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Research Article on Formulation and Evaluation of Medicated Chocolate

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Abstract: *The aim of this study is to be develop a pediatric friendly chocolate by combining medicines with one of children favorite foods. Medicated chocolates have emerged as an innovative drug delivery system aimed at improving patient compliance, especially among pediatric and geriatric populations. This study focuses on the formulation and evaluation of medicated chocolate containing Ornidazole and Ofloxacin, which are commonly used in the treatment of gastrointestinal infections, including amoebiasis, diarrhea, and mixed bacterial infections. The medicated chocolate was prepared using a suitable chocolate base incorporating the active pharmaceutical ingredients with appropriate excipients to ensure uniform drug distribution and stability.*

The formulation was evaluated for parameters such as appearance, texture, drug content uniformity, melting behavior, hardness, and in vitro drug release profile. The results indicated that the medicated chocolate provided acceptable organoleptic properties, making it palatable and patient-friendly. Drug release studies demonstrated effective release of both drugs within the desired time frame, ensuring therapeutic efficacy. Stability studies confirmed that the formulation remained stable under standard storage conditions..

Keywords: Medicated chocolate, Ofloxacin, Ornidazole

I. INTRODUCTION

FIGURE NO.1.1 MEDICATED CHOCOLATE

Chocolate is highly preferred by children, whereas medicines are often disliked due to their bitter taste, leading to poor patient compliance. The present study focuses on developing medicated chocolate containing Ofloxacin and Ornidazole for dual infection therapy in children. Chocolate serves as an excellent drug delivery system because of its pleasant taste, quick onset of action, high drug-loading capacity, and resistance to microbial growth and hydrolysis. It also

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contains beneficial compounds such as polyphenols, sterols, methylxanthines, and serotonin-producing substances that provide relaxation and pleasure. The medicated chocolate is prepared by incorporating drugs into a chocolate base and is evaluated for appearance, hardness, blooming test, drug content, physical stability, moisture content, and thickness. Due to its palatable nature and therapeutic benefits, medicated chocolate can improve patient compliance and has strong potential for future commercial pharmaceutical applications.

1. Amoebiasis (Amebiasis):

Amoebiasis is an intestinal infection caused by the protozoan parasite Entamoeba histolytica infection (Entamoeba histolytica). It mainly affects the large intestine but can sometimes spread to other organs like the liver. [11,27,29,32]

Causes

- Infection occurs by consuming contaminated food or water
- Spread through the fecal–oral route
- Poor sanitation and hygiene increase risk
- Eating unwashed fruits/vegetables or street food in unhygienic conditions

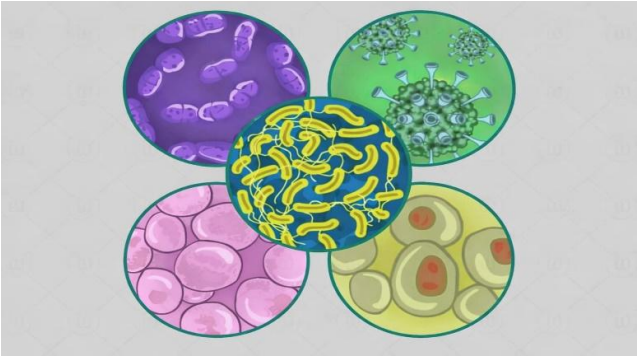

FIGURE NO. 1.2 AMOEBIASIS

Symptoms:

Symptoms may vary from mild to severe:

Mild cases:

- Loose stools or diarrhea
- Stomach cramps
- Nausea
- Severe cases:
- Bloody diarrhea (dysentery)

2. Severe Diarrhea:

It is a condition in which a person passes frequent loose or watery stools. It is commonly caused by infections in the digestive tract. [5,11,28,29,30]

Causes:

- Diarrhea that is treated with Ofloxacin + Ornidazole is usually due to:
- Bacterial infections (e.g., E. coli, Shigella)
- Protozoal infections (e.g., Amoebiasis, giardiasis)
- Contaminated food or water
- Poor hygiene and sanitation

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Symptoms:

- Frequent loose stools
- Abdominal cramps or pain
- Nausea and sometimes vomiting
- Fever (in infection cases)
- Dehydration (dry mouth, weakness, low urine)

