TITLE: EQUIPMENT CLEANING PROCEDURE

1.0 PURPOSE:

To lay down a procedure for cleaning of process Equipment.

2.0 SCOPE:

This procedure is applicable for batch to batch cleaning, periodical cleaning and product change over cleaning of Process Equipment at Discovery laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of the operator to follow the procedure.

3.2 Production in charge is responsible to monitor the activity.

4.0 DEFINITIONS: Nil

5.0 PROCEDURE :

5.1 **General Cleaning Instructions:**

5.1.1 Wear required personnel protective equipment, before start the cleaning ofequipment

5.1.2 Three types of cleanings shall be followed i.e. Batch to Batch Cleaning, Periodical Cleaning and Product change over cleaning.

5.1.3 Accessories shall be cleaned along with respective equipment or whenever required. Once the accessories are cleaned, the status shall be labeled along with sign and date.

5.1.4 After completion of cleaning, if the equipment is not used within 48 hours, the equipment shall be cleaned again as per batch to batch cleaning procedure and record the details in the respective equipment log book.

5.1.5 If the remnants are very sticky on inner surface of the equipment, tie the lint free cloth to a scrapper then swab the required areas.

5.1.6 After completion of preventive maintenance, follow the batch to batch cleaning procedure to clean the equipment.

5.1.7 After cleaning of equipment, Ensure that the equipment is dried by applying vacuum / Air / Nitrogen / steam to equipment jacket.

5.1.8 Record the details of cleaning in respective BPR and/ or equipment logbook and update the status board.

5.1.9 If equipment is proposed to use previous step/ stage of same product, equipment can be used after completion of batch to batch cleaning.

5.2 **Batch to Batch cleaning:**

5.2.1 The acceptable level of cleaning between batches of the same product and stage is to remove the previous batch carry over E.g. un-reacted /decomposed material, byproducts if any, solvents and other materials used in manufacturing is likely to affect the next batch quality.

5.2.2 Cleaning of product contact surface is conducted to remove gross accumulation of product and to ensure the mechanical functionality /use of the equipment.

5.2.3 Use the cleaning solvent / agent and its quantity for respective product and equipment given in the Annexure -01

5.2.4 After completion of cleaning, check the product contact surface visually to ensure the removal of previous batch gross accumulation and also check for any stains / pigments, if any.

5.2.5 If any abnormal stains / pigments / corrosive stains observed, the same shall be investigated and shall be cleaned based on conclusion of investigation.

5.2.6 The equipment status board and the equipment shall indicate the status after cleaning as ‘ready for use’.

5.2.7 After completion of every batch, the equipment shall be cleaned within 12 hours as per procedure defined in this SOP.

5.3 **Bags Cleaning (Between batches):**

5.3.1 If any filter bags (like Centrifuge bag, Nutsche filter bag, Pressure Nutsche filter bag, line filter bag, Candy filter bag, leaf filter …etc.) are present in that Equipment, shall be cleaned.

5.3.2 Wear PPE and take a dedicated Container / tub to clean the bag. Equipment / product dedicated cleaning containers / tubs shall be used for cleaning to avoid cross contamination.

5.3.3 Charge the required quantity of water and / or Solvent.

5.3.4 Dip the bag then wash. Remove the filter bag from container and squeeze the bag.

5.3.5 Transfer the Solvent / Water to respective places for discarding purpose.

5.3.6 Keep the filter bag on angular for drying. For centrifuge bags, place the bag in the centrifuge and spin the centrifuge to dry the bag.

5.3.7 Ensure the dryness of filter bag and keep in dedicated place or put /tie to the respective filter, if next batch of same product is planned in the same filter.

5.4 **Cleaning of Reactors**

5.4.1 Check the Equipment logbook and status board for status of reactor.

5.4.2 Switch on the reactor lamp then check the reactor visually for emptiness. If any previous batch residue present in the reactor, unload into a container for disposal.

5.4.3 Connect one end of the hose pipe to the reactor bottom valve and another end into the drain and open the bottom valve.

5.4.4 Splash the reactor walls, Agitator, Thermo well Pocket clamps, baffles, top dish and all other critical areas with water till all adhering material is completely removed.

5.4.5 If any sticky material is present in the reactor, scrap the material with the help of scraper (PP for Glass lined, SS for Stainless Steel).

