



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: OSCILLATING GRANULATOR

PROTOCOL No.:.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 1 of 7

USER REQUIREMENT SPECIFICATION

(SECTION: FORMULATION)

DEPARTMENT	TABLET
NAME OF THE EQUIPMENT	OSCILLATING GRANULATOR
DOCUMENT NUMBER	



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

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PROTOCOL No.:.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 2 of 7

TABLE OF CONTENTS

S.No.	Title	Page Nos.
A	PROCESS/PRODUCT REQUIREMENTS	3
B	OPERATIONAL REQUIREMENTS	4-5
C	GMP REQUIREMENTS	6
D	DOCUMENTATION REQUIREMENTS	6
E	SAFETY REQUIREMENTS	7
F	DISCUSSION / REVIEW & COMMENTS	8
G	ABBREVIATIONS	9



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PROTOCOL No.:.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 3 of 7

(A) PROCESS/PRODUCT REQUIREMENTS:

1.0 Name of the equipment/facility/system (specify the name most commonly in use)

Oscillating granulator
Dual chamber

2.0 Purpose of the equipment/facility/system

(Specify in 3 to 4 sentences, in short the use of the equipment/facility/system)

Purpose of the equipment is to reduce the size of granules and at the same time obtain granules of uniform size.

3.0 Product dosage type (specify its use in the type of dosage)

Tablets & Capsules.

4.0 Process schematic flow diagram (Write a brief description of each stage)

NA

5.0 Suggested capacity and model with suppliers name

M/s Cadmach machinery
Capacity – Kg/Hr. (Granules)

6.0 Number of equipments required (give calculations where possible to justify)

1 No.

7.0 Requirements for any power failure backup's

To be backed up by DG set.

8.0 Any other specific requirements

To avoid black particle generation during operation of equipment.
Uniform granules size.

(B) OPERATIONAL REQUIREMENTS:

(1) Production stage (During which stage of production it will be used.)

During size reduction stage after drying of granules (Wet granulation method).

(2) Material inputs into the equipment

(Give details of starting material to be added as an input for further



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PROTOCOL No.:.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 4 of 7

processing considering the worst type of input material)

Lumps formation type and uneven size of granules.

(3) Desired out come from the equipment

Uniform sized granules.

(4) Charge size/lot size (Give both the minimum and maximum capacities) litres / kgs./Nos.

Continuous charging.

(5) Method for loading material into the equipment

Continuous charging through lifting and tripling device.

(6) Method for unloading material from the equipment

Collect in cage bin and IPC bin.

(7) Expected running time per day

Total 2 shifts in a day running 14 hours at a stretch. continuously.

(8) Method of cleaning (Whether it shall be manual/CIP/SIP etc.)

Manually.

(9) Recommended solvent for cleaning with its chemical nature

Purified water.

IPA

(10) Utilities required

(Specify the various utilities required giving details for each like Temperature, Working pressure range, Filtration requirement, jacketed heating/cooling, power etc.)

3 Phase power with 2 HP Motor.

(11) Instrumentation

NA

Type	Purpose	Operating Range	Least Count	Indicator	Controller	Recorder



USER REQUIREMENT SPECIFICATION

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PROTOCOL No.:.....

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Page No.: 5 of 7

(12) Process control requirements

NA.

(13) Change over parts requirements

A) (Specify whether it is to be used for dedicated product or for various

B) different types)

Various sieves.

(14) Available size of the room for installation

Comfortable.

(15) Online attachments with other equipments (Specify whether equipments is stand alone or to be attached with other equipments online)

Stand alone.

(16) Any other specific requirements

Up to 150 oscillations/minute.

(C) GMP REQUIREMENTS:

(1) Material of construction specifications

Surface contacted by product:

SS 316

Shaft seal/gasket–Teflon/Silicon/wyton

(2) Working area environment requirement

(Specify the grade of the area required)

Class “O”.

(3) GMP requirements (to avoid cross contamination)

Dust extraction system required to avoid cross contamination.

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

NA.

(D) DOCUMENTATION REQUIREMENTS:

(1) Specify the drawings/certificates/manual required

Operating Manual with list of spares.

Motor Details & Ratings.



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

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PROTOCOL No.:.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 6 of 7

MOC certificates for shaft and impeller.
Equipment drawing.
Calibration certificate of screen.

(2) Any other specific requirements

None.

(E) SAFETY REQUIREMENTS:

(1) Information related to safety

SS 304 guard over motor.

(2) Process Control Alarms (Specify any alarm required for safety of both process and operator)

NA

(3) Safety Interlocks

NA

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

NA

(5) Any other specific requirement

Motor to be protected from water during washing /change over.

[F] DISCUSSION/REVIEW/COMMENTS

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



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Page No.: 7 of 7

[G] ABBREVIATIONS

S.No.	Abbreviation	Full Form
1	NA	Not Applicable
2	GMP	Good Manufacturing Practices
3	No.	Number
4	DG	Diesel generator
5	Kg.	Kilogram
6	Hr.	Hour
7	HP	Horse Power
8	IPA	Isopropyl Alcohol
9	CIP	Clean in place
10	SIP	Steam in place
11	RPM	Rotation per minute
12	SS	Stainless steel
13	MOC	Material of construction
14	PLC	Pneumatic Logic Control
15	DEPT.	Department
16	QA	Quality Assurance
17	URS	User Requirement Specification