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MUCOADHESIVE TABLET: AN OVERVIEW

Swathi P Nair[*], Muhammed Muneer Koolikad[2], Dr L.V Vigneshwaran[3], Dr. Ajith Babu T.K[4]

[*]Lecturer, Malik Deenar College of Pharmacy Seethangoli Kasargod
[2]Malik Deenar College of Pharmacy Seethangoli Kasargod
[3]HOD, Dept. of pharmaceutics, Malik Deenar College of Pharmacy seethangoli, kasargod,
[4]Principal, Malik Deenar College of Pharmacy seethangoli, Kasargod

Corresponding Author: swathipnair8@gmai.com

Keywords:

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ABSTRACT

A mucoadhesive tablet is a type of drug delivery system that adheres to the mucosal lining of the mouth, cheek, or other internal cavities. The article "Mucoadhesive Tablet: An overview" comprises with different matters such as introduction, GMP and GLP requirements. Preformulation, identification and characterization methods, drug-excipient compatibility study, criteria for excipient selection, formulation optimization techniques and formulation are illustrated. Description of the evaluation and stability studies are included. The SOPs of equipment's, packaging and labelling are explained.

INTRODUCTION TO DOSAGE FORM

MUCOADHESIVE TABLET

A mucoadhesive tablet is a type of oral drug delivery system that adheres to the mucosal lining of the mouth, cheek, or other internal cavities. This adherence allows for prolonged drug release and improved absorption compared to conventional oral tablets.

Advantages:

(i) Prolonged Drug Release: Mucoadhesive tablets adhere to the mucosal lining, extending the drug's residence time at the absorption site. This leads to a more sustained release of the drug into the bloodstream.

(ii) Improved Bioavailability: By bypassing first-pass metabolism in the liver, mucoadhesive tablets can improve the bioavailability of certain drugs.

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(iii) Localized Drug Delivery: Mucoadhesive tablets can be used to deliver drugs locally to specific areas of the body, such as the mouth or vagina. beneficial for treating localized infections or conditions.

(iv) Enhanced Patient Compliance: Mucoadhesive tablets are typically small and easy to administer, which can improve patient compliance.

Disadvantages:

(i) Potential for Irritation: Some mucoadhesive polymers can cause irritation or discomfort at the application site.

(ii) Variability in Mucoadhesion: The effectiveness of mucoadhesion can vary depending on individual patient factors, such as saliva flow rate and mucosal conditions.

(iii) Potential for Microbial Growth: Mucoadhesive tablets may provide a favorable environment for microbial growth, which could lead to infections in some cases.

(iv) Limited Drug Loading Capacity: Mucoadhesive tablets have a limited capacity for incorporating large amounts of drugs. This may restrict their use for drugs with high doses.

CLASSIFICATION

I. Classification Based on Target Application

(i) Oral mucoadhesive tablets: These tablets are designed to adhere to the mucosal lining of the mouth, cheek, or tongue. They are used to deliver drugs locally to the oral cavity or systemically into the bloodstream.

(ii) Buccal mucoadhesive tablets: These tablets are designed to adhere to the buccal mucosa, which is the lining of the inner cheek. They are used to deliver drugs systemically into the bloodstream.

(iii) Nasal mucoadhesive tablets: These tablets are designed to adhere to the nasal mucosa, which is the lining of the nose. They are used to deliver drugs locally to the nasal cavity or systemically into the bloodstream.

(iv) Vaginal mucoadhesive tablets: These tablets are designed to adhere to the vaginal mucosa, which is the lining of the vagina. They are used to deliver drugs locally to the vagina or systemically into the bloodstream.

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II. Classification Based on Type of Polymer

(i) Natural polymers: These polymers are derived from natural sources, such as chitosan, alginate, and carrageenan. Natural polymers are often biodegradable and biocompatible, making them suitable for use in mucoadhesive tablets.

(ii) Synthetic polymers: These polymers are synthesized in the laboratory, such as polyacrylates, polycarbophils. Synthetic polymers can be designed with specific properties to optimize mucoadhesion.