5.4.6 Flush reactor walls, Agitator, Thermo well Pocket clamps, baffles, top dish and all other critical areas with respective cleaning solvent / agent.

5.4.7 If the reactor cleaned with the solvent, collect the solvent into the respective container. If the reactor was cleaned with water, allow the washed water to drain completely.

5.4.8 Close the bottom valve and / or keep the hose pipes in their respective places.

5.4.9 Clean outer surface of the equipment with wet cloth moistened with water / solvent.

5.4.10 Clean the accessories of the reactor like scoop, sampler and affix the status label.If accessories are used in between the process, the same shall be cleaned as per requirement.

5.4.11 Ensure visually that the previous batch residues are removed and no abnormal stains / pigments present on product contact surfaces.

5.4.12 If the cleaning is not satisfactory, repeat the above operations till all adhering residues are removed.

5.4.13 Once the cleaning is completed, close the manhole, bottom valve and other valves and switch off the reactor light.

5.4.14 Update the equipment status as “Ready for use”. Enter the cleaning details in equipment log book

5.5 **Cleaning of Centrifuges:**

5.5.1 Open the centrifuge lid and ensure that the centrifuge is empty then remove the bag.

5.5.2 Clean the bag as defined above and check the bag for any damage, if damaged

replace with new one and record the details in BPR.

5.5.3 Splash the centrifuge walls, dish, basket, nozzles and all other critical areas with water till all adhering material is completely removed and drain the water from mother liquor collecting tub.

5.5.4 Splash the centrifuge walls, dish, basket, nozzles and all other critical areas with solvent and collect the solvent from Mother Liquor tub for disposal.

5.5.5 Ensure visually that the previous batch residues are removed and no abnormal stains / pigments present on product contact surfaces.

5.5.6 Place the Centrifuge bag in a centrifuge and spin for 5-10 minutes to dry.

5.5.7 Keep the centrifuge bag in polyethylene bag and store in container or place the bag in centrifuge and close the lid, if next usage is planned.

5.5.8 Clean the accessories like scoop, bag cleaning container, charging line and affix the status label.

5.5.9 Once the cleaning is satisfactory, update the cleaning details in equipment log and change the status as “Ready for use”.

5.6 **Cleaning of Tray Driers&Vacuum Tray Drier:**

5.6.1 Check the Equipment logbook and status board for status.

5.6.2 Open the dryer door and pull out the trolley containing empty trays from air tray drier then take out trays from trolley and for vacuum tray drier take out the empty trays from chamber.

5.6.3 Wipe the chamber,grills, Tray stand (ATD), Tray holding plates (VTD) and other areas with clean cloth, which is wet with water and/or suitable solvent till all adhering material is removed.

5.6.4 Wipe the drier chamber, Tray stand, Tray holding plates and other areas with clean cloth, which is wet with water and/or suitable solvent till all adhering

material is removed.

5.6.5 Put the each tray vertically in a tub; clean the tray with water and/or suitable solvent till all adhering material is removed.

5.6.6 Wash the trays with suitable solvent then revert the trays and place the trays in tray stand or tray holding plate.

5.6.7 Place the trolley stand in drier firmly and close the door.

5.6.8 Start the drier to dry the trays for 5 to 10 minutes. If required apply steam.

5.6.9 Open the drier and check visually that the previous batch residues are removed and no abnormal stains / pigments present on product contact surfaces.

5.6.10 Clean the drier area and accessories like scoop, sampler and affix the status label.

5.6.11 Once the cleaning is satisfactory, update the equipment log and change the status as “Ready for use”.

5.7 **Cleaning of Rotary Cone Vacuum Drier (RCVD):**

5.7.1 Check the Equipment logbook and status board for status.

5.7.2 Open the inter lock system, which is connected the RCVD.

5.7.3 Open the charging manhole and ensure that the Rotary cone vacuum dryer is empty.

5.7.4 Open the cyclone separator bottom valve, collect the condensate, if any.

5.7.5 Flush inside with water till all adhering material is completely removed then collect the water for disposal or charge water and close the charging port then rotate for 5-10 min and discard the water by opening the port.

5.7.6 Wash the RCVD with solvent and collect the washed solvent for disposal. Check the vacuum bulb bag for any damage by using torchlight, If damaged replace with new one and record the details.

