



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: CAGE BIN WASHING MACHINE

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

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USER REQUIREMENT SPECIFICATION

(SECTION: FORMULATION)

DEPARTMENT	TABLET
NAME OF THE EQUIPMENT	IPC , CAGE BIN, BUNKER & UTENSILS WASHING AND DRYING SYSTEM
DOCUMENT NUMBER	



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(A) PROCESS REQUIREMENTS :

1.0 Name of the equipment/facility/system

Fully automatic **IPC/Cage Bin Washing Machine** with features of loading different recipe and process recording facility.

2.0 Purpose of the equipment/facility/system

Purpose of the equipment is to clean and dry the cage bin, bunker, IPC and utensils. (Details are attached in ANNEXURE-I)

3.0 Product dosage type

NA

4.0 Process schematic flow diagram

- 1 Potable water pre-wash from inside.
- 2 Potable water pre-wash from outside.
- 3 Hot potable water wash from inside.
- 4 Hot potable water wash from outside.
- 5 Purified water rinse from inside as well as outside.
- 6 Hot air drying inside and outside.

5.0 Suggested capacity and model with suppliers name

M/s Cybernetik Technologies Pvt. Ltd.

Capacity – Largest cage bin cycle time is 18 Minutes.

6.0 Number of equipments required

01 No.

Wash Area: Granulation (Ground Floor)

7.0 Requirements for any power failure backup's

Machine to be backed up by DG set and PLC to be backed up by UPS.

8.0 Any other specific requirements

- 1 Evidence of cleaning (Print-Out facility)
- 2 Cleaning verification
- 3 Cleaning verification with special exposure to the clean of discharge valve.



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(B) OPERATIONAL REQUIREMENTS:

(1) **Production stage**

During cleaning and drying of cage bin, bunker, IPC and utensils.

(2) **Material inputs into the equipment**

Unclean Cage bin, IPC or Bunker.

(3) **Desired out come from the equipment**

Uniform cleaning and drying within prescribed time limit.

(4) **Charge size/lot size**

NA

(5) **Method for loading material into the equipment**

Through hinged type doors for material entry.

(6) **Method for unloading material from the equipment**

Through hinged type doors for material exit.

(7) **Expected running time per day**

Total 3 shifts in a day running 24 hours continuously.

(8) **Method of cleaning**

CIP

(9) **Recommended solvent for cleaning with its chemical nature**

Purified water.

(10) **Utilities required**

Electrical: Supply to control cabinets and all the field cabling.
(3 ϕ , 440 V AC, 50 Hz)

Water: Potable Water
Purified Water: 3.5 kg/cm²

Steam: Supply to inlet valve on air heaters.
3 bar

Compressed Air: Supply to FRL unit on machine. (It should be oil free) 6 kg/cm²



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(11) Instrumentation

- 1 Temperature gauge for measuring the temperature at the time of drying.
- 2 Pressure gauge to measure the water jet pressure.

(12) Process control requirements

Controlled through PLC in the form of panel view 600 (T).

(13) Change over parts requirements

N/A

(14) Available size of the room for installation

Comfortable.

(15) Online attachments with other equipments

Stand alone.

(16) Any other specific requirements

Process automization

(C) GMP REQUIREMENTS:

(1) Material of construction specifications

- Parts in contact with purified water and hot air-SS316.
- Booth and parts in contact with potable and hot potable water exhaust air -SS 304.
- Non contacts parts and supporting structure for Air /Water Handling unit - M.S. (P.U. Painted).

(2) Working area environment requirement

Loading area class "E" and unloading area class "O".

(3) GMP requirements

Compressed air to be provided 0.01 micron filter.

(4) Filter requirement on utility lines or for vent purpose

Appropriate filter to be provided to meet the class of air coming in contact with cleaned bin.



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(D) DOCUMENTATION REQUIREMENTS :

(1) Specify the drawings/certificates/manual required

Operating Manual with list of spares.
Pump, Spray Ball, Spray nozzles and Control Valves details.
MOC certificates of equipment.
Equipment drawing .
Calibration certificate of all sensors.

(2) Any other specific requirements

Printout facility.

(E) SAFETY REQUIREMENTS :

(1) Information related to safety

- Interlocks with hinged doors.
- Emergency button.
- Halt mode facility.
- Manual mode facility.
- Alarm when lack of utility.

(2) Process Control Alarms

Any abnormal process.

(3) Safety Interlocks

All valves.

(4) Password protection (In case of PLC systems)

For recipe operation.

(5) Any other specific requirement

Proper earthing to eliminate any static charge.

[F] DISCUSSION/REVIEW/COMMENTS:

	NAME	SIGN	DESIGNATION	DATE
USER DEPARTMENT				
ENGINEERING / PROJECTS DEPT.				
QA DEPARTMENT				



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[G] ABBREVIATIONS

S.No.	Abbreviation	Full Form
1.	IPC	In process Containers
2.	NA	Not Applicable
3.	M/S	Messers
4.	NOS	Numbers
5.	URS	User Requirement Specification
6.	PVT	Private
7.	LTD	Limited
8.	GMP	Good Manufacturing Practice
9.	&	And
10.	SIGN	Signature
11.	DG	Diesel Generator
12.	UPS	Uninterrupted Power Supply
13.	PLC	Programmable Logic Control
14.	KGS	Kilograms
15.	CIP	Clean In Place
16.	SIP	System In place
17.	°C	Degree Centigrade
18.	MOC	Material Of Construction.