III. Classification Based on Method of Preparation

(i) Direct compression: This is the simplest method of preparation, and it involves directly compressing a mixture of powdered drug and polymer into a tablet.

(ii) Wet granulation: This method involves wetting the powdered drug and polymer with a granulating liquid to form granules, which are then dried and compressed into tablets.

IV. Classification Based on Mechanism of Mucoadhesion:

(i) Physical mucoadhesion: This type of mucoadhesion relies on non-specific physical interactions between the polymer and the mucus layer. These interactions can be due to hydrogen bonding, van der Waals forces, or electrostatic interactions.

(ii) Chemical mucoadhesion: This type of mucoadhesion involves covalent or ionic bonding between the polymer and the mucus layer. This type of mucoadhesion is typically stronger and more persistent than physical mucoadhesion.

APPLICATIONS

(i) Oral drug delivery: Mucoadhesive tablets are commonly used to deliver drugs for the treatment of oral conditions, such as pain, inflammation, and infection. They can also be used to deliver drugs for systemic absorption, such as nicotine replacement therapy and antiemetics.

(ii) Nasal drug delivery: Mucoadhesive tablets can be used to deliver drugs for the treatment of nasal congestion, rhinitis, and allergies. They can also be used to deliver drugs for systemic absorption, such as vaccines and pain relievers.

(iii) Vaginal drug delivery: Mucoadhesive tablets can be used to deliver drugs for the treatment of vaginal infections, such as candidiasis and bacterial vaginosis. They can also be used to deliver hormonal contraceptives.

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EXAMPLES

(i) Nicotine replacement therapy (NRT) tablets: used to help people quit smoking by providing them with a controlled dose of nicotine.

(ii) Ondansetron hydrochloride tablets: used to prevent nausea and vomiting.

(iii) Fexofenadine hydrochloride tablets: used to treat allergies.

GMP AND GLP REQUIREMENTS FOR MUCOADHESIVE TABLET

GMP (Good Manufacturing Practices) is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. GMP is provided under schedule M of drugs and cosmetic rule, 1945.

PART 1: Good Manufacturing Practices for Premises and Materials.

PART 2: Good Manufacturing Practices for Plant and Equipment.

1. General Requirements

1.1. Location And Surroundings

The factory building for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environmental including open sewage, drain, public lavatory or any factory which product disagreeable odour, fumes, excessive soot, dust, smoke, chemical or biological emissions.

1.2. Building And Premises

The building and premises used for the factory shall be designed, constructed, adapted and maintained to suit the manufacturing operations so as to permit production of drugs under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948

1.3 Water System

There shall be validated system for treatment of water drawn from own or any other source accordance with standards specified by the Bureau of Indian Standards or Local Municipality. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth.

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1.4. Disposal Of Waste

The disposal of sewage and effluents from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board. All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste Management and Handling Rules, 1996.

2. Warehousing Area

Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits, where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials.

3. Production Area

The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations. In order to avoid the risk of corss-contamination, separate dedicated and self-contained facilities shall be made available

4. Ancillary Areas

4Rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas. Facilities for changing, storing clothes and for washing and toilet

5. Quality Control Area

Quality Control Laboratories shall be independent of the production areas. Separate areas shall be provided each for physico-chemical, biological, microbiological or radio-isotope analysis. Adequate space shall be provided to avoid mix-ups and cross-contamination.

6. Personnel

The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience. Number of personnel employed shall be adequate and in direct proportion to the workload.

7. Health, Clothing and Sanitation of Workers

Prior to employment, all personnel, shall undergo medical examination. A high level of personal hygiene shall be observed by all those engaged in the manufacturing processes. All personnel shall wear clean body coverings appropriate to their duties.

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8. Sanitation in the Manufacturing Premises

The manufacturing premises shall be cleaned and maintained in an orderly manner; A validated cleaning procedure shall be maintained. The records of these have to be maintained.

9. Raw Materials

The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per Schedule U. All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions Raw materials in the storage area shall be appropriately labeled.

10. Equipment

Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance.

