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Review on Pharmaceutical Industrial Process

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Abstract: *An ideal dosage regimen in the drug therapy of any disease is the one, which immediately attains the desire therapeutics concentration of drug in plasma (or at the site of action) and maintains it constant for the entire duration of treatment. This is possible through administration of conventional dosage form in a particular dose and at a particular frequency Thus drug may be administered by variety of routes in dosage form. Generally, dosage forms are simply classified as solids or liquids. Solid dosage forms include tablets and powders used in propelled inhalants, such as asthma inhalers. Liquid dosage forms can vary greatly in viscosity of their final mixture, and can range from orally-ingested syrups to topical serums to solutions that are administered intravenously, The key consideration is to choose the ideal dosage eg solid, Liquid, semisoild for Easy administration and produce therapeutic effect.*

Keywords: Dosage form, Types of dosage form, Need, route of Administration, Classification, Excipient, Quality control Test ,Advantages & Disadvantages, Validation process, examples, etc.

I. INTRODUCTION

Pharmaceutical industry is the discovery, development, and manufacture of drugs and medications (pharmaceuticals) by public and private organizations. The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered to patients (or self-administered), with the aim to cure them, vaccinate them, or alleviate symptoms.

Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy using drug testing and marketing of drugs. India is the largest provider of generic drugs globally.

Classification of Dosage form

Dosage form

Combination of drug and different kind of non-drug components called additives is called dosage form Dosage forms are pharmaceutical drug products in the form in which they are marketed for use, with a specific mixture of active ingredients and inactive components, in a particular configuration, and a particular dose.

Several factors state the characteristics of an ideal dosage form, they are outlined below

- It should be safe and simple to administer
- It should be economical for the patient
- It should be physically and chemically stable in environmental conditions

Need for convert drug to dosage forms

- Accurate dose.
- Protection e.g. coated tablets, sealed ampoules.
- Protection from gastric juice.
- Masking taste and odor (to make palatable).
- Convenient to handle, use and store
- Stable during storage and use
- Withstand mechanical shock during transport
- Flexibility in different drug strength
- Provide expected therapeutic effect

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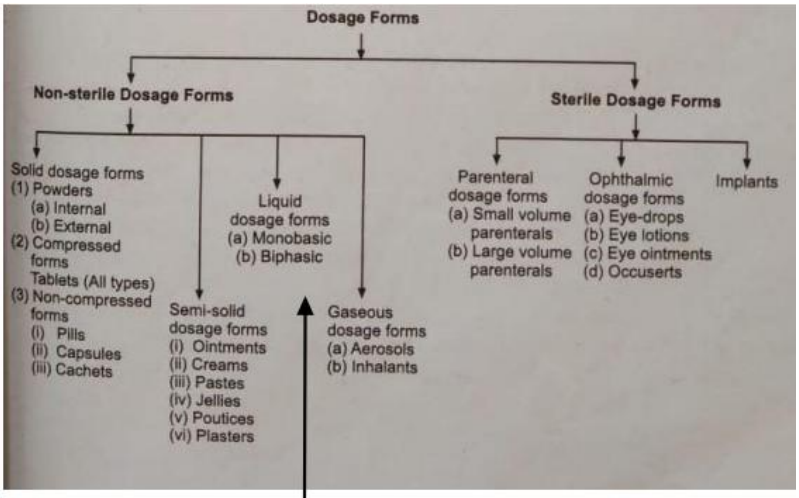
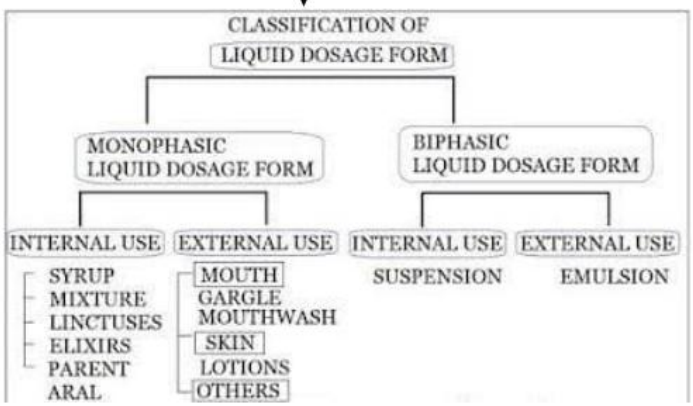
- Extent, drug release, onset, intensity, duration of action predictable
- Economical and elegant

Importance of dosage form

- To protect the drug substance from oxidation, hydrolysis and reduction
- To protect drug from the destructive effect of gastric juice (Hydrochloric acid)of the stomach after oral administration eg. enteric coated tablet
- To provide a safe and convenient delivery of accurate dose
- To mask the bitter taste or odour of drug substance eg capsule, coated tablet, flavoured syrup
- To provide for the optimum drug action through inhalation therapy eg. inhalation aerosols
- To provide maximum drug action from topical administration site eg cream, ointment, opthalmic preparation and ear, nose
- To provide sustain release action through controlled release mechanism eg. sustain released tablets, capsule
- To provide liquid dosage form of drug soluble in suitable vehicle eg solutions





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- Powders: Solid dosage forms containing finely divided Particles in micro size
- Tablets: Solid dosage form containing medicaments with Or without excipient
- Aggregate of particles
- Capsules: Drug enclosed with gelatin capsule
- Drugs enclosed with wafer sheet of rice
- Pills: Small tablet containing excipient
- Lozenges: Solid preparations containing sugar and gum Used to medicate mouth and throat

Basically, liquid dosage forms are divided into two parts according to phase.
Monophasic liquid dosage form: Monophasic means only one phase is there. That is the liquid phase.

- Internal Use- Syrup, mixture, linctuses, elixirs, parenteral
- External use- Gargle, mouthwash, lotions, nasal ,eardrops.

