IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Review on Formulation and their Development

P. H. Gadhire, Sanjay K Bais, Rohit Rajkumar Navale
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India

Abstract: *A crucial area of development that could determine a pharmaceutical product's success in the long run is formulation development. There are numerous different ways that businesses include pre - formulation functions and individuals into their development cycle. Specific departments may exist in fully integrated, sizable pharmaceutical companies to address issues with formulation and physical characterization of medicinal ingredients in these fields. Several times, diagnosis tasks like animal testing could be handled by different departments, frequently in different buildings or places. To fully comprehend its unique drug material, these departments should collaborate closely. Formulation development is typically a departmental responsibility for smaller, growing businesses as well as some biotechnology companies.*

Keywords: Formulation and Development

I. INTRODUCTION

A crucial area of development that could determine a pharmaceutical product's success in the long run is formulation development. There are numerous different ways that businesses include pre - formulation functions and individuals into their development cycle. Specific departments may exist in fully integrated, sizable pharmaceutical companies to address issues with formulation and physical characterization of medicinal ingredients in these fields. Several times, diagnosis tasks like animal testing could be handled by different departments, frequently in different buildings or places. To fully comprehend its unique drug material, these departments should collaborate closely. Formulation development is typically a departmental responsibility for smaller, growing businesses as well as some biotechnology companies.

1.1 Concept of cGMP

A system called good manufacturing practise (GMP) can be used to guarantee that products are consistently created and controlled in accordance with quality standard . Poor-quality medications not only put people at risk, but they also cost both governments and individual patients money.

1.2 List of Products

Generic Products

Sr.No.	Product	Strength
CAPSULES		
1	Amoxycillin Trihydrate	250, 500 mg
2	Ampicillin Trihydrate	250, 500 mg
3	Cephalexin	250, 500 mg

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

INJECTIONS		
1	Cefotaxime Sodium	250, 500, 1000 mg
2	Cefotaxime Sodium and Sulbactam	375, 750, 1500 mg
3	Ceftriaxone Sodium	250, 500, 1000 mg
4	Ceftriaxone Sodium and Sulbactam	375, 750, 1500 mg
5	Ceftazidime	250, 500, 1000 mg
6	Cefoperazone	1000 mg
7	Cefoperazone Sodium and Sulbactam	1000, 2000 mg
8	Benzathine Penicillin	6,12, 24 Lacs
9	Ampicillin Sodium	250, 500 mg
10	Benzyl Sodium Penicillin	5, 10 Lacs
11	Fortified Procaine Penicillin	4, 20, 40 Lacs
12	Meropenem Trihydrate	500, 1000 mg
13	Amoxycillin and Potassium Clavulanate	300, 600, 1200 mg
12	Cephalexin	125 mg
13	Amoxycillin Trihydrate	125, 250 mg
14	Levofloxacin	500 mg
15	Paracetamol	500 mg
16	Albendazole	400 mg
17	Fluconazole	150, 200 mg
18	Potassium Iodate	85 mg
19	Azithromycin	250, 500 mg
20	Cetirizine	10 mg
21	Levocetirizine	5 mg
22	Cefixime	100, 200 mg

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

I.V.FLUID		
1	Ciprofloxacin Hydrochloride	2 mg / ml
2	Dextrose	5, 10, 25 % w/v
3	Sodium Chloride	0.9 % w/v
4	Sodium Chloride + Dextrose	0.9 & 5 % w/v
5	Compound Sodium Lactate	Std.
6	Metronidazole	0.5% w/v
7	Mannitol	20 % w/v
8	Plasma Volume Expander	Std.

Branded

Products

Sr.No.	Brand Name	Composition	Strength
CAPSULES			
1	Delamin	Amoxycillin Trihydrate	250, 500 mg
2	Prilocef	Cephalexin	250, 500 mg

DOI: 10.48175/IJARSCT-7981

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

TABLETS

1	Droxibid	Cefadroxil	250, 500 mg
2	Penquin	Ciprofloxacin Hydrochloride	250, 500 mg
3	Penquin TZ	Ciprofloxacin Hydrochloride + Tinidazole	250, 500 mg
4	Eryster	Erythromycin Stearate	250, 500 mg
5	Nor-U	Norfloxacin	400 mg
6	Kaypen	Phenoxymethyl Penicillin Potassium	125, 250 mg
7	Delamin - DT	Amoxycillin Trihydrate	125, 250 mg
8	Haloran	Diclofenac Sodium	50, 100 mg
9	Haloran Plus	Diclofenac Sodium and Paracetamol	50+325 mg
10	Floquin	Sparfloxacin	100, 200 mg
11	Plaziloc	Levofloxacin	500 mg
12	Prilocef-P	Cephalexin	125 mg
13	Halnaz	Fluconazole	150, 200 mg
14	Haxime	Cefixime	100, 200 mg