11. Documentation and Records

Documentation is an essential part of the Quality assurance system and, as such, shall be related to all aspects Good Manufacturing Practices (GMP). Documents shall be approved, signed and dated by appropriate and authorized persons. Documents shall specify the title, nature and purpose.

GLP REQUIREMENTS

Good Laboratory Practice (GLP) is a quality system covering the organizational process and conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, reported, and archived.

1. Quality Assurance Programme

The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice.

2. Facilities

The test facility should be of suitable size, construction and location to meet the requirements of the study. It should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects

3. Apparatus, Material and Reagents

Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained.

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Materials used in a study should not interfere adversely with the test systems.

Reagents should be labelled to indicate identity with concentration, expiry date and specific storage instructions.

4. Standard Operating Procedures

A test facility should have written Standard Operating Procedures approved by test facility management

Standard Operating Procedures should be available for,

- Test and Reference Items
- Apparatus, Materials and Reagents
- Record Keeping, Reporting, Storage, and Retrieval
- Test System
- Quality Assurance Procedures

5. Organizational and Personnel

- Person requirements include educational qualification, training, and experience to
- There shall be sufficient and a number of personnel for the proper conduct of studies
- The personnel should be provided with appropriate clothing suiting to their needs
- The personnel should be subjected to proper medical examination

6. Reporting of Study Results

A final report should be prepared for each study. Content of the Final Report:

- Identification of the Study, the Test Item and Reference Item
- Information Concerning the Sponsor and the Test Facility
- Dates
- Statement
- A Quality Assurance Programme statement
- Description of Materials and Test Methods
- Results

7. Documentation

Documentation is the accepted method of recording information to future reference. The major documents that need to be provided are protocols, logbook for usage, maintanence and calibration of equipment there should be well established SOPs.

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PREFORMULATION STUDY FOR MUCOADHESIVE TABLET

It studies about the physical and chemical properties of the drug and excipients prior to formulation. This information is then used to optimize the formulation and ensure safe, effective stable mucoadhesive tablet.

Objectives of Preformulation Study:

1. Characterize the physicochemical properties of the drug and excipients
2. Determine the solubility, permeability, and stability of the drug
3. Assess the mucoadhesive properties of polymers
4. Identify compatibility issues between the drug and excipients
5. Select suitable excipients.

Key Parameters to Be Studied

1) Mucoadhesive Property:

Evaluation of the mucoadhesive strength of potential polymers using various techniques like texture analysis,tensile strength measurements and detachment force studies.

2) Drug - Excipients Compatibility Study:

Drug-excipient compatibility assessment to identify potential interactions using techniques like:

- Differential scanning calorimetry (DSC)
- Fourier transform infrared spectroscopy (FTIR)

3) Organoleptic Properties:

Evaluation of drug on the basis of colour, odour, texture, taste.

4) Permeability:

Assessment of the drug's permeability across mucosal membrane

Key parameters in general:

5) Particle size, shape, surface area

6) Solibility

7) Partition Coefficient

8) Cristallinity and polymorphism

9) Density, Flowabilty, Wettability

10) Dissolution

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IDENTIFICATION AND CHARACTERIZATION METHODS FOR DRUG

The identification and characterization of drugs involve a series of tests:

1. Appearance: Visually inspect the drug for size, shape, color, and surface texture
2. pH: Measure the pH of the drug using a pH meter. The pH should be close to physiological pH to ensure compatibility with the buccal mucosa.
3. Solubility study: solution of drug was prepared using 10 ml of distilled water or any other organic solvent in 25 ml volumetric flask. Then by using mechanical shaker, the flasks were kept for 48 hours. The sampling was done 24th and 48th hour. The sample withdrawn (Iml after filtration) was diluted with appropriate medium and was analyzed using UV spectrophotometer at 26Inm
4. Melting point determination: Melting point of drug was determined by taking a small quantity of drug in capillary tube sealed at one end and was placed in Thiel's melting point apparatus and temperature range at which the drug melted was noted. Average triplicate readings were noted.
5. Determination of λ max: In order to ascertain the wavelengths of maximum absorption (λ max) of the drug, different solutions of the drug (10ug/ml or 20 ug/ml) in organic solvent were scanned using UV visible spectrophotometer within the wave length region of 200-3 80nm against organic solvent as blank.