3. Gastrointestinal (GI) Diseases

Gastrointestinal diseases are disorders that affect the digestive system, including the stomach, intestines, and associated organs. [5,29,30,32]

Common Causes

- Infections (bacterial, viral, protozoal)
- Contaminated food or water
- Poor hygiene and sanitation

Symptoms:

- Diarrhea or loose stools
- Abdominal pain or cramps
- Nausea and vomiting
- Bloating
- Fever (in infectious cases)

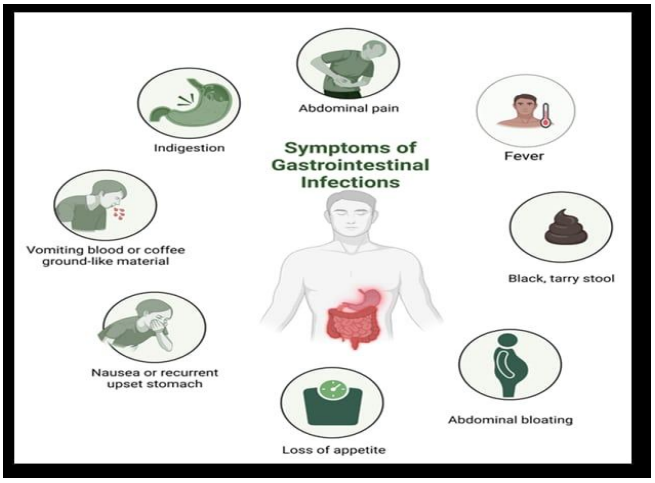

FIGURE NO. 1.3 GASTROINTESTINAL INFECTION

Infectious GI Diseases:

- Some GI diseases are caused by microorganisms such as:
- Bacteria (e.g., E. coli, Salmonella)
- Protozoa (e.g., Amoebiasis, giardiasis)
- These infections often lead to acute gastroenteritis or dysentery.

CHALLENGES:

Medicated chocolate containing Ofloxacin and Ornidazole has several formulation challenges. Both drugs have a strong bitter taste, making masking difficult. Achieving uniform mixing of the drugs in chocolate is not easy. There can be stability problems like melting and possible drug degradation. Also, incorporating high doses may affect the texture and acceptability of the product. [7,17,20,22]

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BENEFITS:

Medicated chocolate formulated with Ofloxacin and Ornidazole provides several advantages. It helps reduce the unpleasant taste of these bitter drugs, making them easier to consume. This dosage form can increase patient compliance, particularly for children and older adults who may struggle with tablets. It is also simple and convenient to administer. Additionally, the chocolate base can give some protection against environmental conditions such as light and moisture, improving overall acceptability. [1,2,3,24]

OBJECTIVE:

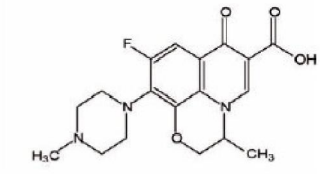
1.To formulate a palatable medicated chocolate incorporating ofloxacin and ornidazole.
2.To mask the bitter taste of the drugs using a chocolate-based delivery system.
3.To evaluate the prepared formulation for physicochemical parameters such as appearance, hardness, weight variation, and drug content.
4.To study the stability of the medicated chocolate under suitable storage conditions.
5.To ensure uniform distribution of both drugs within the chocolate matrix.
6.To assess the suitability of chocolate as a novel drug delivery system for improving patient compliance.
7.To develop a formulation that is effective for treating gastrointestinal infections caused by both bacterial and protozoal organisms.

PLAN OF WORK:

Selection of Research Topic
↓
Literature Survey
↓
Selection of chemical ingredient and Excipients
↓
Procurement of Raw Materials
↓
Compatibility of ingredients
↓
Formulation of dual infection therapy Medicated Chocolate
↓
Evaluation Of Medicated Chocolate
↓
Report Writing /Thesis Typing

DRUG PROFILE:

1. Ofloxacin



CHEMICAL STRUCTURE OF OFLOXACIN

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History of Ofloxacin:

Ofloxacin was developed in the 1980s as a second-generation fluoroquinolone antibiotic derived from earlier quinolones such as Nalidixic acid, which had limited antibacterial activity and poor tissue penetration. The introduction of fluorine atoms into the quinolone structure improved potency, spectrum, and pharmacokinetic properties, resulting in ofloxacin with broad Gram-negative activity and high oral bioavailability. Further refinement led to Levofloxacin, a more effective and safer enantiomer. By the late 1980s and early 1990s, ofloxacin became widely accepted worldwide for treating respiratory, urinary, and gastrointestinal infections because of its broad-spectrum activity and convenient oral dosing.

