides Vials leave their holders by gravity. The slide down short shaped chute until laying their bottom against arched supports called unloading platform. The erectors lift the upright Vials on output platform into the outfeed system. The shaped chute moves them along the arched supports lifting the Vials on the output platform. The outlet is on Platform is equipped with Poly-pic guides.

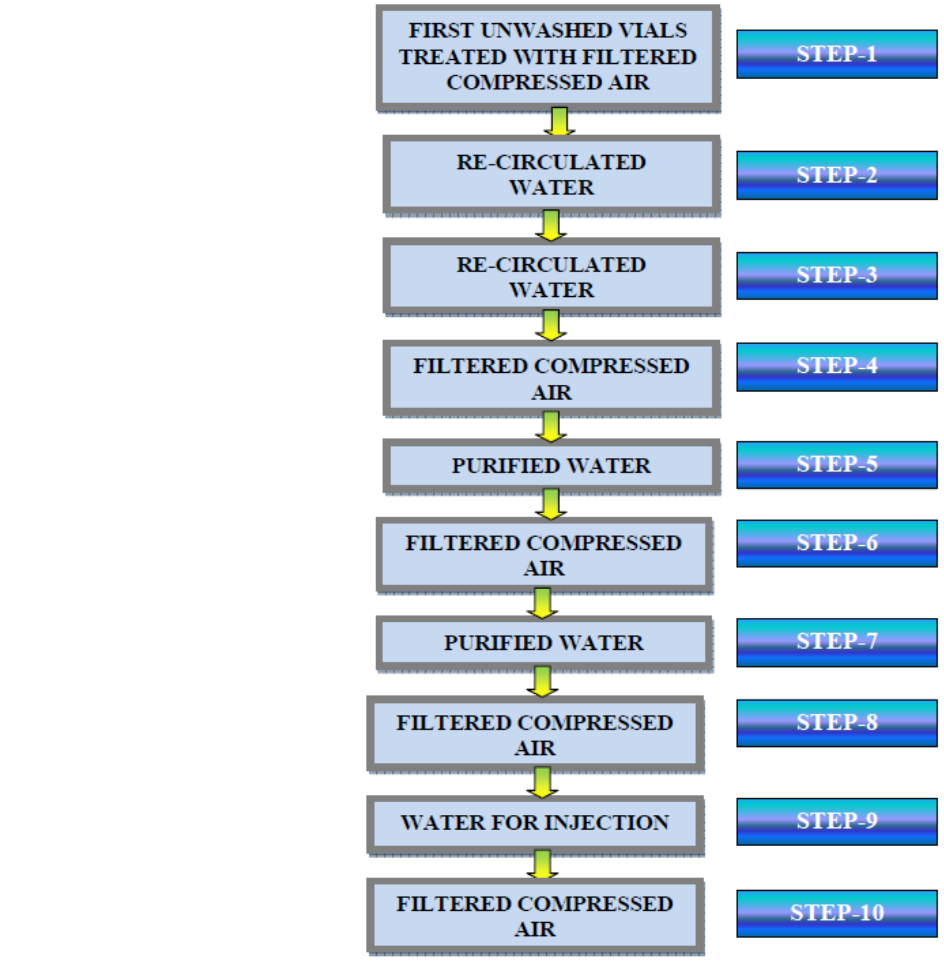
WASHING MACHINE

One of the main features of this machine is that all manifolds carrying the spray nozzles for internal wash are mounting on a vertically moving cart. It is possible to introduce the nozzles into the Vial neck for better cleaning of Vials. Also this additional movement is imparting by the same timing mechanism synchronized with all other movements over the full speed range of the machine.

EXTERNAL WASHING PROCESS:



INTERNAL WASHING PROCESS:



The external washing takes place by means of stationary manifolds carrying spray nozzles. The whole hydraulic circuit is in Stainless Steel. Except the flexible hoses connecting the moving parts is made of Teflon inner tube covered by S.S. braided wire. All manifolds are equipped with Globe valve. This Globe valves will operate only when nozzles enter the neck of the Vials. The entry of nozzles and its withdrawals are regulated through Solenoid Valves. All straight and reciprocating movements of the machine are synchronies by a single timing system.