EXCIPIENT DRUG COMPATIBILITY STUDY

This study detects drug-excipient interaction which may affect stability of mucoadhesive tablet.

Methods:

1. Visual Inspection

Observe any physical changes in the drug-excipient mixture, such as discoloration, clumping, or formation of crystals.

2. Microscopic Evaluation

Examine the drug-excipient mixture under a microscope to detect any morphological changes or incompatibilities.

3. Differential Scanning Calorimetry (DSC)

Analyze the thermal behavior of the drug and excipients individually and in combination to identify potential interactions or incompatibilities. Appearance of new endothermic/exothermic peak indicates incompatibility

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4. Fourier Transform Infrared Spectroscopy (FTIR)

Analyze the infrared spectra of the drug and excipients individually and in combination to detect any chemical changes or interactions.

5. Accelerated Stability Studies

Store the drug-excipient mixture under accelerated conditions (temperature, humidity, and light) to evaluate its stability over time.

Factors affecting drug-excipient compatibility:

1. Physicochemical properties of the drug: solubility, pH, and pKa
2. Excipient Properties: The type and concentration of excipients used can also influence compatibility.
3. Environmental Factors: temperature, humidity, and light, can accelerate drug-excipient interactions and affect compatibility.

CRITERIA FOR EXCIPIENT SELECTION

Excipients play a vital role in various aspects of performance including mucoadhesion, drug release, compatibility, and stability.

1. Mucoadhesive Properties: The selected excipients should possess mucoadhesive properties to facilitate prolonged contact between the tablet and the buccal mucosa, enhancing drug absorption. Common mucoadhesive polymers include polycarbophil, carboxymethylcellulose, and hydroxypropyl methylcellulose.

2. Drug Release: Excipients should influence drug release in a controlled manner to achieve the desired therapeutic effect. This may involve selecting excipients that modulate tablet dissolution and diffusion through the mucosal membrane.

3. Compatibility: The excipients should be compatible with the drug to ensure stability and prevent interactions that could affect drug activity or stability.

4. Excipients should fulfill their intended functions within the tablet formulation. This includes binders to provide tablet strength, disintegrants to facilitate tablet disintegration, and lubricants to ensure smooth tablet ejection during manufacturing.

5. Safety: Excipients should be non-toxic, non-irritating. Toxicological studies may be required to evaluate the safety of excipients.

6. Regulatory Compliance: Excipients should comply with regulatory guidelines, such as those set by the United States Pharmacopeia (USP) or the European Pharmacopoeia.

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7. Cost-Effectiveness: Excipients should be cost-effective without compromising the quality or performance of the mucoadhesive tablet.

8. Manufacturing Considerations: Excipients should be readily available, easy to handle, and compatible with manufacturing processes to ensure efficient and reproducible production.

9. Patient Acceptability: Excipients should not impart undesirable characteristics, such as taste, odor, or color, that could affect patient acceptance of the mucoadhesive tablet.

10. Physiologically inert

11. Physically and Chemically stable

12. Free from impurities and microbial hazards

FORMULATION OPTIMIZATION TECHNIQUE

Optimization means to make mucoadhesive tablet perfect, effective or as functional as possible. It is process of finding best way of using the existing resources.

Key Formulation Optimization Techniques:

1) Excipient Selection: Selecting appropriate excipients with suitable mucoadhesive properties, such as polycarbophil, carboxymethylcellulose, and hydroxypropyl methylcellulose, is essential for achieving prolonged contact time with the buccal mucosa and enhancing drug absorption.

2) Mucoadhesive Polymer Concentration: Optimizing the concentration of mucoadhesive polymers can significantly impact mucoadhesion strength and drug release. Higher polymer concentrations generally enhance mucoadhesion but may also retard drug release.