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

I.V.FLUID			
1	Plaziloc	Levofloxacin	100 ml
2	Hexpan	Polymer From Degraded Gelatin For IV Infusion 3.5%	500 ml
ORAL LIQUID			
1	Hamycin	Hamycin Suspension	10, 100 ml
AHD			
1	HALRUB	Alcoholic Hand Disinfectant	100, 500 ml, 5 lits.

INJECTIONS			
1	Haltax	Cefotaxime Sodium	250, 500, 1000 mg
2	Haltax-S	Cefotaxime Sodium and Sulbactam	375, 750, 1500 mg
3	Haxone	Ceftriaxone Sodium	250, 500, 1000 mg
4	Haxone – S	Ceftriaxone Sodium and Sulbactam	375, 750, 1500 mg
5	Dynacil	Ampicillin Sodium	250, 500 mg
6	Longacillin	Benzathine Penicillin	6,12, 24 Lacs
7	Transuf	Cefoperazone	1000 mg
8	Transuf- S	Cefoperazone Sodium and Sulbactam	1000, 2000 mg
9	Halpen	Meropenem Trihydrate	500, 1000 mg
10	Sodicillin	Benzyl Sodium Penicillin	5, 10 Lacs
11	Halclave	Amoxycillin and Potassium Clavulanate	300, 600, 1200 mg
12	Haltam	Ceftazidime	250, 500, 1000 mg

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

1.3 Basic Techniques

Laboratory Department

1.Quality Assurance

Documentation:

1. Master formula record(mfr)
2. Batch manufacturing record)
3. Process validation protocol/report
4. Ahu maintenance record (filter cleaning/ air change)
5. Rh/rt record
6. Water quality report
7. Purified water tank sanitation/ cleaning record
8. Daily balance check record
9. Balance calibration record
10. Instrument check/ calibration record
11. Fbd filter cleaning record
12. Sanitation record
13. Rejection disposal record
14. Punch/ die inspection record
15. Sieve integrity record
16. Equipment use log
17. Self inspection record
18. Preventive maintenance record/ schedule from mains.
19. Iq/oq/pq file
20. Original sops from instrumentation/ air cond.
21. Plant layout/ site master plan.
22. Bfr batch formula record
23. Quality documentation
24. Quality audit
25. Quality review
26. Distribution records
27. Batch process record
28. Sop standard operating procedure
29. Ipqa
30. Quality control

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

1.4 List of Equipments

	A) CHEMISTRY SECTION
1	Viscometer (Brook Field)
2	Melting Point Apparatus (Gallen Camp)
3	Refractometer (Advanced Research)
4	Polarimeter Autopoll III (Rudolf)
5	FTIR – IR Instrument (Shimadzu)
6	Vertex Mixer (Pharma)
7	Electronic Balance (Anamed)
8	Water Bath (Thermostatic)
9	Bulk Density (DBK Instruments)
10	Electronic Balance (Afcoset) KF Room
11	Vaccuum Oven 100° (Pharmalab Instruments)
12	Centrifuge (Old RM)
13	HPLC (Dionex)
	B) PHARMACOLOGY SECTION
1	Electronic Balance (Afcoset)
2	Vertex Mixer
3	Refrigerator (Allwyn)
4	Hot Air Oven 150°
5	Hot Air Oven 150°
	C) MICROBIOLOGY
1	Double Pan Balance (Ivery)
2	Incubator 55° (Lawrence & Meyo)
3	Refrigerators (Godrej & Kelvinator)
4	Petrimate Machine with Pump (Struers)
5	Incubators 32° & 37°
6	Mettler Balance (E - Mettler)
7	Refrigerator (Godrej M-110)
8	Deep Freezer (-20°) (Spire Automation)
9	Pharmacy Refrigerator (Spire Automation)
10	Electronic Balance (Contech)
11	Microscope
12	Garment Cubicle (Sterile air lock)
13	Manometers
15	Dynamic Passbox (32° room)

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Sub- Department in Quality Control

Store

Manufactured products, rejected, raw materials, packaging materials supplied by vendors before testing stored and labelled as quarantine material products which are ready to market is stored.

