PROTOCOL FOR EVALUATION OF EQUIPMENT & UTILITY RE-QUALIFICATION TO ESTABLISH THE RE-QUALIFICATION FREQUENCY

Document Number :

Effective Date :

PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL FOR EVALUATION OF EQUIPMENT & UTILITY RE-QUALIFICATION TO ESTABLISH THE RE-QUALIFICATION FREQUENCY

PROTOCOL APPROVAL:

Function	Signatories	Name of individual	Signature	Date
Prepared by	Executive-QA			
Checked by	Head-Production			
Checked by	Head-QC			
Checked by	Head-Engineering			
Approved by	QA-Head			
Authorized by	Site Head			

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PROTOCOL FOR EVALUATION OF EQUIPMENT & UTILITY RE-QUALIFICATION TO ESTABLISH THE RE-QUALIFICATION FREQUENCY

1.0 OBJECTIVE:

The objective of this study is to establish the Requalification frequency of equipment & Utility used for production/Utility process to confirm that they remain in a state of control.

2.0 SCOPE:

2.1 This protocol shall be applicable for the evaluation of equipment & Utility requalification to confirm that they remain in a state of control on the basis of various parameters as per Protocol.

2.2 The protocol shall specify the responsibilities for the activity related to establish the requalification frequency of equipment &Utility.

3.0 RESPONSIBILITIES:

The team shall comprise of the following team members and their responsibilities shall be as Specified below.

	Operation	
	Quality Assurance	
	Quality Control	
	Production	
	Engineering	

Quality Assurance

Officer/Executive QA shall monitor and ensure the Complexcity & Criticality of equipment/Utility.

Executive QA is responsible for review included in this protocol and verification of proper scale followed to evaluate the equipment & Utility requalification to establish the requalification frequency to confirm that they remain in a state of control.

The Head Quality Assurance is responsible for ensuring that the required documentation is available and is adequate to support the study.

The Head Quality Assurance is responsible for protocol approval for final review with subsequent

approval of completed study report.

Production

Officer/Executive Production shall monitor and ensure the Complexcity & Criticality of equipment used for production process.

The Executive Production is responsible for review included in this protocol and verification of proper scale followed to evaluate the equipment requalification to establish the requalification frequency to confirm that they remain in a state of control.

The Head production is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process

Quality Control

Officer/Executive Quality Control shall monitor and ensure the Complexcity & Criticality of equipment and Utility used for QC/Microbiology Section.

The Executive Quality Control is responsible for review included in this protocol and verification of proper scale followed to evaluate the equipment/Utility requalification to establish the requalification frequency to confirm that they remain in a state of control.

The Head Quality Control is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process

Engineering

Officer/Executive Engineering shall monitor and ensure the Complexcity & Criticality of Utility.

Executive Engineering is responsible for review included in this protocol and verification of proper scale followed to evaluate the utility requalification to establish the requalification frequency to confirm that they remain in a state of control.

The Head Engineering is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process

4.0 Evaluation of "Equipment & Utility requalification to establish the Requalification frequency" Methodology:

Below listed Scale shall be followed for the evaluation of equipment & Utility requalification to confirm that they remain in a state of control on the basis of their Utilization, Automation, Impact on product, Age of equipment & utility, Breakdown of equipment/utility and complexity of changeover. This evaluation shall be done in annexure-I by multiplying the rating assigned for each parameter.

The total obtained by multiplication of various parameters rating shall be checked with the obtained criteria in section 5.0.

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Factor A: Utilization:

Utilization	Rating
Continuous	5
Daily	4
Weekly	3
Monthly	2
Quaterly /half yearly/ Annualy	1

Factor B: Automation:

Automation	Rating
Completely Automated	1
Significantly automated	2
Partially automated	3
Manual	4

Factor C: Impact on Product:

Impact on Product	Rating
Impacting	4
Significant impact	3
Likely impacting	2
Non impacting	1

Factor D: Age of equipment & utility:

Age	Criteria	Rating
Oldest	Above 15 years	4
Older	10-15 years	3
Old	5-10 Years	2
New	1-5 years	1

Factor E: Breakdown of equipment & utility:

Breakdown	Frequency	Rating
Very frequent	Monthly	5
Frequent	Quarterly	4
Some time	Half yearly	3
Rarely	more than a half yearly	2
Negligible	More than two years	1

Factor F: Complexity of changeover:

Complexity of changeover:	Rating
Tedious	3
Moderate	2
Simple	1

5.0 Requalification Frequency assigning based on the factor:

Requalification Frequency of equipment & utility shall be assign as per Multiplication of Factor for all equipment/utility used at site.