Liquid Dosage Form

- Syrups: Sweet, viscous, concentrated liquid preparations containing with or without sugar There are various medicinal syrups like as cough syrups, iron syrups, calcium syrups, syrups for digestion, anti allergy syrup, anti fever syrup
- Mixture: Liquid oral preparations containing one or more medicaments
- Elixirs : sweetened hydro-alcoholic (water and alcohol) liquids for oral use. Typically, alcohol and water are used as solvents when the drug will not dissolve in water alone
- Parenteral : solutions, suspensions, emulsions for injection or infusion, powders for injection or infusion, gels for injection and implants. . They are sterile preparations intended to be administrated directly into the systemic circulation in humans or animals
- Gargles: Concentrated aqueous solutions for external use used To treat throat infections
- Mouth washes: Concentrated aqueous solutions for external Use used to treat mouth infections
- Lotions: Liquid preparations for external application usually Applied without friction
- Nasal drops: Liquid preparations containing medicaments That are instilled in to the nose with a dropper used to treat Nose infections and blockage of nose

Semisolid dosage forms

Semisolid dosage forms are also contain solid and liquid both. These types of dosage forms are viscous in nature. Normally used for topical or external application. • Ointments: Preparations for external use, intended for application to the skin. Typically, they have an oily or greasy consistency and can appear “stiff” as they are applied to the skin. Ointment is translucent. These are washable and contains 80percent oil

- Cream: Cream is a preparation usually for application to the skin. It has Opaque appearance .cream has equal parts oil and water
- Pastes: That contain one or more drug substances intended for topical/external application to the skin. Pastes form a protective coating to the area where it is applied
- Jellies: Gels are aqueous colloidal suspension of hydrated forms of insoluble medicaments. Jellies are transparent or translucent, non-greasy semi-solid preparation mainly used externally.
- Poultices (Cataplasm):It is a soft, viscous preparation for external use. They Applied to skin when they are hot.applied to the skin to hold the dressing and protective
- Plasters: Substances intended for external application made of such materials and of such consistency as to adhere to the skin and attach to a dressing.

Gaseous dosage form

- Aerosols: Pharmaceutical: Aerosols are pressurized dosage forms containing one or more active ingredients which upon activation emit a fine dispersion of liquid and/or solid materials in a gaseous medium.

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- Inhalants: Inhalants: are volatile substances that produce chemical vapors that can be inhaled to induce a psychoactive, or mind-altering effect.

Sterile dosage form

Sterile dosage forms are those which are free from any microorganisms, dust, fibres, and foreign particles, and should be isotonic. Parenteral preparations as name suggests (par+enteral) are those which are administered other than enteral routes. Sterile dosage form classified into 3types Parenteral dosage form Opthalmic dosage form Implants Parenteral dosage form

Parenteral Dosage Form

Classified into small volume parenteral and large volume parenteral

- Small volume parentral: Small volume (SVPs) according to U.S.P "an injection that is packaged in containers labelled as containing 100ml or less".
- Large volume parenteral: Large volume parenterals (LVPs) according to FDA are aqueous solutions which are supplied in volumes of at least 100ml with sizes of 250ml, 500ml, 1000ml and more

Opthalmic dosage form:

Ophthalmic preparations are specialized dosage forms designed to be instilled onto the external surface of the eye (topical), administered inside the eye (intraocular) or adjacent to it (periocular,

- Eye: medication to be applied in very small amounts to the eyeball.
- Eye lotion: lotion cosisting of a solution used as a cleanser for the eyes.
- Eye ointment :Eye ointments are medicines in an ointment form. They are used when the medicine needs to work directly in your eye to relieve or treat eye conditions. Eye ointments are used to treat conditions such as dry eyes or eye infections.
- Occusert:Ocuserts system is a novel drug delivery system is based on porous membranewhich are designed in such a way that they release the drug at predetermined and predictable rates thus eliminating the frequent administration of the drug. It shows diffusion controlled release. Implants: Material that are securely inserted or placed into the body

Implant

is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure. Medical implants are man-made devices, in contrast to a transplant, which is a transplanted biomedical tissue.

DISPENSING

Dispensing the right materials to the right batches prior to the manufacturing process is a key activity in life sciences and other process industries. The process is critical when working with potent active pharmaceutical ingredients (APIs) in drug manufacturing.

Decimal errors in API calculation can be life threatening. Companies preweigh materials to avoid these errors and to assure rapid delivery at the critical stages of the drug formulation process.

Dispensing Out Starting Materials

Step 1: Room clearance

Room Clarence prior to introducing any new chemical is a GMP rule. The removal of all previous chemicals and any dust residues ensures that the next raw material being introduced will not be contaminated. This is accomplished by physically inspecting the room, the weighing station, the dispensing utensils, and the dispensing booth to make sure that they are free from all contaminants.

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Step 2: Setup

The dispensing setup Is a critical step. This is where the operator matches the paperwork to the chemicals to be dispensed. Take particular care and double- check that the right chemical and the right lot or batch number has been issued by the warehouse against the paperwork.

Step 3: Weighing

When weighing chemicals first make sure that the scales are within calibration. Carefully weigh the exact amount prescribed in the paperwork. Double-check: that the right chemical the right lot number and the right amount are weighed.

Step 4: Clean-up

After finishing weighing, there will be residual dust that must be cleaned up immediately. There should be procedures describing this clean-up plus paperwork to verify that the clean-up has occurred. After clean-up, unused chemicals can be returned to the main store accompanied by the paperwork Record and sign each weighing on the official record as you go. Ensure that you lake all personal protection prescribed in your company's procedures.

TABLET

Tablet is defined as a compressed solid dosage form containing medicaments with Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluent

Advantages

•Easy to administer
•They are easiest and cheapest to package and strip.
•Low in cost.
•Having greatest chemical and microbial stability over all oral dosage forms.
•Suitable for large scale production.

Disadvantage

•Difficult to swallow in case of children and unconscious patient
•Objectionable odour and bitter taste can be masked by coating technique.
•Some drugs resist compression into dense compacts, owing to amorphous nature, low density character
•Irritant effects on the GI mucosa by some solids (e.g., aspirin)
•Possibility of bioavailability problems resulting from slow disintegration and dissolution manner.

INGREDIENTS

Diluents: Diluents are fillers used to make required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk. Also used to improve cohesion, to permit use of direct compression.

Binders: to form cohesive compacts for directly compressed tablet

Lubricants: Lubricants are intended to prevent adhesion of the tablet materials to the surface of dies and punches, reduce inter particle friction and may improve the rate of flow of the tablet granulation

Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles

Anti–adherents: Anti-adherents are added to the tablet formulations to prevent the material from sticking to the walls of the tablet press

Disintegrates: Added to a tablet formulation to facilitate its breaking or disintegration when it contact in water in the GIT.