Chemistry department

Raw materials

Finished goods

Stability and reference samples IPQC

Sampling

Animal house

Pharmacological studies

Packaging

Office

Microbiology

Sterility testing

Bioassay

Media preparation and sterilization

Petriplate

Water analysis

Raw materials, finished products are tested

Research and Development

The research and development team is comprised of 8 Pharmacist, Scientists from different fields. Microbiologists, Chemists, Pharmacologists, which from a part of Hindustan antibiotics Ltd Pharmaceuticals.

IVF : Intra Venous Fluids

IVF visitors entry

Wear apron cap booties provided

Ensure proper garment wear in the mirror

Cross over the bench

Please note - please ensure that the feet with booties should touch the cleaner area wise crossing over

Apply hand sanitizer

Dry hands under hand dryer rubbing both the palms gently and enter

Production of intravenous fluid works on process blow -fill -seal

For checking filter integrity

Diffusion taste and Bubble Prizt test are performed

Equipment list

Autoclave

Membrane filtres 0.2 ,0.5 micrometer

IVF production machine make-Romnelagswitzerland

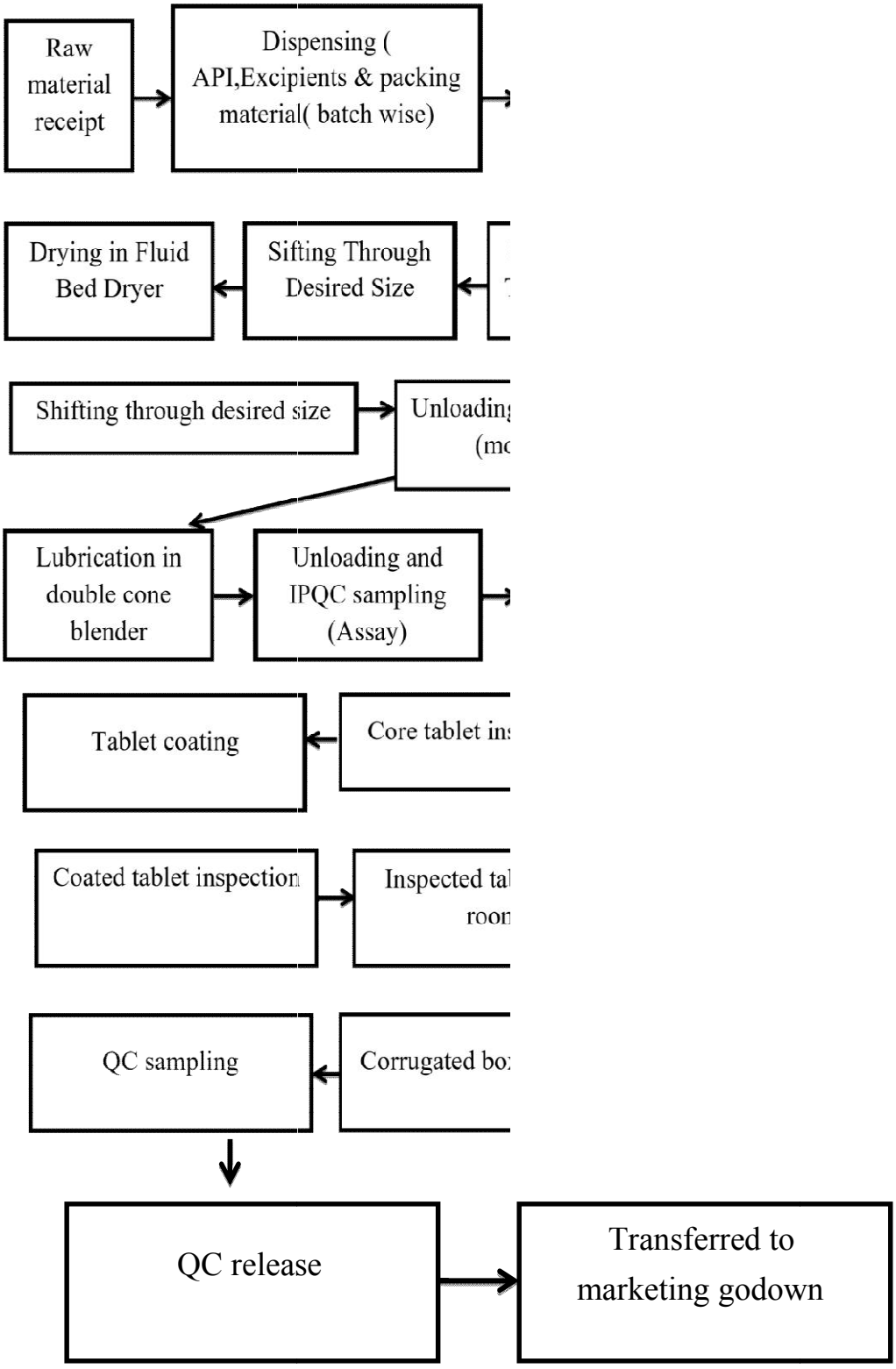
Preformulation studies and flow chart

FR III

Betalactum and non-Betalactum Tablets Capsules.