Multiplication of Factor: A x B x C x D x E x F

Frequency of qualification	Multiplication of Factor
Not required	1-1000
5 yearly	1000-2000
3 yearly	2000-3000
Annualy	3000-4800

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6.0 DEVIATION:

S.No.	Deviation details	Justification(s) / Corrective action(s)	Remarks (Acceptable/ Not acceptable)
1.			
2.			
3.			
4.			

Comments: _____

_____

_____

_____

_____

_____

_____ _____

Checked By Sign Date

_____ _____

Reviewed By Sign Date:

PROTOCOL FOR EVALUATION OF EQUIPMENT & UTILITY RE-QUALIFICATION TO ESTABLISH THE RE-QUALIFICATION FREQUENCY

7.0 EXECUTIVE SUMMARY:

*Note: Use additional pages if required.

Checked By: Date:

Reviewed By: Date:

8.0 REFERENCES:

8.1 Initial Qualification documents of equipment/Utility.

8.2 History card of equipment/Utility.

8.3 Operation and cleaning logbook of specified equipment/Utility.

8.4 Maintenance and Breakdown logbook.

PROTOCOL FOR EVALUATION OF EQUIPMENT & UTILITY RE-QUALIFICATION TO ESTABLISH THE RE-QUALIFICATION FREQUENCY

ANNEXURE I

S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxEx F	Assigned Frequency
Manufacturing Equipment										
1.	Rapid Mixer Granulator									
2.	Rapid Mixer Granulator									
3.	Rapid Mixer Granulator									
4.	Rapid Mixer Granulator									
5.	Fluid Bed Drier									
6.	Fluid Bed Drier									
7.	Fluid Bed Drier									
8.	Fluid Bed Drier									
9.	Octagonal Blender- 4500 Ltr.									
10.	Bin Blender									
11.	Bin Blender									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
12.	Multi-Mill									
13.	Multi-Mill									
14.	Multi-Mill									
15.	Multi-Mill									
16.	Vibro Sifter									
17.	Vibro Sifter									
18.	Vibro Sifter									
19.	Vibro Sifter									
20.	Vibro Sifter									
21.	OGB (2200 L)									
22.	FBP (GEA)									
23.	Vibro Sifter									
24.	Multi-Mill									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
25.	FBE									
26.	Vibro sifter									
27.	OGB (2200 L)									
28.	Compression Machine									
29.	Compression Machine									
30.	Compression Machine									
31.	Compression Machine									
32.	Compression Machine									
33.	Compression Machine (Re-qualification)									
34.	Compression Machine									
35.	Compression Machine									
36.	Coating Machine									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
37.	Coating Machine									
38.	Tablet Capsule Sorter									
39.	Tablet Capsule Sorter									
40.	Tablet Capsule Sorter									
41.	Tablet Capsule Sorter									
42.	Metal Detector									
43.	Metal Detector									
44.	Metal Detector									
45.	Metal Detector									
46.	Metal Detector									
47.	Metal Detector									
48.	Metal Detector									
49.	Metal Detector									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
50.	Metal Detector (Re-qualification)									
51.	Metal Detector (Re-qualification)									
52.	De-duster									
53.	De-duster									
54.	De-duster									
55.	De-duster									
56.	De-duster									
57.	De-duster									
58.	De-duster									
59.	De-duster									
60.	Colloidal Mill									
61.	Blister Packing Machine (230 XT)									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
	Blister Inspection System									
62.	Blister Packing Machine (230 XT)									
63.	BQS Packing Machine Blister Inspection System									
64.	Blister Packing Machine (240 EX) Blister Inspection System									
65.	Strip Packing Machine									
66.	Blister Packing Machine (EPI-2500) Blister Inspection System									
67.	Blister Inspection System									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
68.	De-blistering Machine									
69.	De-blistering Machine									
70.	Carton Packing Machine CP-150									
71.	Carton Packing Machine CP-150									
72.	De-foiling Machine									
73.	Blister Packing Machine (230 XT)									
74.	Blister Packing Machine (230 XT)									
75.	Carton Packing Machine (Hi-Cart)									
76.	De-blistering Machine									
77.	De-blistering Machine									
78.	De-blistering Machine									

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S.No.	Name of Equipment	Equipment ID.	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
79.	De-blistering Machine									
80.	Air Displacement Unit									
81.	Air Displacement Unit									
82.	Air Displacement Unit									
83.	Checkweigher									
84.	Checkweigher									
85.	Checkweigher									