1) Introduction of the Vials into the holders
2) Washing nozzle movement
3) Vials erecting movement

The rotary intermittent motion of the transport system is imparted by an indexing box that gives the time for the above three described movements. The timing is through limit switch which operates solenoid valves. The limit switches mounted on various places. Hence, it's synchronized with main conveyor. The numbers of strokes per minute are multiply by the fluids, before touching the Vials are filtered. According, to the porosity of the filtering cartridges. The filter housings are mounted in an extremely accessible position for easy cleaning, cartridge substitution and maintenance. Filter Cartridges are not part of the machine; same has to be purchased by the Customers.

The system includes:

1) Piping's.
2) Pumps.
3) Ball Valves.
4) Globe Valves.
5) Fittings.

Piping is assembled with S.S. ferrules and can be promptly dismantled in parts and easy to get cleaned. Pumps are sanitary type, without porosity, with mechanical seals. Globe valves are in S.S. with gaskets in Vi-ton. The piloting air is filtered, regulated and lubricated compressed air. The washing fluids are kept at constant level in the tanks by means of fully automatic gauges, float valves and level sensors. Washing liquids is pumped to the washing station through fine filters. S.S. Tanks are located underneath the washing section and mounted on castors to facilitate easy removal for cleaning and maintenance. The pressure of all fluids is measured by pressure gauges placed on top of the machine.

7.0 REASON FOR QUALIFICATION:

- New equipment in Washing & Sterilization Room.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Washing & Sterilization Room.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every year.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Vial Washing Machine.
- Preparation of SOP for Preventive Maintenance of Vial Washing Machine.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Vial Washing Machine.
- SOP for Preventive Maintenance of Vial Washing Machine.

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Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

VIAL FEEDING PROCEDURE DURING VIAL WASHING

FIGURE NO.-1

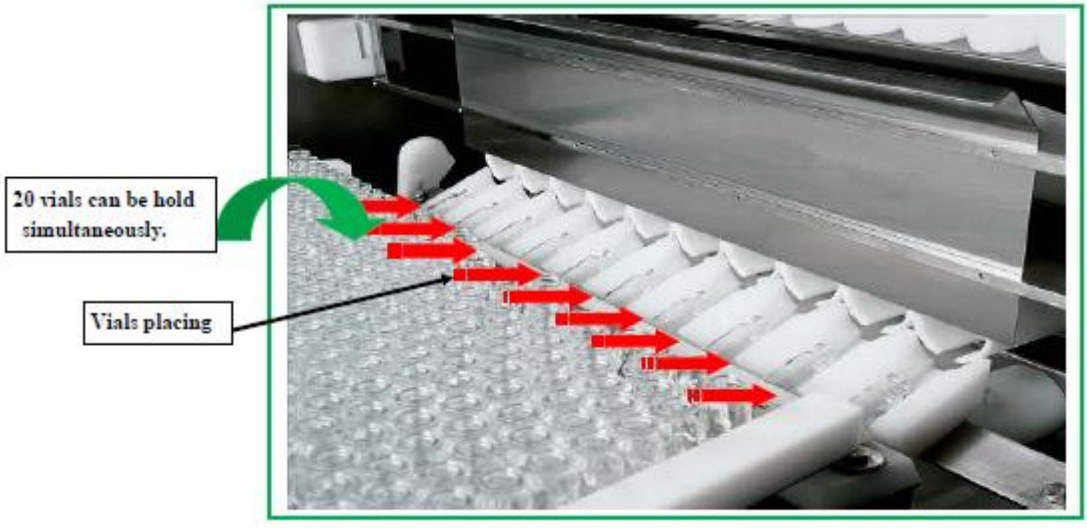
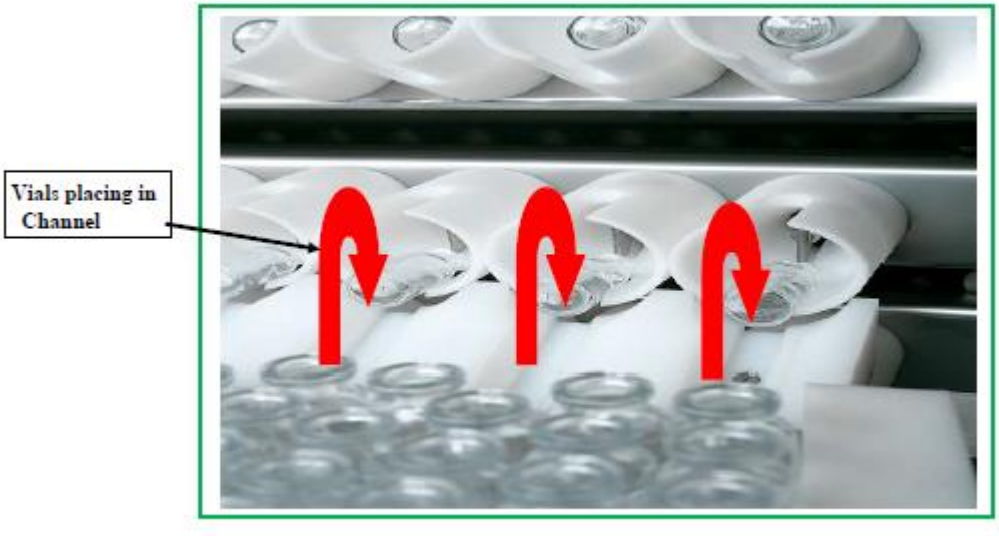