Class & Mechanism:

Ofloxacin belongs to the fluoroquinolone class of antibiotics. It works by inhibiting bacterial enzymes DNA gyrase and topoisomerase IV, which are essential for DNA replication and repair. This leads to bacterial cell death (bactericidal action).

Spectrum of Activity:

Effective against:

Gram-negative bacteria (e.g., E. coli, Salmonella, Shigella)
Some Gram-positive bacteria

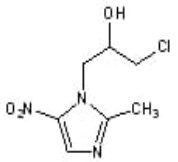
Therapeutic Uses:

- Gastrointestinal infections (e.g., infectious diarrhea)
- Urinary tract infections
- Respiratory infections
- Skin and soft tissue infections

Pharmacokinetics:

- Absorption: High oral bioavailability (~95%)
- Distribution: Widely distributed in tissues
- Half-life: ~5–7 hours
- Elimination: Primarily renal
- Adverse Effects
- Gastrointestinal upset (nausea, diarrhea)
- CNS effects (dizziness, headache)
- Rare: tendonitis or tendon rupture
- Photosensitivity

2. Ornidazole



CHEMICAL STRUCTURE OF ORINDAZOLE

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History of Ornidazole:

Ornidazole belongs to the nitroimidazole class and was developed during the 1970s–1980s as a longer-acting derivative of Metronidazole, which revolutionized the treatment of anaerobic bacterial and protozoal infections in the late 1950s. Ornidazole was designed to provide a longer half-life, better tissue penetration, and improved patient compliance while maintaining strong antimicrobial activity. Due to its prolonged duration of action, it became widely used for treating amoebiasis, giardiasis, and anaerobic infections, particularly in Europe, Asia, and developing countries, often in combination therapies for mixed infections.

Class & Mechanism:

Ornidazole is a nitroimidazole derivative. It acts by forming reactive nitro radicals under anaerobic conditions, damaging microbial DNA and leading to cell death.

Spectrum of Activity:

- Effective against:
- Anaerobic bacteria (Bacteroides, Clostridium)
- Protozoa (Entamoeba histolytica, Giardia lamblia, Trichomonas vaginalis)
- Not effective: Aerobic bacteria

Therapeutic Uses:

- Amoebiasis
- Giardiasis
- Anaerobic infections
- Mixed infections (often combined with antibiotics like ofloxacin)

Pharmacokinetics:

- Absorption: Well, absorbed orally
- Half-life: ~12–14 hours (longer than metronidazole)
- Distribution: Good tissue penetration
- Metabolism: Hepatic

Adverse Effects:

- Metallic taste
- Nausea, vomiting
- CNS effects (rare dizziness, neuropathy)
- Alcohol interaction (disulfiram-like reaction)

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Development of the Combination Therapy:

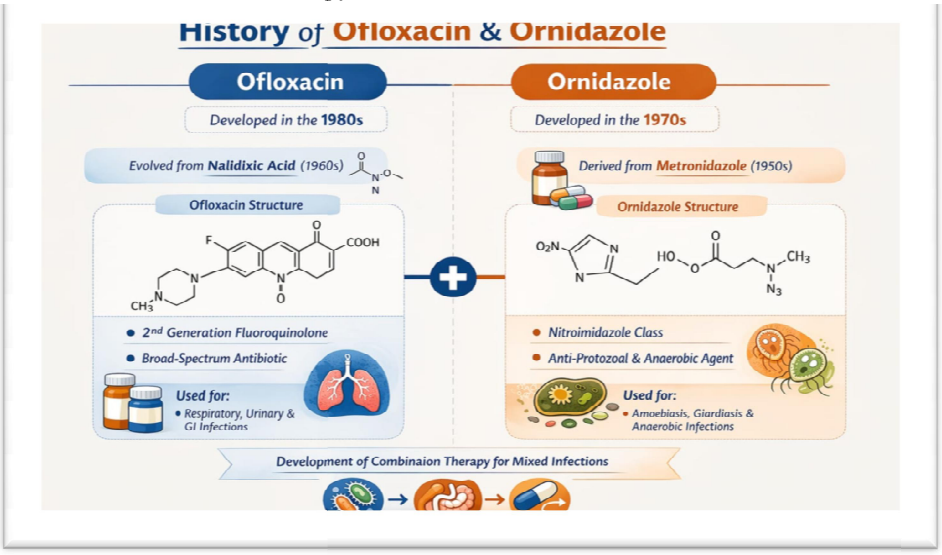

FIGURE NO.1.4 HISTORY OF OFLOXACIN & ORNIDAZOLE

The combination of ofloxacin + ornidazole emerged later as clinicians recognized the need to treat mixed infections involving both aerobic bacteria and anaerobic/protozoal organisms, especially in gastrointestinal diseases like dysentery. [5,30,32]

This fixed-dose combination became popular because it:

- -Reduced the need for multiple medications
- -Improved treatment coverage
- -Enhanced patient compliance

Today, it is commonly prescribed in regions where mixed enteric infections are prevalent, although rational use is emphasized to avoid antibiotic resistance.

SELECTION OF INGRIDENTS:

Dark Chocolate Base:

FIGURE NO. 1.5 DARK CHOCLATE BASE

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Purpose:
A dark chocolate base is used as a palatable carrier to:
-Mask bitter taste of drugs
-Improve patient compliance
-Provide a lipid matrix for drug delivery

2. Ingredients (Typical Composition):
powder (unsweetened) -flavor + color
Sugar (powdered) - taste masking
Lecithin -emulsifier
Vanilla or flavoring agent - Cocoa butter → main fat base
Cocoa improves palatability
For pharmaceutical use, ensure all excipients are food/pharma grade

3. Method of Preparation:
Step 1: Melting the Fat Base
Take cocoa butter in a clean beaker
Heat using water bath method at ~30–40°C
Avoid direct flame to prevent degradation

Step 2: Addition of Dry Ingredients
Add cocoa powder slowly with continuous stirring
Add powdered sugar and mix uniformly

Step 3: Emulsification
Add a small amount of lecithin
Stir continuously to obtain a smooth, uniform mixture

Step 4: Flavoring
Add vanilla or other flavoring agents
Mix thoroughly

Step 5: Molding
Pour the mixture into molds
Allow to cool at room temperature or refrigerate

4. Key Parameters to Control
Temperature: Should not exceed ~45°C (important for drug stability later)
Texture: Smooth, no lumps
Uniformity: Proper mixing to ensure dose accuracy
Hardness: Should solidify properly at room temperature
Role of Dark Compound Base in Medicated Chocolate

- Dark compound is used as a base to carry drugs like Ofloxacin and Ornidazole in medicated chocolate.
- It helps mask the bitter taste of these drugs and improves patient acceptance.
- It provides a solid structure and uniform distribution of the drug in each piece.
- The lipid base may also slow drug release slightly, improving effectiveness.

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- Overall, it supports dual infection therapy by delivering both drugs together in an easy-to-take form.

Marketed Products

Dark compound base is available in various marketed products such as
Morde Dark Compound (Morde Foods Pvt. Ltd.),
Amul Dark Compound (Gujarat Cooperative Milk Marketing Federation Ltd.),
Vanleer Dark Compound (Barry Callebaut Group), which are widely used in chocolate preparation .

FIGURE NO.1.6 MARKETED FORMULATION

Cocca powder

FIGURE NO.1.7 COCOA POWDER

Purpose:

Introduction

Cocoa powder is a dry, fine powder obtained from cocoa beans after removing most of the fat (cocoa butter).
It is widely used in food and pharmaceutical formulations due to its flavor, color, and functional properties.

Source and Preparation

Derived from seeds of Theobroma cacao

Processing steps:

Fermentation of cocoa beans:

- Drying and roasting
- Grinding into cocoa mass
- Pressing to remove cocoa butter
- Remaining solid is powdered - cocoa powder

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Composition

- Carbohydrates
- Proteins
- Small amount of fat (10–20%)
- Polyphenols (antioxidants)
- Minerals (iron, magnesium)

Role Of Cocca Powder In Medicated Chocolate

Cocoa powder acts as a key excipient in chocolate formulations, providing flavor, color, and structural support.