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S.No.	Name of Equipment	Sampling location	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
Utility (Compressed Air)										
1.	Generation Point	Utility								
2.	After 5 micron filter	Utility								
3.	After 0.2 micron filter	Utility								
4.	FBP Technical Area	Granulation-3								
5.	FBP Technical Area	Granulation-3								
6.	Rapid Mixer Granulator	Granulation-3								
7.	Rapid Mixer Granulator	Granulation-2								
8.	Rapid Mixer Granulator	Granulation-1								
9.	Rapid Mixer Granulator	Granulation-5								
10.	Coating Machine-1	Coating Area								
11.	Coating Machine-2	Coating Area								
12.	Packing Line Inlet	Service Floor								

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S.No.	Name of Equipment	Sampling location	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxExF	Assigned Frequency
13.	Packing Line Outlet	Service Floor								
14.	Filter Cleaning Booth	Service Floor								
15.	Capsule Filling M/c	Capsule Filling Area								
16.	Coating Machine-3	Coating Area								
17.	Wash Area	Wash Area								
18.	Drying Area	Equipment Drying								
19.	Utility point Granulation-1	Granulation Area								
20.	Utility Point Granulation-2	Granulation Area								
21.	Compression-3	Compression Area								
22.	Compression-5	Compression Area								
23.	Compression-6	Compression Area								
24.	Compression-8	Compression Area								
25.	FBD	Granulation-1								
26.	FBD	Granulation-2								

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S.No.	Equipment ID	Catering to area	Utilization (A)	Automation (B)	Impact on product (C)	Age of Equipment (D)	Breakdown of Equipment (E)	Complexity of changeover (F)	Factor AxBxCxDxEx F	Assigned Frequency
Utility (HVAC & Water System)										
1.		• Mfg Sec Change Room • Production office • Granulation Corridor • Compression Corridor • Coating Corridor • IPQC								
2.		• Packing Secondary Change Room • Packing Corridor • Capsule Corridor								
3.		• Granulation – III • Air Lock								
4.		• Granulation – II • Air Lock								
5.		• Granulation – I • Paste Preparation • Air Lock								
6.		• Granulation – IV • Air Lock								

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7.		• Dispensing –I • Air Lock • RM Staging								
8.		RM Dispensed Material Store								
9.		• Dispensing – II • Air Lock, RM Staging								
10.		Blend Store								
11.		Compression - VIII								
12.		• Capsule Filling Area • Air Lock								
13.		• Compression –I • Air Lock								
14.		• Compression – II • Air Lock								
15.		• Compression – III • Air Lock								
16.		• Coating –I • Solution Preparation Area								
17.		Coating -II								
18.		• Compression – IV • Air Lock								

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19.		• Compression – V • Air Lock								
20.		• Compression - VI • Air Lock								
21.		Bulk Tab. / Capsule Store -2								
22.		Bulk Tab. / Capsule Store -1								
23.		Inspection -4								
24.		Inspection -3								
25.		Inspection -2								
26.		Inspection - 1								
27.		Packing - 2								
28.		Packing - 3								
29.		Packing - 4								
30.		Packing - 5								
31.		Packing - 7								

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32.		Packing - 9								
33.		Packing - 10								
34.		Clean Equipment Store								
35.		• Sampling Change Room • Sampling - 1								
36.		• Sampling Change Room • Sampling - 2								
37.		Dispensed Solvent Store								
38.		Spare Part Room								
39.		Blending Area								
40.		Microbiology Lab								
41.		• Granulation – 5 • Air Lock								
42.		Tablet Quarantine (To be Coated Area)								
43.		PPM Staging & Dispensing								
44.		Packing Change Part Store								

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45.		Packing - 6								
46.		Packing - 8								
47.		Packing - 11								
48.		Coating -3								
49.		Sampling Area-I(RLAF)								
50.		Sampling Are-II (RLAF)								
51.		Dispensing Area-I(RLAF)								
52.		Dispensing Area-II(RLAF								
53.		Dispensing PPM								
54.		Testing Area (RLAF) Microbiology								
55.		Testing Area (RLAF) Microbiology								
56.		APU-01								
57.		APU-02								

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58.		APU-03								
59.		APU-04								
60.		APU-05								
61.		APU-06								
62.		APU-07								
63.		APU-08								
64.		Vacuum Cleaner								
65.		Vacuum Cleaner								
66.		Vacuum Cleaner								
67.		Vacuum Cleaner								
68.		Vacuum Cleaner								
69.		Fuming Hood								
70.	DM Plant									

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71.	Purified Water System									

Conclusion:

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Prepared By:

(Signature/Date): _____

Checked By:

(Signature/Date): _____