FIGURE NO.-2



11.2 Evaluation of Performance:

The following test parameters to be fixed for the below mentioned Checks:

S.No.	Cycle No.	Type of Load Vial Size	Set Machine Speed	Set Compressed Air Pressure	Set Re-circulated Water Pressure	Set Purified Water Pressure	Set Water For Injection Pressure
1.	I	7.5 mlm Colorless Moulded Vial	240 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
2.	II	7.5 ml Colorless Moulded Vial	240 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2
3.	III	7.5 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
4.	IV	7.5 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2
5.	I	10 ml Colorless Moulzed Vial	240 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
6.	II	10 ml Colorless Moulded Vial	240 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	2.0 Kg/cm^2
7.	III	10 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
8.	IV	10 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2
9.	I	20 ml Colorless Moulded Vial	240 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
10.	II	20 ml Colorless Moulded Vial	240 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	2.0 Kg/cm^2
11.	III	20 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2	2.0 Kg/cm^2
12.	IV	20 ml Colorless Moulded Vial	160 Vials/minute	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2	1.5 Kg/cm^2

11.2.1 Objective:

To evaluate and to provide documented evidences for performance of equipment for proper washing of vials. The objective of the test is to determine whether the machine is able to clean the containers and eliminate the contamination (Chemical Substances) from the container itself. This test shall be carried out for different-different vial size, employed for washing.

11.2.2 Checks for machine:

- Charcoal Test
- Chloride Content Test
- Glass Particle Test

11.2.3 Test & Method:

CHARCOAL TEST:

