



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLETT COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 1 of 8

USER REQUIREMENT SPECIFICATION

(SECTION: FORMULATION)

DEPARTMENT	TABLET
NAME OF THE EQUIPMENT	GLATT
DOCUMENT NUMBER	



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USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLETT COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 2 of 8

TABLE OF CONTENTS

Sr. No.	Title	Page Nos.
A	PROCESS/PRODUCT REQUIREMENTS	3 – 5
B	OPERATIONAL REQUIREMENTS	5 – 8
C	GMP REQUIREMENTS	8 – 9
D	DOCUMENTATION REQUIREMENTS	9
E	SAFETY REQUIREMENTS	10
F	DISCUSSION / REVIEW & COMMENTS	11
G	ABBREVIATIONS	12



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLETT COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 3 of 8

(A) PROCESS/PRODUCT REQUIREMENTS

1.0 Description of the equipment/facility/system

Equipment is required, which can be used for pellet coating as well as for granulating the powder.

2.0 Purpose of the equipment/facility/system

The equipment is envisaged for new product called “.....”, which is sustain release pellets of Diltazem Hydrochloride. Since the product is to be used for Cardiac patients, the release profile of drug is of the prime importance. For such application FBD coaters are available, well known equipment available is Glatt processor of different capacities. The equipment has following facilities –

- (a) Bottom spray for pellet coating
- (b) Top spray for mixing/granulation and drying –cum–sizing process.

The most important use of equipment is processing of granules in one single load from mixing to sizing in very short time compared to other conventional processes.

3.0 Product dosage type

- (1) Pallet coating Plain Sustain release
- (2) Granulation process in Tablet manufacturing.



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLETT COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 4 of 8

4.0 Tentative process schematic flow diagram

(A) PELLETT COATING

Air Exhaust
Cloth bag
Product
Hot air and solvent

(B) WET GRANULATION

Air Exhaust
Top spray of binding solution
Cloth bag
Product
Hot air

5.0 Suppliers name

M/s. Glatt , Germany

6.0 Number of equipments required

Number of equipment - 1 No

The equipment is required for Diltazem and Omeprazole coating and excess/balance capacity to be washed out for granulation process.

This apart from any new product may also be developed, as F & D has laboratory model of Glatt.

7.0 Requirements for any power failure backup's

Not required for power failure of 5 to 10 minutes.

However in case of long power failure, material should be taken out manually.

8.0 Any other specific requirements

(1) Equipment should be flameproof, and should be able to handle solvent coating.

(2) Since we have to take feature provided by Glatt in particular model, more requirement/information can be put forward after discussion with party and necessary FRS/DQ can be prepared.



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLETT COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 5 of 8

(B) OPERATIONAL REQUIREMENTS

1.0 Production stage

- (1) Pellet coating
- (2) Dry mixing cum granulation operation.

2.0 Material inputs into the equipment

- (1) Sugar pellets
- (2) Active Raw material
Aqueous
- (3) Solvents
Non aqueous

The material may be used of different chemical nature – hazardous/toxic/corrosive/
Colour/solvent granulated.

3.0 Desired out come from the equipment

Coated pellets
Sized granules

4.0 Charge size /lot size

For granulation – 100 to 150 Kg.
For pelletization – 250 to 300 Kg.

5.0 Method for loading material into the equipment

There should be pneumatic conveying system or mechanical conveying system be provided to avoid dusting during the process.

6.0 Method for unloading material from the equipment

Either using gravitational flow from bottom discharge or by pneumatic flow or tipping device like in FBD.

7.0 Expected running time per day

2 shifts

8.0 Method of cleaning

- (1) Equipment:

As the height of machine would be almost upto first floor which is too much, therefore necessary aids to be provided to reach highest



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLET COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 6 of 8

spot in case of manual cleaning is to be done. However, it would be desirable to have equipment with CIP. Even in case CIP is provided, it would be from inside and so necessary aids to be provided to reach high spots from outside. In case of manual cleaning following methods can be used:

- (i) Manually using dry cloth
- (ii) Manually scrubbing with water
- (iii) Manually using wet cloth soaked in soap solution
- (iv) Pressurised potable/purified water

(2) Cloth bags:

Suitable washing cum drying machine is required to wash cloth bags.

9.0 Recommended solvent for cleaning with its chemical nature

- (1) Potable water
- (2) Purified water
- (3) Soap water
- (4) IPA
- (5) Any other organic solvent as per product requirement

10.0 Utilities required

Since Glatt is an equipment which comes as standard; all utilities recommended by Glatt are required.

11.0 Instrumentation

As per Glatt standard model.

12.0 Process control requirements (Temperature pressure etc.)

As per Glatt standard features.

13.0 Change over parts requirements

Different perforated plates for different types of pellets.

14.0 Available size of the room for installation

Area allotted for Glatt erection in project plan.



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLET COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 7 of 8

(C) GMP REQUIREMENTS

1.0 Material of construction specifications

Surface contacted by product	-	SS 316
Seals/gaskets	-	Neoprene
Non contact	-	SS 304

2.0 Working area environment requirement

- (1) Equipment is to be placed in production ("O") area.
- (2) Equipment is to be placed in such a way that most of the maintenance work is attended through technical ("E") area.

3.0 GMP requirements (to avoid cross contamination)

Point for dust extraction to be provided at loading platform.

4.0 Filter requirement on utility lines or for vent purpose

As per standard Glatt design, however, it is essential to have HEPA filter in air inlet and dehumidification system for air which would come in contact with product.

(D) DOCUMENTATION REQUIREMENTS:

- (1) Manual (Operational & maintenance)
- (2) Electrical wiring diagram
- (3) Material of construction (MOC) certificate
- (4) Gauge calibration certificate
- (5) Bought-out item certificate
- (6) P & I diagram

(E) SAFETY REQUIREMENTS

1.0 Information related to safety

As per standard Glatt features to handle aqueous/non-aqueous process.

2.0 Process Control Alarms

As per standard Glatt features.

3.0 Safety Interlocks

At all relevant places as per Glatt design. However, cloth bag returning indicator process is a must.



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: PELLET COATING

PROTOCOL No.....

FUNCTIONAL AREA: PRODUCTION

Page No.: 8 of 8

4.0 Password protection (In case of PLC systems)

Desired

(F) DISCUSSION/REVIEW/COMMENTS

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

(G) ABBREVIATIONS

Sr. No.	Abbreviation	Full Form
1	Kg.	Kilogram
2	FBD	Fluid Bed Dryer
3	GMP	General Manufacturing Practices
4	CIP	Cleaning in process
5	SS	Stainless Steel
6	IPA	Isopropyl Alcohol
7	HEPA	High Efficiency Particulate Air
8	No.	Number
9	PLC	Programmable Logic Control
10	P & I	Piping & Instrument
11	TAB	Tablet
12	DEPT	Department
13	QA	Quality Assurance
14	FRS	Functional Requirement Specification
15	URS	User Requirement Specification
16	DQ	Design qualification