The use of colors and dyes in a tablet has three purposes: (A) Masking of off color drugs (B) Product Identification (C) Production of more elegant product

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Flavoring Agents: Flavoring oils are needed for chewable tablets. The oil is generally added in a dry form such as spray-dried beadlets

The inclusion of absorbents in a tablet formulation is necessary if the product
contains a substance with a high affinity to water. Hygroscopic materials, if present, render the blend wet and difficult to handle during manufacture.

MANUFACTURING

Procedure for Manufacturing of Tablets:-

1.Dispensing: Each ingredient in the tablet formula is weighed and accurately dispensed as per dose. This is one of the critical steps in any type of formulation process and should be done under technical supervision.

2.Sizing: Formulation ingredients must be in finely divided form, otherwise, size reduction should be carried out for better flow property and easy mixing.

3.Mixing equipment:e.g., pneumatic tumbling mixers diffusion/ mixers (e.g., Vblender, double cone blender, cubic mixer, drum blender).

4.Granulators: e.g. , Rotating shape granulators , dry granulator , high shear granulator etc.

5.Drying:e.g. spray dryer , rotary dryer , fluidized bed dryer etc .e.g. single punch tablet press and multi station /rotary tablet press Exp. Fette Press, CardPress etc

6. Evaluation /Quality control (QC) equipment :e.g., disintegration equipment , USP Dissolution Tester, Tablet Hardness Tester, Tablet Thickness Tester, Tablet Friability Testers etc.

8.Coating and polishing machines for coated tablets: e.g., standard coating pan, perforated pan, fluidized bed/ Air suspension coating system etc.

9. Packaging machines:e.g., blister packing machine, aluminium foil packaging machine, etc. Machine name Dph-220/260 High Speed Blister Packing Machine.

Tablet Manufacturing Equipment:-

1. Size reduction equipment: e.g., Hammer mill , roller mill , fluidized energy mill , cutter mill and ball mill .

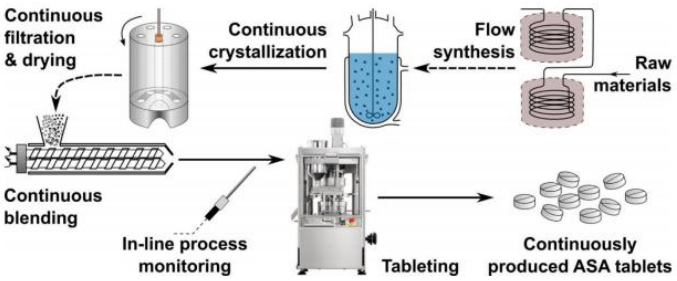
2. Weighing balance/ balances: e.g., bulk weighing balance (weighs in kilogram), electronic weighing balance (weighs in grams and milligrams).

3. Granulation: Here small powder particles are gathered together into layers, and permanent aggregates to render them into free-flowing states.

4. Drying and dry screening: Screened wet granules need to be dried for a particular time period in tray dryer or fluid bed dryer at controlled temperature not exceeding 550 degree C . Dried granules are screened through the appropriate mesh screen .

5. Tablet compression: This step involves the compression of granules into a flat or convex, round, oblong, or unique shaped, scored or unscored tablets; engraved with an identifying symbol and/ or code number using tablet press.

6. Coating: Tablets and granules are coated if there is need to mask the unpleasant taste/odour of some drug substance or to increase the aesthetic appeal of uncoated tablets as well as to modify the release or control the release of drug substance from tablets. This is achieved by enclosing or covering the core tablet or granules with coating solutions.



Evaluation and Quality Assurance test

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DOCUMENTATION:

Document is any written statement or proof. Documentation is an essential part of Quality Assurance and Quality Control system and it is related to all aspects of Good Manufacturing Practices (GMP).

CGMP:

CGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities

SOP:

SOP is a procedure specific to your operation that describes the activities necessary to complete tasks in accordance with industry regulations, provincial laws or

Deviation:

Deviations are measured differences between observed value and expected or normal value for a process or product condition

Validation:

Establishing documented evidence that provide high degree of assurance that specific process will consistently produce a product meet its predetermined specification and quality attributes.

Qualification

DQ:

Design Qualification (DQ) is the documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose, meeting regulatory and process needs

IQ:

Installation qualification, or IQ, is a documented verification process that the instrument or piece of equipment has been properly delivered, installed and configured according to standards set by the manufacturer or by an approved installation checklist.

OQ:

Series of tests which ensure that equipment and its sub-systems will operate within their specified limits consistently and dependably.

PQ:

Collection of test cases used to verify that a system performs as expected under simulated real-world conditions.

APR:

Annual product review is an evaluation conducted annually to assess the quality standard of each drug product with the view to verify the consistency of existing process and to check the appropriateness of current specifications and to highlight any tends in order to determine the need to change any drug product

CAPA:

Corrective Action Preventive Action (CAPA) is the process used to examine and solve problems, identify causes, and takes any corrective actions, all in order to prevent any recurrences of the root cause.

QM:

Quality Management (QM) means a systematic, data-driven effort to assess, monitor, evaluate, report, and compare outcomes on all health care services and functions using appropriate quality indicators and tools, as well as, Corrective Action Plans when errors and/or deficiencies are identified

IPQC:

IPQC stands for in process quality control. These are checks that are carried out before the manufacturing process is completed. The function of of in-process controls is monitoring and if necessary adaption of the manufacturing process in order to comply with the specifications

Active Pharmaceutical Ingredient /Content uniformating

The term used to refer to the biologically active component of a drug product i.e. tablet, capsule. Generally, drug products are included with various components.

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Assay of Active Ingredient:

An assay is an investigative (analytic) procedure for qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of a target entity

Weight uniformity test/ weight variation test:

20 tablets are weighed individually and the average weight is calculated. The individual tablet weights are then compared to the average weight.

Not more than two of the tablets must differ from the average weight by not more than the percentages stated in table.

Weight variation USP/IP

Average weight USP	Percent difference	Average weight IP/BP
130mg or less	±10 %	80mg or less
130mg to 324mg	±7.5 %	80mg to 250mg
More than 324 mg	±5 %	More than 250mg

Friability Test :

Friability is defined as the % of weight loss by tablets due to mechanical action during the test.