5.7.7 Close the RCVD and dry by applying vacuum / purge with Nitrogen.

5.7.8 Clean the drier area and also accessories like scoop, sampler then affix the status label on accessories.

5.7.9 Open and check visually by using light that the previous batch residues are removed and no abnormal stains / pigments present on product contact surfaces.

5.7.10 If the RCVD cleanliness is not satisfactory repeat the above operations up to satisfactory level.

5.7.11 Once the cleaning is satisfactory, close the charging and discharge ports and cyclone separator bottom valve. Enter cleaning details in equipment logbook and update the status as "Ready for use".

5.8 **Cleaning of Multi Mill:**

5.8.1 Switch off the power supply and open the clamp of multi mill dish and remove the mesh and blades.

5.8.2 Clean the mesh, blades and dish with water till adhering material is removed.

5.8.3 Wash the multi mill blades, dish and mesh in water /suitable solvent.

5.8.4 Check the condition of the mesh, if damaged replace with new one. Record the details in respective BPR.

5.8.5 Wipe the Multi mill outer surface and other areas with dry cloth.

5.8.6 Collect the washed water/solvent in a container and send for disposal.

5.8.7 Dry the multi mill parts by flushing with air / nitrogen.

5.8.8 Ensure visually that the previous batch material is removed and no abnormal stains / pigments present on product contact surfaces.

5.8.9 If the cleaning is not satisfactory repeat above operations.

5.8.10 Once the cleaning is completed, rearrange the mesh and dish and fix the

clamp. Record the details in equipment log and change the status board as "Ready for use".

5.9 **Cleaning of Nutsche Filter:**

5.9.1 Open the Nutsche filter lid.

5.9.2 Unload the salt / carbon/Hyflo/material from Nutsche filter into bags, if any and affix the label with details send it to disposal area.

5.9.3 Remove the bag from Nutsche filter.

5.9.4 Clean the Nutsche filter with Water to remove gross accumulations of material.

5.9.5 Clean the Nutsche filter with water followed by solvent, if any

5.9.6 If the cleaning is with solvent, unload it into respective container and if it is with water drain it.

5.9.7 Clean the Nutsche filter bag with Water / solvent to remove gross accumulations of material as per procedure defined above.

5.9.8 Check the Nutsche filter bag for any damage. If any damage is observed replace it with new one.

5.9.9 Clean the accessories like scoop along with equipment and put the status label.

5.9.10 Ensure that the Nutsche filter is cleaned to remove all adhering material.

5.9.11 If the cleaning is not satisfactory repeat above operations.

5.9.12 Keep the Nutsche filter bag in polyethylene bag and store in its respective place.

5.9.13 Update the cleaning details in respective equipment logbook and update the status as "Ready to use".

5.10 **Cleaning of Pressure Nutsche Filter:**

5.10.1 Ensure that the pressure in the Nutsche filter is zero. Open the manhole of the Pressure Nutsche filter.

5.10.2 Unload the carbon/Hyflo/material from Nutsche filter into bag and label with details.

5.10.3 If carbon/Hyflo/material is used again then store in respective place with proper labeling and if it is not required, send it to disposal area.

5.10.4 Remove the filter cloth from Pressure Nutsche filter. Clean the pressure Nutsche filter bag with water followed by solvent.

5.10.5 Check the filter cloth for any damage. If any damage is observed replace it with new one and record the details in bag changing record.

5.10.6 Clean the pressure Nutsche filter with water to remove gross accumulations of material.

5.10.7 Clean the pressure Nutsche filter with solvent.

5.10.8 Clean the accessories like scoop along with equipment and put the status label.

5.10.9 If the cleaning is with solvent, unload it into respective container and if it is with water drain it.

5.10.10 Ensure that the pressure Nutsche filter is cleaned. If the cleaning is not satisfactory repeat above operations.

5.10.11 Keep the filter cloth in polyethylene bag and store in its respective place.

5.10.12 Update the equipment log with cleaning details and also update the status as “Ready to use”

5.11 **Cleaning of Leaf Filter, Candy filter :**

5.11.1 Open the filter.

5.11.2 Unload the salt / carbon into a bag and affix the label with details and send for

disposal.