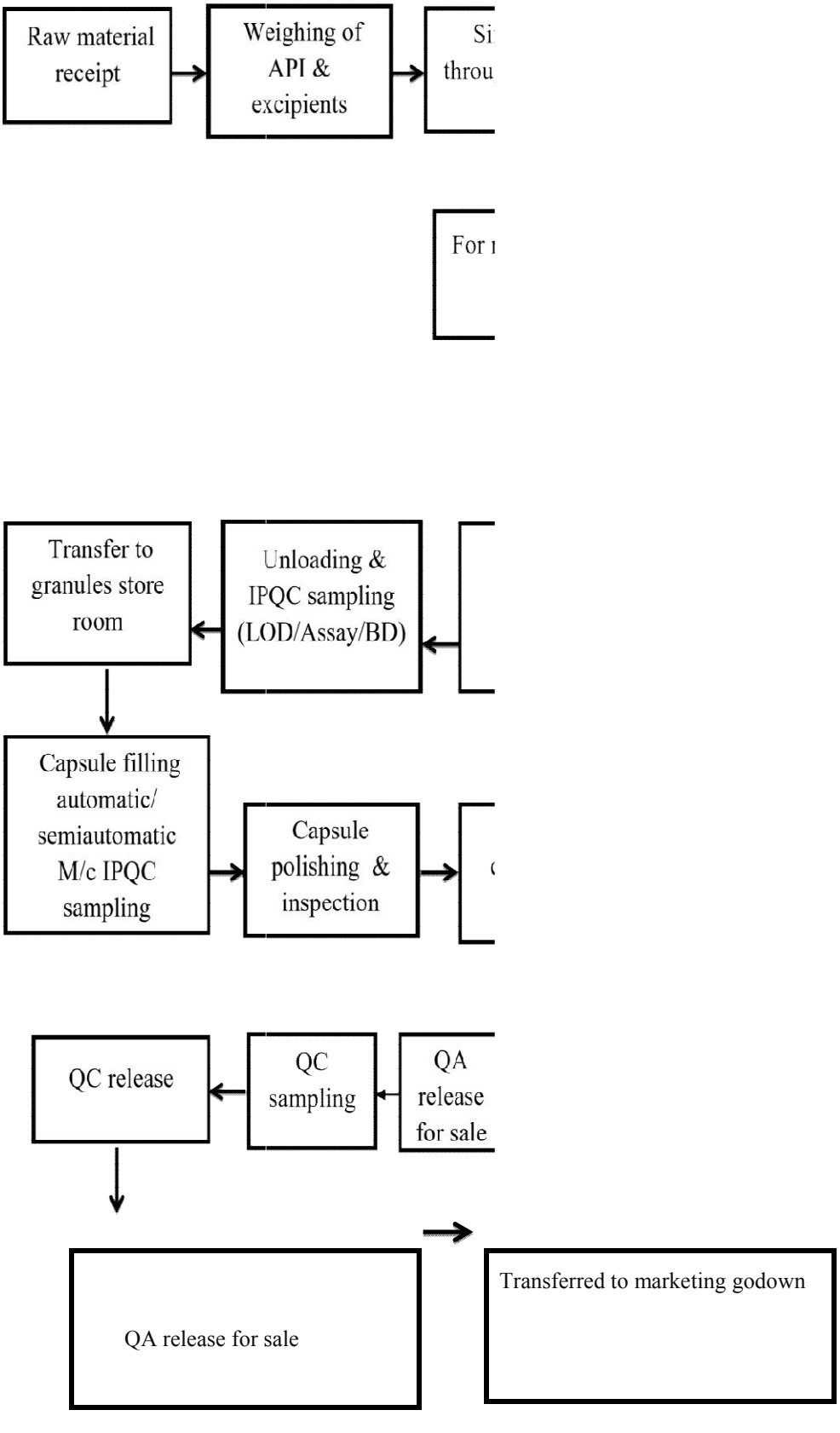
IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Process