Marketed Products:

Cocoa powder is widely available in the market in different branded forms.
Some commonly used products include,
Cadbury Cocoa Powder (Mondelez India Foods Pvt. Ltd.),
Hershey's Cocoa Powder (The Hershey Company),
Weikfield Cocoa Powder (Weikfield Products Co. Pvt. Ltd.), and Nestlé Cocoa Powder (Nestlé India Ltd.).

FIGURE NO. 1.8 MARKETED FORMULATION

3. Milk Powder:

FIGURE NO.1.9 MILK POWDER

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Purpose:

Introduction

Milk powder is a dry product obtained by removing water from milk. It is widely used in food and pharmaceutical formulations due to its nutritional value, taste, and functional properties.

Composition

- Proteins (casein, whey proteins)
- Lactose (milk sugar)
- Fats (in whole milk powder)
- Vitamins and minerals (calcium, phosphorus)

Role of Milk powder in Medicated Chocolate

Milk powder helps to improve the taste by giving a creamy and sweet flavor, which masks the bitterness of drugs like Ofloxacin and Ornidazole.

It provides a smooth texture and better mouthfeel to the chocolate.

It acts as a bulking agent, helping in proper shape and uniformity

Marketed Product:

Milk powder is widely available in different branded forms in the market. Amul Sagar Skim Milk Powder (Gujarat Cooperative Milk Marketing Federation Ltd.), Nestlé Everyday Milk Powder (Nestlé India Ltd.), Nandini Skimmed Milk Powder (Karnataka Cooperative Milk Producers' Federation Ltd.),

FIGURE NO. 1.9 MARKETED FORMULATION

4. Vanila Flavors (For Taste Masking):

FIGURE NO.1.10 VANILA FLAVOUR

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Purpose:

Introduction

Vanilla flavor is a widely used flavoring agent obtained from the pods of the Vanilla planifolia or prepared synthetically. It is commonly used in food and pharmaceutical formulations due to its pleasant aroma and taste.

2. Composition

- Main component: Vanillin
- Other minor aromatic compounds
- Available as liquid extract, essence, or powder

Role in Medicated Chocolate

- Taste Masking
- Masks the bitter taste of drugs like:
- Ofloxacin
- Ornidazole
- Flavor Enhancement
- Provides pleasant aroma and sweet taste
- Improves overall palatability of chocolate
- Patient Acceptability
- Makes medicated chocolate more acceptable, especially for children
- Reduces unpleasant medicinal feel

Marketed Products

Vanilla flavor is available in various marketed forms such as
Weikfield Vanilla Essence (Weikfield Products Co. Pvt. Ltd.),
Blue Bird Vanilla Essence (Blue Bird Foods India Pvt. Ltd.),
Dr. Oetker Vanilla Essence (Dr. Oetker India Pvt. Ltd.), and Patanjali Vanilla Flavor (Patanjali Ayurved Ltd.).
These products are widely used in chocolate and confectionery preparations due to their good quality, pleasant aroma, and easy availability.

FIGURE NO.1.11 MARKETED FORMULATION

MATERIALS AND METHOD:

Enlist the materials, apparatus/equipment used for experimental work respectively.

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Sr. No.	APPARATUS	USE	MODEL EXAMPLE
1	Heating Mantle	Used to melt the chocolate base	Remi HP-02 / Bio Technics
2	Water Bath	Maintains controlled temperature (35–45°C)	TC-3 Chocolate Warmer
3	Glass Rod/Spatula	Used for manual stirring	Standard Lab Spatula
4	Digital Analytical Balance	Used for accurate weighing of ingredients	Shimadzu AY220 / Citizen CY204
5	China Dish (Porcelain Bowl)	Used for mixing and heating	Borosil / Standard Lab Ware
6	Beaker(50-250ml)	Used for preparation of solutions	Borosil Glass Beaker
7	Silicone chocolate mould	Used to give shape to chocolates	Generic Food Grade Mould
8	Dropper	Used for filling moulds accurately	Borosil Dropper
9	Butter Paper	Used for setting and handling chocolates	Standard Food Grade Paper
10	Refrigerator	Used for cooling and solidification	LG/Blue Star Lab Refrigerator