Rotate the drum 100 times with a speed of 25 rpm.

For tablets with a unit mass equal to or less than 650 mg, take a sample of whole tablets corresponding to 6.5 g.

For tablets with a unit mass of more than 650 mg, take a sample of 10 whole tablets.

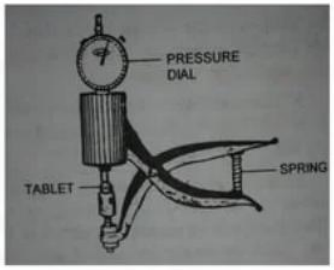
Limit: Friability % : Not more than: 1.0%

It is usually measured by the use of the Roche friabilator.

A number of tablets are weighed and placed in the apparatus where they are exposed to rolling and repeated shocks as they fall 6 inches in each turn within the apparatus.

After 4 minutes of this treatment or 100 revolutions, the tablets are weighed and the weight compared with the initial weight. The loss due to abrasion is a measure of the tablet friability. The value is expressed as a percentage.

Pfizer tablets hardness tester



Hardness Test :

• The resistance of tablets to capping, abrasion or breakage under conditions of storage, transportation and handling before usage depends on its hardness.

• The Monsanto or Stokes hardness tester measures the force required to break the tablet when the force generated by a coil spring is applied diametrically to the tablet unit is kg/cm

• The Strong-Cobb Pfizer and Schleuniger apparatus which were later introduced, masure the diametrically applied force required to break the tablet

Dissolution test:

Dissolution testing measures the extent and rate of solution formation from a dosage form, such as tablet, capsule, ointment, etc.

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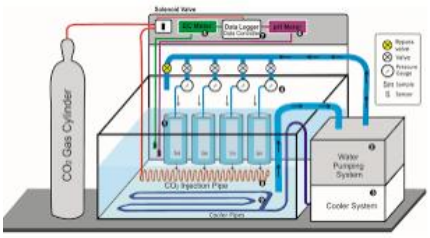
As per IP:

Dissolution apparatus	Name
1	Basket type
2	Paddle type
3	Reciprocating cylinder
4	Flow through cell
5	Paddle over disk
6	Rotating cylinder
7	Reciprocating disk



Disintegration time test :

The disintegration test is used to show how quickly the tablet breaks down into smaller particles, allowing for a greater surface area and availability of the drug when taken by a patient.

Disintegration time	Range
Uncoated Tablet	NMT 15 minutes
Film and Sugar coated Tablet	NMT 60 minutes
Enteric Coated Tablet	02 hours in 0.1 N HCL & 60 min in buffer
Hard Gelatin Capsule	NMT 30 minutes
Soft Gelatin Capsule	NMT 60 minute

Quality Control test

The construction industry has been scuffling with quality issues for several years, and therefore the cost to our economy is dramatic. The price could potentially be reduced significantly if the industry were to embrace the concept of quality assurance that has been used with great success by many other sectors of the economy.

REQUIREMENTS FOR QUALITY CONTROL

The Quality Control process includes quality planning, training, providing clear decisions and directions, constant supervision, immediate review of completed activities for accuracy and completeness, and documenting all decisions, assumptions and recommendations.

In the construction plan development process, it is the clear responsibility of the designer to ensure all project elements are economical, accurate, properly prepared, coordinated, checked, and completed.

In order for the project to consistently meet the needs and expectations of our citizens, quality must be as important as the schedule and budget.

Design personnel shall follow established design policies, procedures, standards and guidelines in the preparation and review of all design products.

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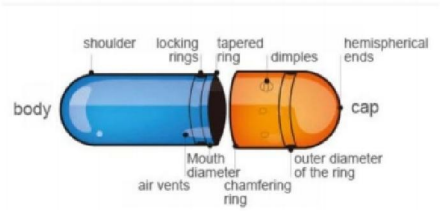
Design consultants are agents for the project with the primary responsibility for preparation of construction plans. Consultants must ensure quality and adhere to established design policies.

For Tablet And Capsule

Leak test:

which is used to check the integrity of packed strips blisters, bottels and small sachets containing tablets capsules and dry powder.

Capsule:



A solid dosage form in which the drug enclosed in hard or soft gelatin

Advantages

Capsules can mask the odor and taste of unpleasant medicines and can be simply administered

Easy to swallow with water

Capsule have highest bioavailability than tablet form

Disadvantages

It may not be suitable for high-dose of drugs

It may cause gastric irritation

For storage require special condition

Ingredient

Aditives	Examples
Plasticizer	Glycerin,Sorbitil,Glycerol
Preservatives	Methyl Paraben,Propyl Paraben
Flavouring Agent	Peppermint Oil,Anise Oil
Surfactant	Tween ,Propyl Sorbate
Binder	Mineral Oil,Sucrose,Lactose
Lubricants	Magnesium Stearate,Tal
Diluent	Lactose,Bentonite,Mannitol
Glidants	Silican Dioxide
Viscosity Modifier	Lecithin
Coating	Shellac
Opacifier	Titanium Dioxide

MANUFACTURING OF CAPSULE

THERE ARE TWO METHOD FOR MANUFACTURING OF CAPSULE

CENTRIFUGAL CASTING METHOD: Process that use centrifugal force to form cylindrical part

There are two types of centrifugal casting method

Vertical centrifugal casting

Horizontal centrifugal casting

Dip pin method

The method involves heating the pins, dipping the pins into the solution to cause the solution to gelatinize on the surface of the pins, removing the pins and drying the gelatinized solution on the surface of the pins to form capsule bodies and capsule caps.

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DIP PIN METHOD INCLUDES; time of dipping 12 sec.
Temperature of solution 50 °C
Temperature of pin 22 °C
Spinning :pins are rotate to get uniform distribution of gelatin to get desire thickness.
Drying: pin or mould are subjected to dry and dehumification occur to get proper shape.
Stripping :capsule are stripped from pinby bronz jaw.
Trimming ; cutting of capsule into cap and body.
Rejoining: Joining of cap and body.
The basic steps in filling capsules Include
Rectification of capsules (placing empty gelatin Capsules on the removable plate with bodies facing downward
Separation of caps from bodies.
Dosing of fill material (The body is filled with the Formulation)
Automatic Capsule fill machine:-Automatic Capsule filling machine automatically fills the capsule by the dry forms of powders. It is used in the industries for a large number of production of
the capsules. They are extremely durable in nature.
Semi-Automatic Capsule Fill Machine:-The semi-automatic capsule fill name itself says that it is partially working both automatic and manual both. Their equipment is very simple in design and very
easy to operate. It's very hygiene in use.