3) Plasticizer Selection and Concentration: Plasticizers, such as polyethylene glycol (PEG) and glycerin, can improve the flexibility and deformability of mucoadhesive tablets, enhancing their adaptation to the irregular mucosal surface and promoting intimate contact. The concentration of plasticizers should be carefully controlled to balance mucoadhesion and drug release.

4) Tablet Shape and Size: The shape and size of mucoadhesive tablets can influence their mucoadhesion and drug release behavior. Smaller, round-shaped tablets may exhibit better mucoadhesion due to their larger surface area relative to volume.

5) Surface Modification: Modifying the tablet surface using techniques like co-precipitation or electrostatic layer-by-layer deposition can introduce mucoadhesive ligands, such as chitosan or hyaluronic acid, to enhance mucoadhesion and improve drug targeting.

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6) Incorporation of Penetration Enhancers: Incorporating penetration enhancers, such as fatty acids or bile salts, can temporarily disrupt the mucosal barrier, facilitating drug permeation and enhancing bioavailability.

FORMULATION OF MUCOADHESIVE TABLET

Components Of Mucoadhesive Tablet

1. Drug: The active pharmaceutical ingredient (API) that provides the therapeutic effect.

2. Mucoadhesive polymers: These polymers interact with the mucins present in the mucosal lining, forming strong adhesive bonds that prolong the residence time of the tablet at the absorption site.

Examples:

- Carbopol: A polyacrylic acid derivative that forms a viscous gel upon hydration.
- Hydroxypropyl methylcellulose (HPMC): A semi-synthetic polymer with swelling and mucoadhesive properties.
- Sodium carboxymethylcellulose (CMC): A cellulose derivative that acts as a gelling agent and mucoadhesive.

3. Fillers: These inert substances provide bulk to the tablet and aid in uniform mixing and compression. Examples: lactose, microcrystalline cellulose, and mannitol.

4. Binders: These agents bind the drug and other excipients together, ensuring the tablet's integrity and stability. Examples: polyvinylpyrrolidone (PVP), povidone (Kollidon), and gelatin.

5. Lubricants: These substances reduce friction during tablet compression and prevent sticking to the dies and punches of the compression machine. Examples: magnesium stearate, talc, and sodium stearyl fumarate.

6. Disintegrants: These agents promote the tablet's breakup in the oral cavity, releasing the drug for absorption. Examples: sodium starch glycolate, croscarmellose sodium, and crospovidone.

Formulation Methods for Mucoadhesive Tablets

1. Direct compression: This is a simple and widely used method that involves blending all the ingredients and directly compressing the powder mixture into tablets using a compression machine.

2. Wet granulation: This method is suitable for drugs that are poorly soluble or compressible. The drug and excipients are mixed with a granulating liquid to form granules, which are then dried and compressed into tablets.

3. Dry granulation: This method is similar to wet granulation but uses a dry binding agent instead of a liquid. This method is preferred for drugs that are sensitive to moisture.

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Evaluation Of Mucoadhesive Tablet

The evaluation of the tablet is an essential step for the complete dosage form design of the tablet.

1. Size and shape
2. Organoleptic properties
3. Weight and weight variation.
4. Content uniformity
5. Hardness
6. Friability
7. Thickness
8. Swelling index
9. Surface pH
10. Stability in human saliva
11. Mucoadhesive strength

1. Size and shape

The size and shape of a mucoadhesive tablet should be suitable for intended site of administration. The tablet should be in uniform shape and size.

2. Organoleptic Properties

Organoleptic evaluation includes the taste, presence of odor, colour and surface texture etc.

3.Weight and Weight Variation

The weight of all tablets should be uniform and the variation limits are ±10% for tablet weight 130mg or less, ±7.5 % for tablet weight more than 130mg and up to 324mg, and ±5 % for tablet weight 325mg or more.

4. Content Uniformity

According to label claim the standard deviation should be less than 6%. The active ingredients in dosage form should be lies between 85% to 115%.