Table no1: List of Apparatus

The ingredients used for the preparation of medicated chocolate include:

- Ofloxacin
- Ornidazole
- Dark chocolate compound (chocolate base)
- Cocoa powder
- Milk powder (optional, for taste and texture)
- Vanilla essence (for flavor enhancement)

Table No.2: List Of Ingredients

INGREDIENTS	F1(mg)	F2(mg)	F3(mg)	F4(mg)
Ofloxacin	50	50	50	50
Ornidazole	125	130	125	125
Dark chocolate compound	500	450	400	350
Cocoa powder	100	120	140	160
Milk powder	100	110	120	130
Vanila essence	q.s	q.s	q.s	q.s

q.s. = quantity sufficient

TABLE 2: FORMULATION OF OFLOXACIN AND ORNIDAZOLE MEDICATED CHOCOLATE

Method of Preparation:

- All the required ingredients were accurately weighed using a suitable balance.
- Ofloxacin and Ornidazole were finely powdered separately and passed through a sieve (#60) to obtain uniform particle size.
- Cocoa butter (chocolate base) was melted using a double boiler method at a controlled temperature of about 50–60°C.
- Cocoa powder, sugar, and milk powder were gradually added to the melted base with continuous stirring to obtain a smooth and uniform mixture.
- The previously sieved drug powders were slowly incorporated into the molten chocolate base with constant stirring to ensure uniform distribution.
- Vanilla essence was added to enhance the flavor of the formulation.

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- The mixture was stirred continuously until a homogeneous mass was obtained.
- The prepared mixture was then poured into clean and dry molds.
- The molds were allowed to cool at room temperature for initial setting.
- Further solidification was achieved by placing the molds in a refrigerator until the chocolates became completely firm.

The medicated chocolates were carefully removed from the molds, packed properly, and stored in a cool and dry place for further evaluation.

FIGURE NO. 1.12 METHOD OF PREPARATION MEDICATED CHOCOLATE

EVALUTION PARAMETER:

1. Organoleptic Properties

The prepared medicated chocolates were evaluated for their physical characteristics such as color, odor, taste, and texture. These parameters help in determining patient acceptability.

2. Hardness Test

The hardness of the medicated chocolate was determined using a suitable hardness tester. This test ensures that the chocolate has sufficient strength to withstand handling without breaking.

3. Weight Variation Test

Individually weighed medicated chocolates were compared with the average weight. The variation in weight was calculated to ensure uniform distribution of ingredients.

4. Drug Content Uniformity

The drug content was analyzed by dissolving a known quantity of medicated chocolate in a suitable solvent. The solution was filtered and analyzed spectrophotometrically to determine the amount of Ofloxacin and Ornidazole present. This ensures uniform distribution of drugs in each unit.

5. Blooming Test (Fat/Sugar Bloom)

The prepared chocolates were observed for the formation of a whitish layer on the surface during storage.

Fat bloom occurs due to improper crystallization of fats.

Sugar bloom occurs due to moisture exposure.

This test helps in evaluating the stability and appearance of the formulation.

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6. Physical Stability Study

The medicated chocolates were stored in closed containers at room temperature (around 25–28°C) for a period of one month. Samples were periodically examined for any changes in color, texture, odor, and overall appearance.

7. Moisture Content

Moisture content was determined by weighing the sample before and after drying in a hot air oven at 100–105°C.

Formula:

Moisture Content (%) = W2-W3/W2-W2 ×100

Where:

W = Initial weight of sample

W_2 = Weight of sample + container before drying

W_3 = Weight after drying

8. In-vitro Drug Release Study

The release of drugs from the medicated chocolate was studied using a suitable dissolution medium. Samples were withdrawn at specific time intervals and analyzed to determine the percentage of drug released over time.

9. pH Determination

The pH of the chocolate formulation was determined by dissolving a small quantity in distilled water and measuring using a pH meter. This ensures compatibility with oral use.

10. Microbial Limit Test

The prepared chocolates were evaluated for microbial contamination using standard microbiological methods to ensure safety for consumption.