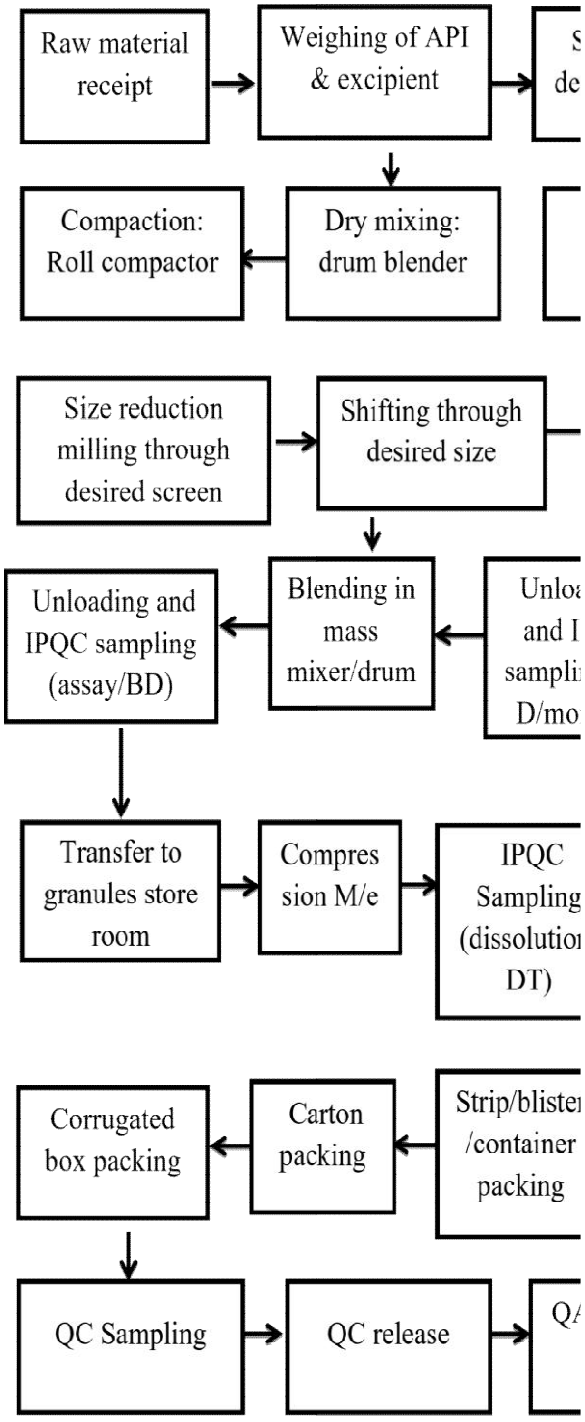
IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Capsule (beta- lactam)



IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Tablet (beta-lactam)



IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Equipment for Capsule and Tablet