5. Hardness

The hardness is a value which is required to crush the tablet in hardness tester machine. Generally, it is express in term of load/pressure. There are some testers that are used to determine hardness are given below:

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a. Monsanto tester
b. Strong-cobb tester
c. Pfizer tester
d. Erweka tester

6. Friability

For the testing of friability, apparatus used is Roche friabilator. The friability test is used for the determination of physical stability when tablet faces friction, shock and breaks. The apparatus consist of 2-3 compartments, this chamber rotates at the Speed of 25 RPM and the tablet is dropdown with the height of 15 cm with each revolution.

7. Thickness

The thickness of a tablet is generally measured in micrometer. According to standard thickness of a tablet, the deviation should not by ±5%. The variation in thickness of tablet may cause problem in packaging and in mucoadhesion.

8. Swelling index

Measures the tablet's ability to absorb water and swell, which can influence mucoadhesion.There should be optimum swelling index for mucoadhesive property.

9. Surface pH

Indicates the acidity or alkalinity of the tablet surface, which can influence its interaction with the mucosal surface. The surface pH should be equivalent to saliva,GI fluid or other body fluid involved.

10. Stability in human saliva

Buccal mucoadhesive tablet is placed in a 5ml of human saliva and observed for any change in texture, characteristics etc.

11. Mucoadhesion test

Porcine buccal mucosa was used as a model mucosal surface for bioadhesion test. Mucoadhesive forces of the tablets were determined utilizing modified balance.

STABILITY TESTTING OF MUCOADHESIVE TABLET

Stability testing provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, light.

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Stability Studies are performed on:

1. Drug Substances: the unformulated drug substance that may subsequently be formulated with Excipients.

2. Drug Products: The dosage form in the final intended for marketing

- Photo stability Testing: Photo stability testing should be conducted on at least one primary batch of the drug product if appropriate.
- Selection of Batches: At least three primary batches. The batches should be manufactured to a minimum of pilot scale by the same synthetic route and same method of manufacture and procedure.
- Container Closure System: The stability studies should be conducted on the drug substance packaged in a container closure system that is the same as or simulates the packaging proposed for storage and distribution.

Testing Frequency

Long term studies - every 3 months over the first year, every 6 months

Over the second year, and annually thereafter through the proposed shelf life.

Accelerated studies - minimum of three time points, including the initial and final time points.

Stability Testing Methods

1. Real-Time stability testing
2. Accelerated stability testing.
3. Cyclic temperature stress testing

1. Real-Time Stability Testing

Real-time stability testing is normally performed for a longer duration of the test period in order to allow significant product degradation under recommended storage conditions.

2. Accelerated Stability Testing

In accelerated stability testing, a product is stressed at several high temperatures and the amount of heat input required to cause product failure is determined.

This is done to subject the product to a condition that accelerates degradation.

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3. Cyclic Temperature Stress Testing

In this method, cyclic temperature stress tests are designed on knowledge of the product so as to mimic likely conditions in market place storage. The period of cycle mostly considered is 24 hours since the diurnal rhythm on earth is 24 hours, which the marketed mucoadhesive tablet are most likely to experience during storage.

Study	Storage condition	Minimum time period covered by data at submission
Long term	5°C ± 3°C	12 months
Accelerated	25°C ± 2°C/60% RH ± 5% RH	6 months

Study	Storage condition	Minimum time period covered by data at submission
Long term*	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH	12 months
Intermediate**	30°C ± 2°C/65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months

SOP OF VARIOUS EQUIPMENTS INVOLVED IN PREPARATION

SOP of tablet compression machine

Purpose

The purpose of this SOP is to establish a standard procedure for operating the compression machine.

Scope

This SOP will be applicable for the compression machine in the compression area of the production section.

Responsibility

- Machine Operator is responsible for operating the Compression Machine.
- Production Pharmacist is responsible for the implementation of this SOP.
- HOP is responsible to ensure the implementation of this SOP.
- Quality Assurance Officer monitors the compliance of this SOP.