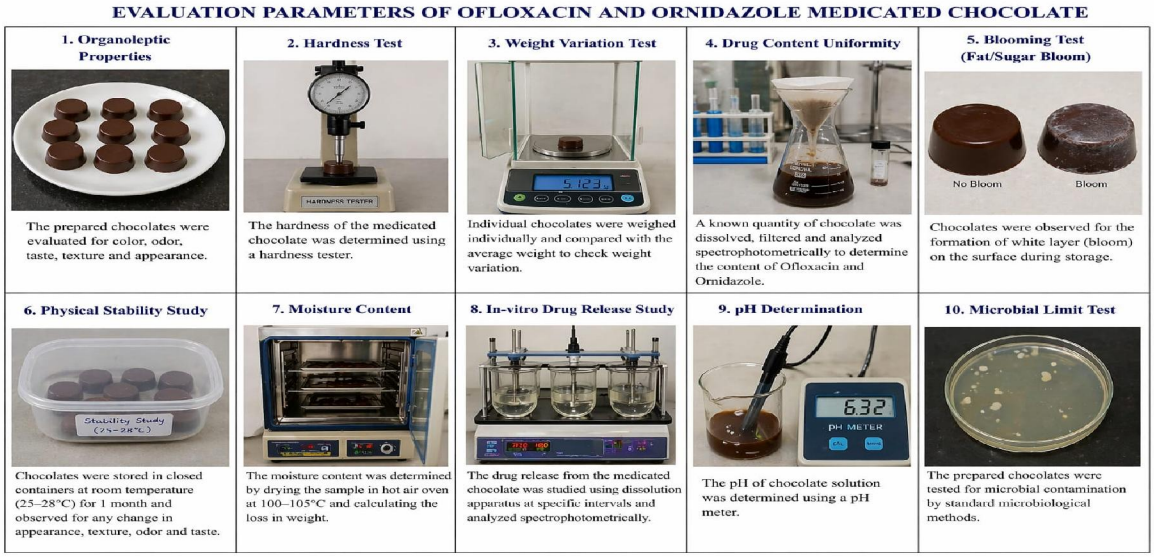

FIGURE NO.1.13 EVALUATION PARAMETER OF MEDICATED CHOCOLATE

RESULTS AND DISCUSSION:

General Appearance

BATCH	COLOUR	ODOUR	TASTE	TEXTURE
F1	Light brown	Mild chocolate	Slight bitter	Slightly rough
F2	brown	Chocolate odour	Bitter	Rough
F3	Dark brown	Pleasant cocoa	Slight bitter	Smooth
F4	Dark brown	Strong cocca	Slight bitter	Smooth

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Observation:
Batch F3 showed better organoleptic properties with acceptable taste masking and smooth texture compared to other formulations.

BATCH	HARDNESS (kg/cm^2)
F1	0.7
F2	1.0
F3	0.4
F4	0.6

2. Hardness Test
Observation:
F3 exhibited moderate hardness, making it suitable for easy chewing without breaking during handling.

3. Physical Stability

BATCH	STABILITY RESULT
F1	Slight deformation
F2	Softening observed
F3	Stable
F4	Slight stickiness

Observation:
F3 remained stable under storage conditions, indicating better formulation compatibility.

BATCH	MOISTURE CONTENT (%)
F1	1.1%
F2	0.9%
F3	1.2%
F4	1.0%

4. Moisture Content (%)
Observation:
F3 exhibited acceptable moisture content with good stability and suitable softness.

5. Drug content (assay)

BATCH	DRUG CONTENT (%)
F1	98.5%
F2	99.2%
F3	99.5%
F4	98.8%

Observation:
F3 showed maximum drug content uniformity, indicating proper mixing and distribution of Ofloxacin and Ornidazole.

6. Bloom Test

BATCH	RESULT
F1	Dull appearance
F2	Slight whitening

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F3	No bloom(stable)
F4	Fat bloom observed

Observation:
F3 did not show bloom formation, indicating good fat stability in chocolate base.

FORMULATION OF MEDICATED CHOCLATE IN LAB:




II. CONCLUSION

The medicated chocolate containing Ofloxacin and Ornidazole was successfully formulated for dual infection therapy. Among all batches, F3 formulation was found to be optimal due to:

- Good taste masking of bitter drugs
- Smooth texture and acceptable hardness
- Better physical stability
- Uniform drug distribution
- Low moisture content and no bloom formation

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