HOLD TIME STUDY PROTOCOL

FOR

DIRTY EQUIPMENTS

Protocol No.	
Supersedes	**Nil**
Protocol Effective Date	
Report Effective Date	

DIRTY EQUIPMENT HOLD TIME STUDY PROTOCOL CUM REPORT

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DIRTY EQUIPMENT HOLD TIME STUDY PROTOCOL CUM REPORT

1.0 PRE-APPROVAL:

PREPARED BY:				
DEPARTMENT	**NAME**	**DESIGNATION**	**SIGNATURE**	**DATE**
QUALITY ASSURANCE				
CHECKED BY:				
DEPARTMENT	**NAME**	**DESIGNATION**	**SIGNATURE**	**DATE**
MICROBIOLOGIST				
QUALITY CONTROL				
PRODUCTION				
APPROVED BY:				
DEPARTMENT	**NAME**	**DESIGNATION**	**SIGNATURE**	**DATE**
QUALITY ASSURANCE				

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2.0 OBJECTIVE:

The objective of this protocol is to lay down a procedure for carrying unclean equipment Hold time study and to establish the stabilization period for hold time for Dirty equipment or vessel of Tablet manufacturing facility.

3.0 SCOPE:

This Protocol is applicable in cleaning validation for Dirty Equipment used in Tablet manufacturing facility. The Samples of Dirty Equipment subjected to Hold Time Study shall be stored under simulated conditions and shall be analyzed as per the established specifications at different time points of study as specified.

Microbiological methods for testing of Dirty Equipments have been satisfactorily adopted into the Microbiology laboratory.

4.0 RESPONSIBILITY:

Departments	Responsibilities
Quality Assurance	• Monitoring of protocol completeness, accuracy, technical excellence and applicability. • Preparation of Protocol. • Review of Protocol. • Approval of Protocol. • To review analytical reports & Compilation.
Production	• To review the Protocol & report. • Cleaning of equipment & control on equipment during hold time study • To provide details of equipments.
Quality Control	• To review the Protocol & Report. • Microbial sampling • Analyzing the samples withdrawn during the execution of the protocol • Preparation of raw data of analysis. • Submission of data to QA and review of final report.

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5.0 SELECTION OF DIRTY EQUIPMENT FOR HOLD TIME STUDY

The following Dirty Equipments matrix is described in **Table No. 1.**

S.No.	EQUIPMENTS NAME	EQUIPMENTS ID
01	Mass Mixer	
02	FBD Bowl	
03	Paste Kettle with Binding Scoops	
04	Sieves	
05	Coating Solution Tank (SS)	
06	Coating Pan	
07	Compression Machine	
08	De-Duster	
09	Colloidal Mill	
10	Multi-Mill	

6.0 EXPERIMENTAL PLAN:

6.1 Hold Time for Dirty Equipment:

S.No.	Hold Time Interval	Experimental Study	Test to be performed	Acceptance Criteria
01	0 Hrs.	To set a time frame in which the dirty equipments can be reuse for process safely.	Microbial	To monitor & Establish Limit for Microbial Counts.
02	12 Hrs.		Microbial	
03	24 Hrs.		Microbial	
04	48 Hrs.		Microbial	
05	72 Hrs.		Microbial	
06	96 Hrs.		Microbial	

7.0 SAMPLING PROCEDURE:

- Use the sterile Swab Sticks, mask, gloves and marker for the collection of sample from Dirty Equipments**.**
- Sample shall be collected aseptically.
- During sampling should wear gloves and mask.
- Take the microbial sample from the Dirty Equipment by using the sterilized Swab Sticks.
- Take the micro sample from a swab area of 5 X 5 Inch
- After completion of sampling immidiatelly place the swab stick into the solvent and close the test tube properly. Write the Name of the sample, Equipment ID No., sampled by and date of sampling on the suitable label.
- Sample shall be collected individually on the time interval as defined in above experimental plan.
- Each and Every time the sample collected on the different time intervals should be from different location.

7.1 Swab sampling Location:

Sampling shall be carried out as per current version of SOP. Microbial sampling location shall be different from each other. The locations from where, swab sample is to be taken is identified are in **Annexure-I.**

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8.0 MICROBIOLOGICAL ANALYSIS TESTING PROCEDURE:

Method	Pour Plate Analysis Method
Solvent	Purified Water
Media	Sterile Soybean Casein Digest Agar (SCDA), Sterile Sabouraud Dextrose Agar (SDA)
Glass Wares	Petri dishes, Sterile Tip (1.0 ml), Sterile 1 ml Micro Pipette, Sterilized Tip Box and Sterilized Gloves.