Procedure

1. Production Pharmacist will ensure that the compression machine and the area are properly cleaned.
2. Production Pharmacist will ensure that the compression machine and Area is labeled with Cleaned label status.
3. Before starting the operation of a compression Machine ensure that the machine is installed with tooling as mentioned in BMR or batch manufacturing record.
4. The production Pharmacist should ensure that all the tooling is properly installed, meaning punches are free to move in dies and dies are tightly screwed.

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5. After ensuring that hoppers and feed frames are installed correctly, award line clearance.
6. After production line clearance, take line clearance from the QA officer.
7. After line clearance, add powder or granules in the hoppers of the compression machine and ensure that the pressure rollers and weight regulators are neutral.
8. Rotate the machine manually to ensure proper filing of feed frame housings and dies.
9. Operate the machine at jog speed, apply little pressure and adjust the weight of the tablet according to BMR or batch manufacturing record.
10. When required tablet weight is achieved apply more pressure to set hardness and thickness of tablet according to the batch manufacturing record.
11. When required tablet weight, hardness and thickness are achieved, turn on the tablet deduster and metal detector & increase the speed or RPMs of the compression machine.
12. Adjust tablet weight, hardness and thickness again if required.
13. Take samples for in-process testing and after clearance of all the parameters compress the whole batch.
14. After compression, turn off the machine, affix to be cleaned label and record the activity in the logbook.

Tablet compressing machine

PACKAGING AND LABELLING OF MUCOADHESIVE TABLET

Types Of Packaging for Tablets

1. Blister packing
2. Strip packing
3. Alu packaging

1. Blister Packaging

Used for unit dose packaging two primary components are cavity made from either plastic or aluminum and the lidding made from paper, plastic or aluminum. The cavity contains the product and the lidding seals the product.

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2. Strip Packaging

Formed by feeding two webs of heat sealable flexible film through heated crimping rollers. Materials used: foil laminations, paper, polyethylene, cellophane.

3. ALU ALU Packaging

Alu alu packaging means aluminium foil at upper and lower side of pack. Similar to blister packaging, difference is forming film is aluminum instead of plastic.

Blister Packing Strip Packing Alu Packing

REFERENCES

1. Warbrick, Encyclopedia of Pharmaceutical Technology. Third edition - 6 Volume.
2. B. Venkateswara Reddy, K. Navaneetha, P. Sandeep. Improved tablet production by modified granulation techniques, International Journal of research in pharmacy and life sciences, ijrpls, 2014; 2(2): 224-235.
3. Physical and chemical stability testing of tablet dosage form by Leo Lachman journal of pharmaceutical science volume 54 p.1519-1526.
4. Asian journal of pharmaceutical and clinical research, volume 11, issue 6,2018.
5. The ability of the geriatric population to read labels on over-the-counter medication containers Article Feb 1994 J Am Optom Assoc, R K Watanabe.
6. Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth report. Geneva, World Health Organization, 1996, Annex 5 (WHO Technical Report Series, No. 863).
7. Stability of drug dosage forms. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first report. Geneva, World Health Organization, 1990.

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8. Packaging and labelling for patient and site compliance. Clinical Research and Regulatory Affairs, 1994, 11(1):61-65. Santhosh T.A brief overview on tablet and its types. Journal of advancement in pharmacology.2020;5(4):21-31.
9. Choudhury P, Saikia U. A Review Article on the Formulation and Evaluation of Fast Dissolving Tablet of Naproxen. Scientific Pharmacology.2020;1(10): 44-47.
10. Parashar B, Chandel A. Prashar D. Formulation and Evaluation of aspects of Tablets. American Journal of Pharmtech Research. 2012; 2(1):68-7.
11. Pharmacy and Pharmaceutical Research. 2015;2(3):1-17. 11. Jishan A. A Review on Immediate Release Tablet Dosage Form.
12. Rai VK, Pathak N, Bhaskar R. Optimization of immediate release tablet of raloxifene hydrochloride by wet granulation method. International journal of pharmaceutical sciences and drug research.2009;1(1):51 - 54.
13. Mukesh Gohel. A Review of coprocessed directly compressive excipients. Journal pharmacy and pharmaceutical sciences. 2005;1(10):76-93.