5.11.3 Wash the filter inside, outside and bag with Water till adhering material is removed.

5.11.4 Wash the filter inside, outside, Bag with Suitable Solvent.

5.11.5 Check the bags for any damage, if damaged replace the bag with new bag.

5.11.6 After completion of cleaning, check Filter for cleanliness.

5.11.7 If the cleaning is not satisfactory repeat above operations.

5.11.8 If cleaning is satisfactory, update the cleaning details in equipment log book and update the status as "Ready to use"

5.12 **Cleaning of Micro Filter:**

5.12.1 Check the Micro Filter

5.12.2 Open the Micro Filter and Remove the Cartridge, wash with Water both Micro Filter & Cartridge.

5.12.3 After Cleaning with water Dry the Micro Filter & Cartridge with Suitable Solvent.

5.12.4 After completion of cleaning, check the micro filter for cleanliness.

5.12.5 If the cleaning is not satisfactory repeat above operations.

5.13 **Cleaning of Blender:**

5.13.1 Open the charging port.

5.13.2 Adjust the manhole to downward position by rotating the blender by pushing "ON" and "OFF" buttons.

5.13.3 Wash inside of the Blender with water till adhering material is removed.

5.13.4 Charged suitable solvent into the blender and close the ports and rotate for 5-10 min then collect the solvent for disposal.

5.13.5 Clean the outer surface of the blender, stand and other areas with wet cloth

moistened with water / solvent.

5.13.6 Rotate the blender till it becomes dryand check visually by using light that the previous batch residues are removed and no abnormal stains / pigments present on product contact surfaces.

5.13.7 Clean the drier area and also accessories like scoop, sampler then affix the status label on accessories.

5.13.8 If the cleaning is not satisfactory repeat above operations.

5.13.9 Once the cleaning is satisfactory completed, change the status as “Ready for use” and recordthe details in respective record like equipment log book.

5.14 **Cleaning of Sifter:**

5.14.1 Check whether the sifter is empty.

5.14.2 Remove the sifter mesh then clean with water till all adhering material is removed

5.14.3 Clean the sifter inner side with required quantity of Solvent.

5.14.4 Dry the mesh (if required Nitrogen can apply to dry the mesh) and Check the integrity of the mesh, if damaged replace with new one.

5.14.5 Wipe the sifter outer surface and other areas with cloth till all adhering material is completely removed

5.14.6 Collect the washed water / solvent in a container and send for disposal.

5.14.7 Allow the sifter to dry and Check for cleanliness of the sifter.

5.14.8 If the cleaning is not satisfactory repeat above operations.

5.14.9 If the cleaning is satisfactory change the status card as “Ready to use”.

5.15 **Cleaning of Receiving Tank/Charging Tank/Storage Tank / Holding Tanks:**

5.15.1 Ensure the tank is empty.

5.15.2 If the tank is dedicated for single solvent / chemical, the tank need not be cleaned for every usage. The cleaning frequency shall be defined in respective Batch production record.

5.15.3 If tank required to cleanbetween batches of the same product and stage, clean the tank by charging required quantity of solvent / water by applying vacuum.

5.15.4 Apply the vacuum to the tank and bump solvent in the tank by slightly opening the bottom valve of the tank then release the vacuum and unload the solvent.

5.15.5 If the tank is used for multiple solvent / chemical purpose for the same stage of the product, the tank shall be cleaned as per below procedure.

5.15.5.1 Open the manhole of tank and bottom valve of the tank and ensure it is empty.

5.15.5.2 Flush the tank with water till all adhering material is completely removed. Check the washed water for clarity. Continue the flushing till water is clear.

5.15.5.3 Flush the tank with suitable solvent and check the solvent for clarity.

5.15.5.4 Close the manhole, bottom valve of tank.

5.15.5.5 Apply nitrogen / vacuum till it becomes dry.

5.16 **Periodical cleaning:**

5.16.1 Periodical cleaning shall be followed, where continuous manufacturing of same product in the respective equipment. i.e. full cleaning shall be performed after completion of 30 ±5 batches or 45 days, whichever is early by following the product change over cleaning record.

5.16.2 To perform periodical cleaning, follow the same procedure as product change over cleaning and does not required sampling as the same product is going to manufacture in the respective equipment.

5.17 **Product Change Over:**

5.17.1 Product change over cleaning shall be performed where the equipment is proposed to use for another product, in which full cleaning shall be performed to remove the previous product residues up to an acceptable limit.