Manual Capsule Fill Machine:

Manual Capsule machines are mostly used for the small-scale Pharma industries as they produce less amount of capsules so it can be done manually. It requires no power and it is operated by hand.

Quality Assurance Evaluation:

Content of active ingredient/ absolute drug content test/ assay of active ingredient:

Content Uniformity test

This test is performed only when the content is specified in the individual monographs.
If weight of capsules is completely filled no need of this test.
If any weight difference is there this test is performed.
In this 30 capsules are selected and 10 of them are for assay so that by proper analysis we can determine the amount of drug.
If 9 of 10 is in the specified potency range of 85 to 115% and 10th is not outside 75 to 125%.
If more than 1 but less than 3 deviate, we have to go for remaining 20 and assayed.
Test requirements are met if none of capsules is outside 75-125% range and not less than 27 of 30 are within 85-115% range. Then particular batch passes this test

Capsule capacity:

Size	Actual Volume (ml)	Typical Fill Weights (mg) 0.70 Powder Density
000	1.37	960
00	0.95	665
0	0.68	475
1	0.50	350
2	0.37	260
3	0.30	210
4	0.21	145
5	0.13	90

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WEIGHT VARIATION;FOR 20 CAPSULES

IP	Limit
Less Than 300 Mg	± 10%
300 Mg Or More	± 7.5%

Solubility limit for empty capsule:

Water resistance:fail to dissolve in water at 20 to 30 degree celsius in 15 min.

Acid solubility: should get dissolved in less than 5min in 0.5% aq.HCL at 36-38 °C

Hardness test :

Hardness	Ratio(Dry glycerin to soft gelatin)
Hard	0.4/1
Medium	0.6/1
Soft	0.8/1

DISINTEGEATION TEST: The ability of sample to break into smaller partical

Capsule Type	Time
Soft Gelatin Capsule	NMT60 Min.
Hard Gelatin Capsule	NMT30 Min.

LIQUID DOSAGE FORM

ADVANTAGES

Liquid dosage forms (for oral use) are the most suitable dosage form for patients who have difficulty taking tablets or capsules, as might be the case with pediatric or geriatric patients.

They are attractive in appearance and gives beneficial psychological effects.

Drugs with bitter and unpleasant taste can be given in sweetened, coloured and flavoured vehicles.

DISADVANTAGES

Liquid dosage forms are usually more susceptible to chemical degradation when compared to solid dosage forms.

They are bulky and therefore inconvenient to transport and store.

Accidental breakage of the container results in loss of whole dosage form.

MANUFACTURING OF LIQUID DOSAGE FORM :

PROCESS :

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Oral Liquid Syrup Manufacturing Plant Values like current, product temperature are displayed digitally on the electrical control panel.

The mechanical seal is equipped with a water circulating system and has a water detection sensor which trips the motor, if the water circulation to the seal is interrupted.

Our Syrup Manufacturing Plants, Mixing machines and equipments including Pharmaceuticals Syrup Manufacturing Plants, Oral Suspension Manufacturing Plants, Oral Solution Manufacturing Plants, Oral Drop Manufacturing Plants, Oral Emulsion Manufacturing Plants, Mixture Manufacturing Plants, Linctuse and Elixir LIQUID ORAL Manufacturing Plants are ideal tools for the pharmaceutical industry for the production of Oral dose Liquids.

Oral Liquid Syrup Manufacturing Plant Values like current, product temperature are displayed digitally on the electrical control panel.

The mechanical seal is equipped with a water circulating system and has a water detection sensor which trips the motor, if the water circulation to the seal is interrupted.

Liquid formulations are an essential part of any pharmaceutical portfolio. As your ideal partner for liquid applications we provide excipients for both small molecule and large molecule liquid formulations, and for liquid formulations that target different administration routes such as parenteral, ophthalmic, oral, nasal and otic preparations.

Our wide range of excipients for liquid dosage forms includes:

Formulation /Manufacturing procedure:

COMPONENTS

• Surfactant Solubilising agents – eg- Polysorbate 80. Flocculating agent – eg- gum acacia,wool fat,methylcellulose, Wetting agent – eg- Tweens 80, spans ,SLS. Emulsifying agents Antifoaming agents –eg- Castor oil, fatty acids.

• Colouring agent – example- coal tar dyes such as amaranth (red),caramel(brown),indigo(blue), napthol(black).

• Flavouring agents - Tinctures- tincture lemon, and tincture ginger . Fruit juicesraspberry juice , wild cherry. Essence- vanilla, orange.

• Preservative –example-methyl paraben , sodium benzoate, benzoic acid.

• Antioxidant agent-example- BHA,BHT

PROCEDURE

1. General preparation for monophasic dosage form- For soluble compound :- Dissolve solid In ¾ th of vehicle add any liquid ingredient make up to the volume by vehicle For diffusible solids powder in mortar Add soluble drug and mix Add vehicle 3/4 Make cream and add remaining vehicle Transfer content mortar to measuring cylinder Add any liquid ingredient Make it up to the volume by vehicle

• For indiffusible solid:- mix all powder and suspending agent (tragacanth) add¾ the vehicle slowly Triturate it till form cream Add other liquid ingredient Transfer the mixture into measuring cylinder Add vehicle for required volume Emulsion: Dry gum method, Wet gum method

Dry gum method

Measure the required quantity of oil in a dry measuring cylinder and transfer it into dry mortar

• Add calculated amount of gum into it and triturate rapidly to form uniform mixture

• Add required amount of water and triturate it till clicking sound is produced –(primary emulsion)

• Add more water to produce required volume .

Wet gum method

• Calculate the quantity of oil, water and gum required for preparation of primary emulsion Powder gum in a mortar Add water and triturate it with gum so as to form a mucilage Add required quantity of oil in small proportion with rapid trituration until clicking sound is produced and product becomes white (primary emulsion).