8.1 Method:

- Prepare the required quantity of Soyabean Casein Digest Agar and Sabouraud Dextrose Agar as per respective SOP.
- Analyzes the media for Growth Promotion Test as per respective SOP.
- Arrange all the materials like sample, Media, Petriplates, Tip Box etc in the Microbial Limit Test Room.
- Take 1 ml of sample from test tube and pour into petri plate for Bacterial count and for fungal count separately, pour media in this petri plates and incubate the plates at defined temperature for microbes and for fungus.
- Take 10 ml of sample solution from above test tube and pour into a test tube, than add 90 ml of pathogen medium in the test tube and incubate the test tube at defined conditions according to SOP.
- After completion of incubation period, observe the plates for Bacterial, Fungal and Pathogen count and record the results in **Annexure II**.

9.0 ACCEPTANCE CRITERIA:

S.No.	Tests	Limits
01	**Microbial Limit test**	
	A. Total viable aerobic count	
	Aerobic bacteria	NMT 10^2 cfu/ml
	Fungi	NMT 10^1 cfu/ml
	B. Pathogens	
	1. *E. coli*	Absent
	2. *Salmonellae*	Absent
	3. *Staphylococcus aureus*	Absent
	4. *Pseudomonas aeruginosa*	Absent

10.0 DEVIATION AND CHANGE CONTROL:

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11.0 DATA RECORDING:

Annexure I: Sampling Plan for Dirty Equipment

Annexure II: Data Recording for Microbes, Fungus and Pathogen Count.

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12.0 SUMMARY AND CONCLUSION:

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13.0 REPORT APPROVAL:

COMPLIED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

REVIEWED & CHECKED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				
QUALITY CONTROL				
PRODUCTION				

APPROVED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

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14.0 ABBREVIATION:

QA	:	Quality Assurance
cfu	:	Colony Forming unit.
hrs	:	Hours
ml	:	Milliliter
SOP	:	Standard Operating Procedure
SS	:	Stainless Steel
QC	:	Quality Control
DHT	:	Dirty Hold Time
SDA	:	Sabouraud Dextrose Agar
SCDA	:	Soyabean Casein Digest Agar
NMT	:	Not More Than

15.0 REVISION HISTORY:

S. No.	Effective Date	Revision No.	Reason for Revision
1.		00	New

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ANNEXURE I

SAMPLING PLAN FOR DIRTY EQUIPMENTS

Microbial Swab Sampling				
S. No.	**Name of the Equipment**	**Location**	**Sample Name**	**No. of Swab Location**
1.	Mass Mixer	Blades	S1	3
		Bowl	S2	
		Lid	S3	
2.	FBD Bowl	Inner wall	G1	3
		Cone wall	G2	
		Sieves	G3	
3.	Paste Kettle with Binder Scoop	Inner wall	P1	3
		Bottom wall	P2	
		Scoop Surface	P3	
4.	Sieves	Upper Surface	F1	2
		Lower Surface	F2	
5.	Coating Solution Tank (SS) with Stirrer	Inner wall	C1	3
		Lid	C2	
		Bottom wall	C3	
6.	Coating Pan	Inner wall	V1	2
		Spray Gun	V2	
7.	Compression Machine	Hopper	T1	3
		Discharge Chute	T2	
		Turret	T3	
8.	De-Duster	Discharge Chute	D1	2
		Perforated Plate	D2	
9.	Colloidal Mill	Inlet wall	M1	3
		Outlet Wall	M2	
		Turbo Homonizer	M3	
10.	Multi-Mill	Inlet Wall	Q1	3
		Middle Cabinet	Q2	
		Blades	Q3	

PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE II

Data Recording for Microbes, Fungus and Pathogen count for Dirty Equipments

Product Name ……. **Batch No. ……**

Equipment Name…… **Equipment ID No. …….**

S. No.	Tests	Limits	0 hours	12 hours	24 hours	48 hours	72 hours	96 hours
01		Microbial limit test						
		A. Total viable aerobic count						
	Aerobic bacteria	NMT 10^2 cfu/ml						
	Fungi	NMT 10^1 cfu/ml						
		B. Pathogens						
	1. *E. coli*	Absent						
	2. *Salmonellae*	Absent						
	3. *Staphylococcus aureus*	Absent						
	4. *Pseudomonas aeruginosa*	Absent						