5.17.2 The step wise cleaning procedure for product change over cleaning shall be defined in the respective equipment cleaning record (ECR).

5.17.3 Product change over cleaning solvent and periodical cleaning solvent quantity and rinse solvent details are defined in annexure -01. The annexure shall be revised as when new product is added.

5.17.4 Since the Company is involved in manufacturing of starting materials and basic intermediates, a general acceptable residue limit of 100 ppm shall be considered as acceptable limit for product change over.

5.17.5 **Note:** The limit is considered as 10 times lower than the identification threshold (0.10% of 1.0mg) of impurities as per ICH Q3A; where up to 0.1% (1000ppm) of unknown individual impurity may be present in the product being tested.

5.17.6 Visual cleanliness checking shall be considered as other acceptable criteria for cleaning along with sampling & testing.

5.17.7 The Equipment status shall be defined as “Cleaned” once both visual and sampling criteria meets the requirement

5.17.8 A stringent limit shall be applied for intermediate stages especially close to final API based on assessment.

5.17.9 Cleaning procedures shall be validated with minimum of 3 cleaning runs.

5.17.10 The cleaning validation protocol shall be included with cleaning solvent / agent.

5.17.11 Sampling procedure / locations with justification.

5.17.12 **Selection of Cleaning Agent:**

The product to be removed should be soluble in the selected cleaning agent.

The cleaning solvent / agent should not degrade the product.

The cleaning solvent / agent should be compatible with the equipment.

The cleaning solvent / agent should not cause environment/health hazards.

The cleaning solvent / agent should not be a contaminant for subsequent product.

The cleaning solvent / agent must be safe to handle and easily available.

5.17.13 **Equipment Cleaning Procedure:**

5.17.13.1 Equipment cleaning procedure (ECR) shall be prepared respective equipment wise and procedure shall be defined in sequential steps e.g. pretreatment, disassembly, wash or rinse cycles, drying, reassembly and storage.

5.17.13.2 Define all cleaning process key variables to deliver a consistent cleaning process. The procedure shall include:

a. Specifying cleaning agent, total quantity
b. Specifying water quality, if the cleaning agent is water
c. Concentration and temperature of the cleaning agent where applicable

d. Where equipment is washed, number of wash cycle, volume of wash cycle to be established.

e. Where equipment is rinsed, the rinsing is done for product contact surfaces. The time of the contact, temperature of the rinse and volume of the rinse is established and specified.

f. Where method of cleaning is manual include details such as use of brush or hand scrubbing, use of hand spray or jets etc.

5.17.13.3 **First step (removing gross accumulations):**

a. Remove the gross accumulations of the previous manufactured product with suitable cleaning agent.

b. Disassemble the equipment.

c. Clean all the disassembled parts as per procedure and assemble allSpare parts

5.17.13.4 **Second Step (Washing of the Equipment):**

a. Perform actual washing of all product contact surface areas.

b. Wash the equipment with sufficient quantity of the cleaning agent.

c. Reflux / Boil with cleaning agent

5.17.13.5 **Third Step (Initial rinses):**

a. Flush the entire equipment surface area thoroughly (Product Contact) ex: Inner top dish of the reactor, piping etc., with the fixed volume of the cleaning agent.

5.17.13.6 **Fourth Step (Second rinse / Final rinse):**

a. Rinse the entire equipment surface area thoroughly (ProductContact) ex: Inner top of the reactor, piping etc., with

the fixed volumeof the cleaning agent.

b. Check the equipment for visual cleanliness before collecting the Rinseand Swab samples to QC for analysis.

5.18 **Procedure to check the visual cleanliness of the equipment :**

5.18.1 Check the equipment logbook whether the equipment is cleaned or not.

5.18.2 Switch on the equipment lamp, if present or use torchlight

5.18.3 Open the manhole /door / lid of respective equipment. If it is miller, open all parts of the miller if they are fixed.

5.18.4 Visually check the all product contact surfaces to ensure all previous product residues are removed completely.

5.18.5 Visual inspection shall be carried out by visually checking all the critical areas of the equipment. Use torch light and / or by swabbing the accessible areas with white and / or black cloth.

5.18.6 Check for any residue stains / pigments on surface of the equipment and other product contact surfaces.

5.18.7 For equipments that are completely dismantled for cleaning like sifter, miller, centrifuge, tray dryer etc., shall be visually inspected for cleanliness before assembling.