• Add more of water in small portion to the primary emulsion with trituration to produced the required volume, stir thoroughly so as to form a uniform emulsion.Liquid form of a dose of a drug used as a drug or medication intended for administration or consumption. Liquid form of a dose of a drug used as a drug or medication intended for administration or consumption.

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There are potential advantages of oral liquid dosage forms, such as no dissolution time and rapid absorption from the stomach/intestine compared to tablets, which may be an important factor for pain-relieving drugs. Inherent in this benefit is the risk of reaching peak plasma levels too fast, which could be harmful. Finally, as the excipient technology advances, a controlled release profile in liquid forms will likely become readily available.

EVALUATION PARAMETER OF LIQUID DOSAGE FORM

SYRUP

Transmittance of light: A light transmittance meter is a newer tool that is used to check syrup color. In a light transmittance meter, a syrup sample is checked for color by passing light through the sample. The percent of light transmission is compared to light transmission rates set for different grades. When using one, you need to be sure there are no fingerprints on the syrup test bottle, and that the syrup sample has no bubbles or cloudiness.

pH measurement: The measurement and maintenance of pH is also a very important step in quality control testing. Generally, there are two different types of methods used in the measurement of pH.

Elixirs:

Determination of alcohol content:

Elixir usually contains 5 to 40% alcohol. The determination of alcohol unless otherwise specified in the individual monograph. It is suitable for examining most fluid extracts, tinctures and elixirs provided the capacity of the distilling flask is sufficient (commonly two to four times the volume of the liquid to be heated) and the rate of distillation is such that clear distillates are produced. Cloudy distillates may be clarified by agitation with talc, or with calcium carbonate. And filtration is done.

Suspension:

Sedimentation method: Two parameters are studied for the determination of sedimentation. They are (i) Sedimentation volume and (ii) Degree of flocculation. (i) Sedimentation Volume: The suspension formulation (50 ml) is poured separately into 100 ml measuring cylinders and sedimentation volume is read after 1, 2, 3, and 7 days, and thereafter at weekly intervals for 12 weeks. Triplicate results are obtained for each formulation. Sedimentation volume is calculated according to the equation:

$$F = \frac{V_u}{V_o}$$

where, F = sedimentation volume
V_u = ultimate height of sediment
V_o = initial height of total suspension

(ii) Degree of flocculation (β): It is the ratio of the sedimentation volume of the flocculated suspension (F), to the sedimentation volume of the deflocculated suspension,

SEMI-SOLID DOSAGE FORM

Application on the skin or accessible mucous membranes to provide localized and sometimes systemic effects at the site of application. In general, semisolid dosage forms are complex formulations having complex structural elements. They are often composed of two phases (oil and water), one of which is a continuous(external) phase and the other a dispersed (internal) phase. The active ingredient is often dissolved in one or both phases, thus creating a three-phase system.

Semisolids are characterized by a three-dimensional structure that is sufficient to impart solid-like character to the undisturbed system but that is easily broken down and realigned under an applied force.

Ideal Properties of Semisolid Dosage Forms:

1. Physical Properties:
2. Smooth texture
3. Elegant in appearance
4. Non dehydrating
5. Non gritty
6. Non greasy and non-staining

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7. Smooth texture
8. Elegant in appearance
9. Non dehydrating
10.Non gritty
11. Non greasy and non-staining
a) Smooth texture
b) Elegant in appearance
c) Non dehydrating
d) Non gritty
e) Non greasy and non-staining

2. Physiological Properties:
a) Non irritating
b) Do not alter membrane / skin functioning
c) Miscible with skin secretion
d) Have low sensitization index

Advantages of semi-solid dosage form:

o It is used externally
o The probability of side effects can be reduced
o First, pass gut and hepatic metabolism is avoided

Disadvantages of semi-solid dosage form:

o The accuracy can't be measured, for the semisolid dosage form.
o May cause staining.
o They are bulky to handle.

MANUFACTURING OF SEMISOLID DOSAGE FORM:

Add ingredients in the optimal phase and order:

Generally, topical formulations comprise one or more phases. Emulsions, for example, primarily comprise an aqueous phase and a hydrophobic phase. Adding ingredients in the correct phase contributes to overall stability.

Protect APIs from degradation:

The manufacturing process must be designed to protect APIs from physical degradation. Some APIs, such as retinoic acid compounds, are sensitive to both UV light and oxygen. These APIs can be protected by using yellow or amber light that is free from harmful low-wavelength UV rays and by using nitrogen, argon, or another inert gas to purge the product of oxygen.

Identify equipment constrains:

The manufacturer must be able to perform all processes using its current equipment capabilities. The scale-up path for a 1:10 batch size from the pilot or clinical size to commercial level must exist with similar equipment. Guidance from FDA's Scale-Up and Post approval Changes Semisolids (SUPAC-SS) Working Group provides the basis of comparison for the design and operating principles of equipment.

Understand critical process parameters

temperature Processing at the right temperature is critical for successful manufacturing. Too much heating during processing can result in chemical degradation.

Insufficient heat can lead to batch failures, and excess cooling can result in the precipitation of solubilized ingredients. An example of the need for good temperature control is the emulsification step of a traditional oil-in-water emulsion. If the temperature of the water phase is much cooler than that of the oil phase, the melted constituents of the oil phase may solidify upon introduction into the aqueous phase and never properly form the emulsion, possibly even resulting in solid matter in the batch.

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Heating and cooling rates

Heating too slowly can result in poor yields from evaporative loss. Heating too rapidly may burn areas of the batch in contact with the heating surface, which raises the potential for burnt material in the batch. Rapid cooling can result in precipitation/crystallization or increased viscosity When top, middle, and bottom active uniformity samples differed by more than 15%, DPT added a recirculation loop during mixing. The loop produced a far more uniform product without increasing the speed or time of mixing. The successful consistency of ointments, for example, depends on proper rates of heating and cooling.

Mixing methods and speeds:

It is essential to determine the required amount of shear and the optimal mixing methods and speeds. Emulsification typically requires high shear or homogenization to obtain the optimal droplet size and dispersion, while the mixing of a gel may require low shear in order to preserve certain physical characteristics, such as viscosity. Proper mixing speeds must be obtained for each phase at every batch scale. Optimal hydration depends on the amount of shear imparted to initially disperse the polymer into the medium. If the process involves only very low shear mixing, a polymer may never be completely dispersed and hydrated, which may result in an out of specification viscosity. Equipment, such as a recirculation loop, may also be used to correct uniformity without changing mixing speed or time. Mixing of gels require low shear .Obtaining proper mixing speeds for each phase at very batch scale.