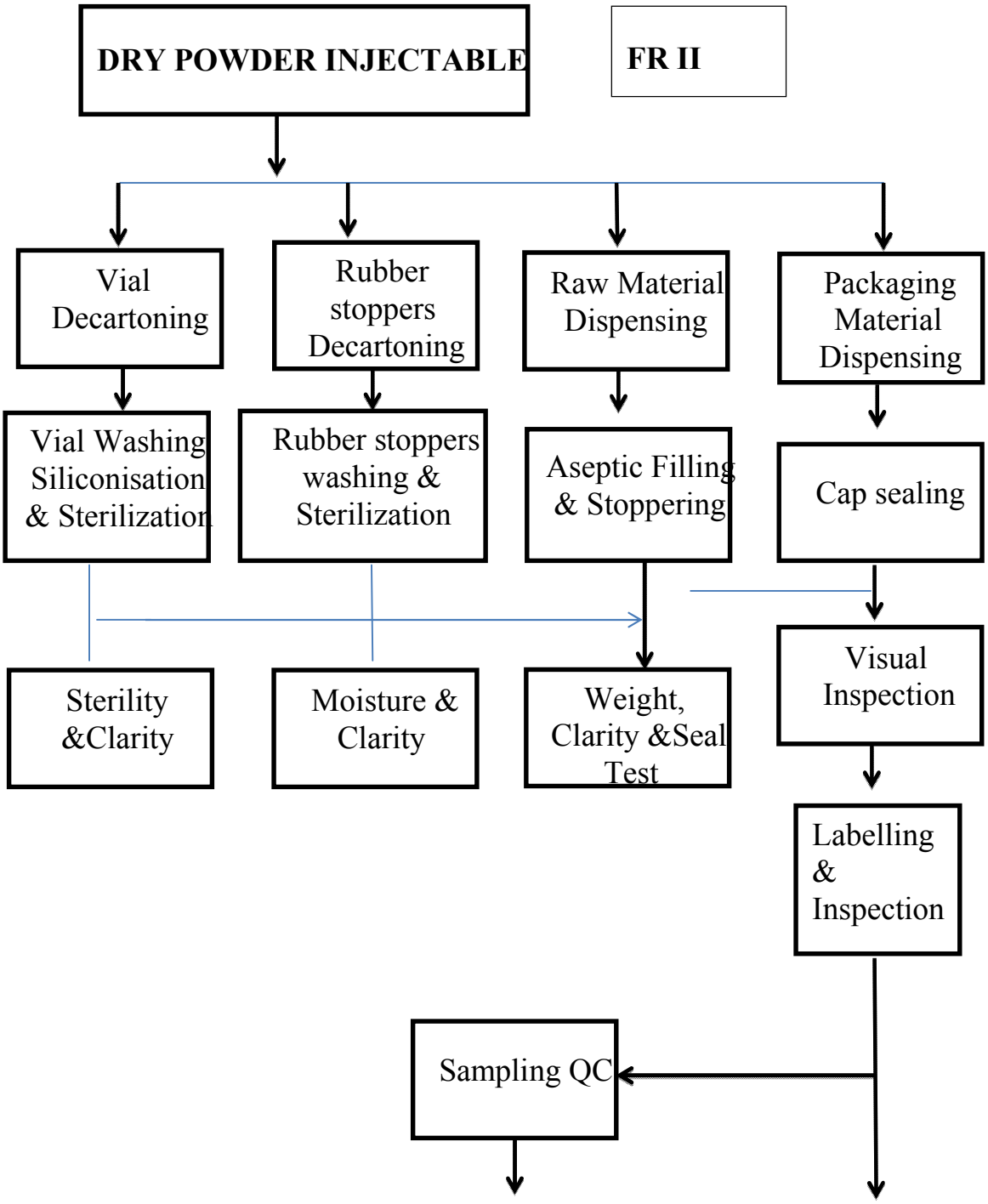
Sr. No.	Area	Machine/Equipment	Make
1	Bulk packing room	Platform balance	Essae
2	Tablet form area 1	Shifter	Ganson
3		Drum blender	Marvald
4		Planetary mixer	Ganson
5		FBD	Alliance
6			Alliance
7		Multimill	Ganson
8	Paste prepare room	Paste prepare vessel	Pfaudler
9	Tablet form area 2	Multimill	Ganson
10		Mass mixer	Unimek
11	Mixing room	Double cone blender	
12		Tray dryer	Magumps
13		Shifter	Ganson
14	Tablet storage room	Platform balance	Contech
15	Tablet comp area 2(room no. 12 A)	Double rotary comp m/c(27)	Cadmach
16		Deburring m/c	Karnavati
17		Industrial vaccum cleaner	Karnavati
18		Electronic balance	Ohus
19	Tablet comp area 3 room no. 13A	Double cone rotary comp m/c 27	Karnavati
20		Debuster	Karnavati
21		Industrial Vaccum cleaner 2	Karnavati
22		Electronic balance	Afcoset
23		Hardness tester	Thermonic