5.18.8 For reactor, whichever parts are removed for cleaning like Nozzles, bottom valve etc., visual inspection shall be done individually before fixing it and the reactors shall be visually inspected for cleanliness using the light available in the reactor.

5.18.9 The cleanliness status as “Cleaned” shall be entered in the Batch Cleaning record and status board.

5.19 **Sampling techniques:**

Use the Following sampling techniques for collecting the samples from the equipment for product change over

5.19.1 **Rinse sampling**:

5.19.1.1 Use rinse sampling technique for large vessels, hoses etc., (Reactors, pumps, big equipment etc.,)

5.19.1.2 Rinse the entire equipment surface area with fixed quantity of the cleaning agent.

5.19.1.3 Take cleaned and dried sample bottle and collect the sample from theequipment.

5.19.2 **Swab Sampling:**

5.19.2.1 Use swab sampling technique, wherever equipment Surface area is accessible for swabbing. Swab locations shall be selected based on accessibility and critical to clean areas.

5.19.2.2 Direct surface sampling is preferred sampling option, where hard to clean areas are present in equipment and product residues that are dried out.

5.19.2.3 After unloading final rinse from the equipment, collect the swab sample from selected areas(wherever possibility of more residue).

5.19.2.4 Swab location selection shall be detailed in respective Equipment cleaning record and validation protocol.

5.19.2.5 The process equipment wise swab locations shall be identified and shall approve by quality.

5.19.2.6 Take sufficient fixed quantity of disorbent to collect the swab sample.

5.19.2.7 Disorbent used for swab sampling shall be the cleaning agent in

finalrinse.

5.19.2.8 Use a swab of suitable type and size to collect the swab sample from the equipment surface in the area of 10cm X 10cm (If swabbing from 10cm X 10cm area is not possible, then swab the required area and calculate the swab limits accordingly).

5.19.2.9 Swab a portion of sampling area vertically in top to bottom and dip into the disorbent. Squeeze the swab to press out disorbent. Repeat the sameoperation to cover the sampling area selected. Collect the sample in horizontal direction from right to left as mentioned above in the same area.

5.19.2.10 Swab defined sampling points and collect the sample in a cleaned sample bottle and send for analysis

5.19.3 **Selection of Swab Sampler:**

5.19.3.1 Swab shall be compatible with the product.

5.19.3.2 Swab should not cause degradation of product.

5.19.3.3 It should allow extraction of the compound for analysis.

5.19.3.4 Swab should not release fibers

6.0 FORMATS / ANNEXURE(S):

6.1 Annexure-01

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	11.12.2012	New SOP is introduced.	----
01	01.03.2014	Vacuum Tray Drier, Pressure Nutche Filter, Blender and Leaf Filters are periodically cleaning is introduced. Vacuum Tray Drier and Pressure Nutche Filters are product change over cleaning is introduced. Used Qty of cleaning media solvent are revised.	----

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Sk. Saleem Basha	K.V. Ramana Reddy	N. Sreedhar
Department	Production	Production	Quality

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
02	20.07.2014	Centrifuge bags cleaning procedure included, Storage tanks cleaning procedure introduced.	----
03	07.11.2014	MTV2HCL,5,6,7,8-Tetrahydro-naphthalene-1,6,7-Triol, 2,2-Dimethyl-3A,4,9,9A-Tetrahydro-naptho[2,3-D][1,3]dioxol-5-ol were included.	----
04	03.03.2016	Revised as per more clarity on cleaning procedure, PD-001, PD-038 & PD-047 SOPs was included.	----
05	01.01.2017	Equipment Cleaning Procedures incorporated.	PD-CRF-024/16
06	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/ GEN/ 17035
07	30.05.2019	1. The status for batch to batch cleaning is defined as “Ready for use”. 2. The “Cleaned” status shall be applicable for full cleaning. 3. Cleaning agent selection criteria is defied in the procedure. 4. Swab locations identification and its pre-approval requirements defined in the procedure. 5. The acceptable criteria for full cleaning is defined based general threshold limit for intermediate manufacturing.	CCF/ GEN/ 19020

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Sk. Saleem Basha	K.V. Ramana Reddy	N. Sreedhar
Department	Production	Production	Quality