Mixing times:

Optimizing mixing time requires identifying the minimum time required for ingredients to dissolve and the maximum mixing time before product failure (e.g., when viscosity begins to drop). For polymeric gels, particularly acrylic acid-based types, over-mixing, especially high shear, can break down the polymer's structure. In an emulsion, overmixing may cause the product to separate prematurely, resulting in a drastic decline in viscosity.

Processes that must be validated in pharmaceutical manufacturing are

o Cleaning
o Sanitization
o Fumigation
o Depyrogenation
o Sterilization
o Sterile filling
o Fermentation
o Bulk production
o Purification
o Filling, capping, sealing
o Lyophilization

EVALUATION PARAMETER:

Ointment:

Content uniformity of drug

A known weight of ointment is taken and assayed for amount of the drug.

Penetration

A weighed quantity of ointment is rubbed over skin for a given period of time and unabsorbed ointment is collected and weighed. The differences in weights represent the amount absorbed

IRRITANT EFFECT

In general no ointment should possess irritant effect on the skin or mucous membranes the tests for irritancy can be carried out on the skin and eyes of rabbits or the skin of human beings.

Suppositories:

Uniformity of weight test

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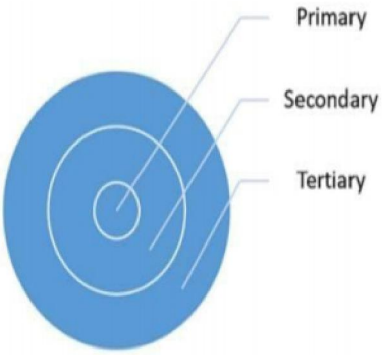
To perform this 20 suppositories are weighed and average weight is calculated.
Then each suppository is weighed individually and weight noted.
No suppository should deviate from the average weight by more than 5%except that two should not deviate by more than 7.5%.
The weight variation may result if some cavities are under filled and other are overfilled

PACKAGING

Packaging can be defined as an economical means of providing presentation, protection, identification information, containment, convenience and compliance for a product during storage, carriage, display and until the product is consumed.



Types of packaging material.

Primary packaging:

is designed to provide protection from excessive transmission of moisture or solvents into or out of the product, provide light protection for the product, provide additional microbiological protection by protecting the product from microbial intrusion, and provide protection from excessive transmission of reactive gases (atmospheric oxygen, inert headspace filler gas, or other organic vapors) into or out of the product. Examples of primary packaging include vials, syringes, ampules, stoppers, closures, bottles, pouches, and blisters. The primary packaging consist of those packaging components which have a direct contact with the product (i.e. bottle, cap, cap liner, label etc). The main functions of the primary package are to contain and to restrict any chemical, climatic or biological or occasionally mechanical hazards that may cause or lead to product deterioration.Packaging must also function as a means of drug administration.

Solid Dosage Forms :

Tamper – evident containers are closed containers fitted with a device that irreversibly indicates if the container has been opened.

Strip packages: have at least one sealed pocket of material with each pocket containing a single dose of the product. The package is made of two layers of film or laminate material. The nature and level of protection which is required by the contained product will affect the composition of these layers.

Strip packaging machine

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A strip package is a form of unit dose packaging that is commonly used for the packaging of tablets and capsules. A strip package is formed by feeding two webs of a heat-sealable flexible film through either a heated crimping roller or a heated reciprocating plate.

The product is dropped into the pocket formed prior to forming the final set of seals. A continuous strip of packets is formed, generally several packets wide depending on the packaging machine's limitations. The strip of packets is cut to the desired number of packets in length.

The strips formed are usually collated and packaged into a folding carton. The product sealed between the two sheets of film usually has a seal around each tablet, with perforations usually separating adjacent packets. The seals can be in a simple rectangular or "picture-frame" format or can be contoured to the shape of the product. Since the sealing is usually accomplished between pressure rollers, a high degree of seal integrity is possible. The use of high-barrier materials such as foil laminations or saran-coated films, in conjunction with the excellent seal formation, makes this packaging mode appropriate for the packaging of moisture-sensitive products.

Blister packages:

A package holding and displaying merchandise in a clear plastic case sealed to a sheet of cardboard are composed of a base layer, with cavities called blisters which contain the pharmaceutical product, and a lid. This lid is sealed to the base layer by heat, pressure or both. They are more rigid than strip packages and are not used for powders or semisolids. In tropical areas blister packages with an additional aluminium membrane is used which provide greater protection against high humidity. When one thinks of unit dose in pharmaceutical packaging, the package that invariably comes to mind is the blister package.

This packaging mode has been used extensively for pharmaceutical packaging for several good reasons. It is a packaging configuration capable of providing excellent environmental protection, coupled with an esthetically pleasing and efficacious appearance. It also provides user functionality in terms of convenience, child resistance, and now, tamper resistance.6 The blister package is formed by heat-softening a sheet of thermoplastic resin and vacuum-drawing the softened sheet of plastic into a contoured mold.

After cooling, the sheet is released from the mold and proceeds to the filling station of the packaging machine. The semi-rigid blister previously formed is filled with product and lidded with a heat-sealable backing material. The backing material, or lidding, can be of either a push-through or peelable type. For a push-through type of blister, the backing material is usually heat-seal-coated aluminum foil. The coating on the foil must be compatible with the blister material to ensure satisfactory sealing, both for product protection and for tamper resistance.

Peelable backing materials have been used to meet the requirements of childresistant packaging. This type of backing must have a degree of puncture resistance to prevent a child from pushing the product through the lidding and must also have sufficient tensile strength to allow the lidding to be pulled away from the blister even when the lidding is strongly adhered to it. To accomplish this, a material such as polyester or paper is used as a component of the backing lamination.