DOI: 10.48175/IJARSCT-7981

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

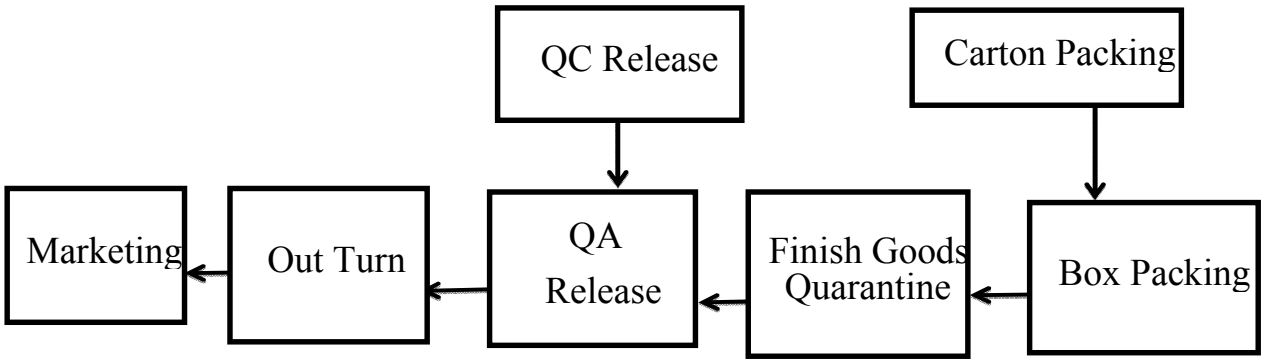
24	IPC room	Friability test apparatus	Campbel l elect
25		Metal detector	Shiva system Pvt.
26	Coating room	Colloidal mill	Clit jemkay
27		Pneumatic stirrer	
28		Peristaltic pump	Bullows
29		Coating pan	Cadmaz
30		Coating pan	Pharma fab
31		Trey dryer	Manestymitchell
32	Packing area		
33	Blister packing room	Blister packing m/c	Rota vac-210s
34		Chiller	Ambience
35		Leak test apparatus	
36	Room no. 17	Strip packing	Ganson
37	Carton printing room	Carton printing m/c	
38	Paste preparation area	UV Sterilizer	Alphaa(ace hygiene products pvt. Ltd.)
39	Issue counter		
40	Dispensing area	Platform balance	Contech

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301



DOI: 10.48175/IJARSCT-7981

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301



Name of Machinery or Equipment
Purified water storagetank(Distribution System)
Water for injection storage tank(Distribution System)
Pure steam generator
Multi column distillation(WFI generation Plant)
Vial washing
Vial sterilizing and depyrogenating tunnel
High Pressure Vacuum Sterilizer (Bung processor)
Dry heat sterilizer class 100
Powder filling (2station) and rubber stoppering machine with change parts
Vial sealing machine with change parts
Vial inspection belt
Vial Labelling machine with change parts

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Vial arranging and lifting machine
Electronic Balances

Module 4

Determination and Evaluation of Tablets(FR-III)

General Appearance:

For management of lot-to-lot consistency and tablet-to-tablet uniformity, as well as for user acceptance, a tablet's overall design, identity, and beauty are crucial. Measurements of size, form, colour, the existence or absence of odour, taste, etc. are used to control overall appearance. Size & Structure: It can be regulated & specified in dimensions. A tablet's thickness is only subject to change. Micrometers or other measuring tools can be used to determine a tablet's thickness. Tablet width should be kept to no more than 5% of the normal value..

Unique identification marking:

These markings use printing, engraving, or embossing in some way. These markings include the name or symbol of the corporation, the product code, the product name, etc.

Organoleptic properties:

There needs to be no mottling or an uniform colour dispersion.

Compare the sample's colour to a standard colour to make a visual colour comparison. If there is an odour in a group of tablets, there may be a stability issue, as in the case of the distinctive acetic acid odour in an active ingredient.

An odour could be indicative of the medication (a vitamin), additional components (a taste agent), or the dosing type (film-coated tablet have a characteristic odor). The existence or absence of a given flavour in a chewable tablet can be determined. There may be zero defects in a tablet's amount of flaws, including chips, cracks, interference from foreign solids (hair, oily drips, dirt), surface characteristics (smooth vs. rough), and look (shiny vs. drab).

Hardness and Friability:

- Tablet There shouldn't be any mottling or uneven colour distribution.
- To make a visible color comparison, contrast the sample's colour with a reference colour. As in the instance of the characteristic acetic acid smell in an active ingredient, there may be a durability issue if a batch of tablets exhibits an odour.
- An odour may be a sign of the vitamin, the medication, extra ingredients, or the form of administration (film-coated tablet have a characteristic odor). A chewable tablet's presence or lack of a certain flavour can be identified. A tablet's number of imperfections, such as chips, cracks, obstruction from external substances (hair, oily drips, dirt), texture qualities (smooth vs. rough), and appearance, may be zero (shiny vs. drab). a specific degree of hardness or strength, as well as resistance to friability, to survive mechanical handling during production, packaging, and transportation. The strength of a tablet's crushing is typically measured by hardness. The methods listed below were used to determine a tablet's strength; Using the thumb and second and third fingers, break the tablet between them.

Generally, used Hardness testers are:

- Testers include Monsanto, Strong-Cobb, and Pfizer.
- Tester, Erweka
- Tester Schleuniger
- A compressed tablet ranges in hardness from 5 to 8 kg.
- A tablet's friability can be tested in the lab using the Roche friabilator.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

- It consists of a polymer chamber that rotates at 25 rpm and drops the tablets into a friabilator at a range of six inches; the friabilator is then turned 100 times. The pills are weighed again. Tablets that are crushed and lose between 0.5% and 1.0% of their original weight are deemed acceptable.