- Take 60 vials from each selected parameter and spike the vials with approximate 1mg of Activated Charcoal powder slurry made with 1 ml of WFI. The vials were swirled manually so that slurry uniformly coats the inner surface of vials. The solution was evaporated to dryness by heating the vials at 105°C in hot air oven for 1 hour; mark the vials by putting Teflon thread in the neck side.
- Load these marked vials along with similar sized vials in the in feed SS guide channel as per the Figure no.-1 & 2 (1 vial for each pocket).
- Operate the Vial Washing Machine as per current version of SOP.
- Tested vials shall have identification code & marked on it.
- Collect marked 20 vials from all 20 channels for Visual inspection test and liquid particle counts for Liquid Particle Counter after washing from the out feed conveyor.
- Visually inspect the vials against white and black background for the presence of any visible particulate matter. At the same time perform blank for the visual inspection also.
- For Liquid Particle Count Test, add 5 ml WFI in to 7.5ml vials, 8 ml WFI in to 10ml vials, 10 ml WFI in to 15ml vials, 15 ml WFI in to 20ml vials, 20 ml WFI in to 30ml vials, at 25°C, in each vial, poured WFI from all tested vials shall be combined in a cleaned container and tested in Liquid Particle Counter and simultaneously for Blank repeat the same procedure with good vials.
- Record the observation in Performance Qualification Report.

Acceptance criteria:

Visible particles	**:**	The vials should be free from visible particles.
Sub visible particles	**:**	$\geq$10 µ: Not more than 6000 $\geq$25 µ: Not more than 600

CHLORIDE CONTENT TEST:

- Prepare 5 liters of 10 % w/v a Standard Sodium Chloride Solution.
- Take 20 vials for each and spike the sodium chloride solution 0.1 ml. qty. for 5 & 7.5 ml. vial and 1 ml. qty. for 20 ml. or more than 20 ml. vials. Take out the vials and dry the vials in hot air oven at 105°C for at least 01 hours.
- Load these marked vials along with similar sized vials in the in feed SS guide channel as per the following pattern (1 vial for each pocket, refer figure no. 01 & 02).
- For the chloride identification test add 0.2 ml of 1.0M Silver Nitrate reagent plus 1ml dilute nitric acid in every vial and for Blank repeat the same procedure with good vials. Test passes if no opalescence or no turbidity is seen in all the vials including the blank also.
- Record the observation in Performance Qualification Report.

Acceptance criteria:

All individual Tested vials should be showing no turbidity or no opalescence after adding the above mentioned reagents.

GLASS PARTICLE TEST

- Take 20 vials for each and spike the vials with fine glass fragments; mark the vials by putting Teflon thread in the neck side.
- Load these marked vials along with similar sized vials in the in feed SS guide channel as per the Fig no.-1 & 2 (1 vial for each pocket).
- Collect one vial from each nozzle for Visual inspection after Washing from the out feed conveyor. For Visual Inspection, add 4 ml WFI in to 5ml vials, 8 ml WFI in to 10ml vials, 10 ml WFI in to 15 ml vials, 15 ml WFI in to 20 ml vials, 20 ml WFI in to 30 ml vials, at 25°C, in each vial.
- Visually inspect the vials for the presence of any glass fragments against white and black background.
- Record the observation in Performance Qualification.

Acceptance criteria:

The vials should be free from the glass particles (Visual inspection).

11.2.4 Sampling Plan:

Batch No.	Visual Inspection & Liquid Particle Count test		Chloride test		Glass particle test		Total sampled vials	Justification for sampling
	Sampling Stage	No. of Sampled Vials	Sampling Stage	No. of Sampled Vials	Sampling Stage	No. of Sampled Vials		
1st Cycle	Initially	20	Initially	20	Initially	20	60	To ensure proper washing of vials
	Middle	20	Middle	20	Middle	20		
	End	20	End	20	End	20		
2nd Cycle	Initially	20	Initially	20	Initially	20	60	To ensure proper washing of vials
	Middle	20	Middle	20	Middle	20		
	End	20	End	20	End	20		
3rd Cycle	Initially	20	Initially	20	Initially	20	60	To ensure proper washing of vials
	Middle	20	Middle	20	Middle	20		
	End	20	End	20	End	20		
4th Cycle	Initially	20	Initially	20	Initially	20	60	To ensure proper washing of vials
	Middle	20	Middle	20	Middle	20		
	End	20	End	20	End	20		

Note: Sample shall be drawn by each nozzle.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using test for sodium chloride and charcoal.

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."

14.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual
- Copy of SOP's
- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
SS	:	Stainless Steel
ID.	:	Identification