Foil is generally used as a component of the backing lamination if barrier protection is a critical requirement; however, metallized polyester is replacing foil for some barrier applications. A peelable sealant compatible with the heat-seal coating on the blister is also required since the degree of difficulty of opening is a critical parameter for childresistant packaging. The use of peelable backing materials for blister packaging must be carefully evaluated to ensure that peelstrengths are sufficient to meet tamperresistance objectives. Materials commonly used for the thermo-formable blister are poly vinyl chloride (PVC), PVC/polyethylene combinations, polystyrene, and polypropylene. For commercial reasons and because of certain machine performance characteristics, the blisters on most unit dose packages are made of polyvinyl chloride.

For added moisture protection, polyvinylidene chloride (saran) or polychlorotrifluoroethylene (Aclar) films may be laminated to PVC. The moisture barrier of PVC/Aclar is superior to that of saran-coated PVC.

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Alu alu blister packaging machine

Automatic Blister Packing Machine Model:

LI-MAC 40+ design of the machine is ergonomic used for both the Cold Forming (ALU/ALU) and Thermo Forming (PVC/ALU) blister packs. This machine is suitable for Large production batches in pharmaceutical industry. We have used the best ideas from the past and developed with the future. The main movements are mechanical and pneumatic, all the control systems used in the equipment are the best in the electronic market.

Liquid Dosage Forms :

Glass containers Glass is commonly used in pharmaceutical packaging because it possesses superior protective qualities.

Ampoules:

Ampoules are thin-walled glass containers, which after filling, are sealed by either tip sealing or pull sealing. The contents are withdrawn after rupture of the glass, or a single occasion only. These are great packaging for a variety of drugs. The filed – in product is in contact with glass only and the packaging is 100% tamper proof. The break system OPC(one –point cut) or the color break ring offer consistent breaking force. There are wide variety of ampoule types from 0.5 to 50ml. Up to 3 color rings can be placed the stem or body for identification purpose. Printed ampoules with heavy metal free colors are available.

Some of them are:

• Type B straight –stem
• Type C funnel –tip
• Type D closed .

Bottles, vials and syringes:

These are more or less thick walled containers with closures of glass or of material other than glass such as plastic materials or elastomers. The contents may be removed in several proportions on one of or more occasions.

Plastic container:

Plastics in packaging have proved useful for a number of reasons, including the ease with which they can be formed, their high quality, and the freedom of design to which they lend themselves. Plastic containers are extremely resistant to breakage and thus offer safety to consumers along with reduction of breakage losses at all levels of distribution and use. Plastic containers for pharmaceutical products are primarily made from the following polymers: polyethylene, polypropylene, polyvinyl chloride, polystyrene, and to a lesser extent, polymethyl methacrylate, polyethylene terephthalate, polytrifluoroethylene, the amino formaldehydes, and polyamides.Plastic containers consist of one or more polymers together with certain additives. Those manufactured for pharmaceutical purposes must be free of substances that can be extracted in significant quantities by the product contained. Thus, the hazards of toxicity or physical and chemical instability are avoided. The amount and nature of the additives are determined by the nature of the polymer, the process used to convert the plastic into the containers, and the service expected from the container. For plastic containers in general, additives may consist of antioxidants, antistatic agents, colors, impact modifiers, lubricants, plasticizers, and stabilizers. Mold release agents are not usually used unless they are required for a specific purpose.

Metal container:

Tin: Tin containers are preferred for foods, pharmaceuticals, or any product for which purity is an important consideration. Tin is chemically inert of all collapsible tube metals. It offers a good appearance and compatibility with a

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wide range of products. Aluminum: Aluminum tubes offer significant savings in product shipping costs because of their light weight. They provide good appearance.

Lead: Lead has the lowest cost of all tube metals and is widely used for nonfood products such as adhesives, inks, paints, and lubricants. Lead should never be used alone for anything taken internally because of the risk of lead poisoning. The inner surface of the lead tubes are coated and are used for products like fluoride toothpaste.

Closures: The closure is normally the most vulnerable and critical component of a container in so far as stability and compatibility with the product are concerned. An effective closure must prevent the contents from escaping and allow no substance to enter the container. The adequacy of the seal depends on a number of things, such as the resiliency of the liner, the flatness of the sealing surface on the container, and most important, the tightness or torque with which it is applied. In evaluating an effective closure system, the major considerations are the type of container, the physical and chemical properties of the product, and the stabilitycompatibility requirements for a given period under certain conditions.

Secondary packaging:

main purpose is for branding display, logistical purposes, and protecting and collating individual units during storage. Secondary packaging also includes packaging purposely made to display multiple product units for sale, which speeds restocking from storeroom to shelf; this packaging includes retail-ready packaging, shelfready packaging, or countertop display units. Examples of secondary packaging include pouches, boxes, and trays.

Tertiary packaging:

facilitates the protection, handling, and transportation of a series of sales units or secondary packages in order to group everything into unit loads during transit. This type of packaging is rarely seen by the consumer. Examples of tertiary packaging include boxes, totes, shrink wrap, and pallets. Packaging components can be made using paper, paperboard, plastics (rigid and flexible), natural materials, metal, and glass and a multitude of modern production processes including injection molding, stretch blow molding, extrusion blow bolding,injection blow molding , compression molding ,rolling etc

Shrink Wrapping Machine

DISPATCH

The dispatch of finished good Is acritical phase in the pharmaceutical supply chain , as it involves the efficient distribution of safe and effective medication to patients in need. Pharmaceutical companies invest substantial efforts and resources to manufacture high finished product.

II. CONCLUSION

As a solid dosage form , tablets are popular among patients and practitioners alike they provide a means of self administration.the formulation of a tablet contains ,in addition to the API, various substance to assure proper delivery of the API to the patient. Liquid dosage forms are easy to administer for childrens and elderly as well as patient who finds difficulty in swallowing solid dosage forms.

ABBREVIATION

- Svps-Small volume parenteral
- Lvps-Large volume parenteral

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- APl-Active pharmaceutical Ingredients
- GMP-Good manufacturing practices
- cGMP-Current good manufacturing practice
- SOP-Standard operating procedure
- QC -Quality Control
- DQ-Design Qualification
- IQ -Installation Qualification
- OQ-Operational Qualification
- PQ-Performance Qualification
- APR-Annual product review
- CAPA-Corrective and preventive action
- QM-Quality management
- IPQC-In process quality control
- USP-United State Pharmacopoeia.
- IP-Indian pharmacopoeia
- NRA -National regulatory authority

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