Drug Release and Content:

- Test for Weight Variation (U.S.P.):
- 20 pills, each weighed separately.
- Calculate the average weight before comparing it to the weight of each tablet.
- If no more than two tablets deviate by more than the permitted % and no tablets differs by much more than twice the permitted percentage, the tablet passes the USP test.

Sr. No.	Average weight	Maximum percentage difference allowed
1 2 3	130 or less 130-324 More than 324	10 7.5 5

Content Uniformity Test:

30 tablets should be chosen at random.

10 of them were individually examined.

The pill is successful if nine out of ten pills contain no more than 85 percent and no and over 115 percent of the drug content listed on the label, and if the tenth tablet has no more than 75 percent and exactly 125 percent.

If these parameters don't appear to be met, the remaining 20 pills will be individually tested to ensure that none of them will fall beyond the range of 85 to 115.

Disintegration check (U.S.P.):

A half-dozen glass tubes, each measuring 3" in length, are used in the U.S.P. apparatus to test for disintegration; the glass tubes are open at the top and have ten mesh screens at the bottom.

One pill is placed in each tube, and the basket rack is placed in a 1-L beaker filled with water, simulated stomachic fluid, or simulated viscus fluid at 37 20 C, with the condition that the pill remain two.5 cm below the surface of the liquid on its upward movement and not closer than two.5 cm from the beaker's highest point on its downward movement.

Move the tablet-containing basket up and down over a distance of 5–6 cm at a rate of 28–32 cycles per minute.

Every tablet will have perforated rubber discs to stop the pills from floating.

The pill should dissolve as expected, and each fragment should pass through the ten mesh sieve in the allotted period.

If there is any residue left, it ought to have a soft bulk.

Disintegration time:

Uncoated tablet: 5 to 30 minutes; tablet: 1 to 2 hours; USP-required dissolution check:

Two equipment sets:

Apparatus-1:

One pill is put in a very small wire mesh basket that is attached to the lowest point of the shaft that is powered by a speed control motor.

The basket is submerged in a very strong extraction solvent (as per the monograph) that is housed in a very strong flask with a 100 metric capacity.

The flask has a subfigure bottom and is cylindrical.

The flask is kept at a constant temperature of 37.50C by a continuous temperature bath.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

To determine the amount of medication in solutions, the motor is set to run at the desired rate and fluid samples are periodically taken.

Apparatus-2:

Similar to apparatus 1, but with a paddle in place of the basket. Before stirring, the unit dosage type is permitted to reach the lowest point in the flask. U.S.P. specifies the dissolving check medium and volume, equipment type, shaft rev, check point, and assay technique for the dissolution check. The indicated amount of drug dissolving within the specified period of time is how the check sensitivity is expressed. Three stages of stability studies and analysis will be completed:
Six pills are tested in Stage 1; if none of them appear to be higher than the treatment tolerance limit (Q),
Stage 1 is acceptable; if it fails,
Stage 2 involves testing an additional six tablets. The tablets meet requirements.
Take six tablets and inspect each one to see if they are larger or more capable than the others, but no one but (Q-15) nada
If the average of the twelve exceeds or is capable of satisfying Q, and also no unit is less than (Q-15), then the test for failure is true.
Stage 3 involves testing twelve additional pills. The tablets are accepted if the average size of all twenty-four tablets is greater than or equal to Q, and if not nearly two tablets are acceptable.

II. CONCLUSION

Read and understand different documents in QA department such as MFR, BFR,BMR, SOP, Certificate Of analysis, validation documents, etc
Observed raw material testing by HPLC, dissolution test of capsule and tablet formulation by uv .
Generation of distil water ,water for injection, sterilewater, Filling and packaging of intravenous fluids and its sterilization by autoclave were observed.
Evaluation test like leak test , inspection of particles in intravenous fluids against black and white background ,label inspection,were performed
Dry powder injectionables
Process of filling and packaging of dry powder injectionables, blending of ingredients were observed
Leak test , weight variation, test against white and black background
Packaging were performed
Tablets compression , coating blister packing weight variation performed
Capsule filling strip and blister packaging inspection of shape , filled and empty capsule against white background were performed

- Completed One Month Training In Hindustan Antibiotics Limited (A Govt. of India Enterprise)

REFERENCES

[1]. http://hindantibiotics.in