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Design and Evaluation of Medicated Soft Lozenges and Medicated Chocolates Containing Paracetamol, Ibuprofen, and Caffeine for Enhanced Patient Compliance

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ABSTRACT:

This study focuses on the development and evaluation of two innovative oral dosage forms—Medicated Soft Lozenges (MSL) and Medicated Chocolates (MC)—containing a fixed-dose combination of Paracetamol, Ibuprofen, and Caffeine Anhydrous to leverage their synergistic analgesic and antipyretic effects. Six formulations (MSL1–3 and MC1–3) were prepared using varying excipient concentrations, ensuring uniform drug dispersion through low-temperature processing to prevent API degradation. All formulations were assessed for physicochemical and organoleptic properties, including disintegration time, weight variation, moisture content, and taste acceptability. Both dosage forms exhibited rapid disintegration (within 4–5 minutes), suitable for oral use, and remained physically stable under accelerated storage conditions (40°C/75% RH) for one month. Medicated chocolates, particularly formulation MC1, demonstrated superior taste masking and overall acceptability, attributed to the effective use of cocoa. These findings support the potential of medicated lozenges and chocolates as patient-friendly, palatable alternatives for delivering combination analgesics, especially in populations with swallowing difficulties.

Keywords: Medicated chocolates, Medicated soft lozenges, Palatable dosage forms, Patient compliance, Taste masking.

1. INTRODUCTION:

Oral drug delivery remains the most preferred route for medication administration, with tablets being the most commonly accepted dosage form due to their ease of use, dosing accuracy, and high patient compliance. However, conventional tablets pose swallowing difficulties for many individuals, especially in the absence of water, limiting their usability. This is particularly problematic for pediatric, geriatric, mentally ill, uncooperative patients, and those experiencing nausea, motion sickness, or sudden allergic reactions. Dispersible tablet systems have emerged as an effective alternative, offering rapid disintegration, quick dissolution, and enhanced patient compliance. These challenges have driven the development of novel solid oral dosage forms that are not only effective but also palatable and capable of masking unpleasant tastes, making them more acceptable and practical across diverse patient populations.

1.1 MEDICATED LOZENGES:

Lozenges are flavored medicated dosage forms designed to be slowly dissolved in the mouth or pharynx, typically formulated in a sweetened base and containing one or more active pharmaceutical ingredients. Primarily intended for the relief of oropharyngeal symptoms caused by local infections, lozenges may also provide systemic effects if the drug is absorbed through the buccal mucosa or swallowed. They offer an effective alternative for patients who have difficulty swallowing traditional solid oral dosage forms and are ideal for medications that benefit from gradual release in the oral cavity. Commonly incorporated drugs include analgesics, anesthetics, antimicrobials, antiseptics, antitussives, and corticosteroids, among others. Lozenges are particularly useful in managing conditions such as sore throats, mouth sores, and other pharyngeal irritations, delivering targeted, localized relief.

Fig: 1 Medicated Lozenges

Soft lozenges have gained popularity due to their ease of extemporaneous preparation and versatility in accommodating a wide range of active pharmaceutical ingredients. Typically formulated using bases such as polyethylene glycols, acacia, or similar materials, soft lozenges offer flexible drug delivery options. A notable subtype is the *pastille*, a soft, often transparent lozenge composed of a gelatin, glycerogelatin, or acacia-sucrose base. Pastilles may be colored and flavored, and are designed to either dissolve slowly in the mouth or be chewed, depending on the intended therapeutic effect. Soft lozenges share similarities with traditional *confections*—sweetened, pliable preparations historically used to deliver medications—reflecting a renewed interest in patient-friendly, palatable dosage forms.

Fig: 2 Marketed Lozenges

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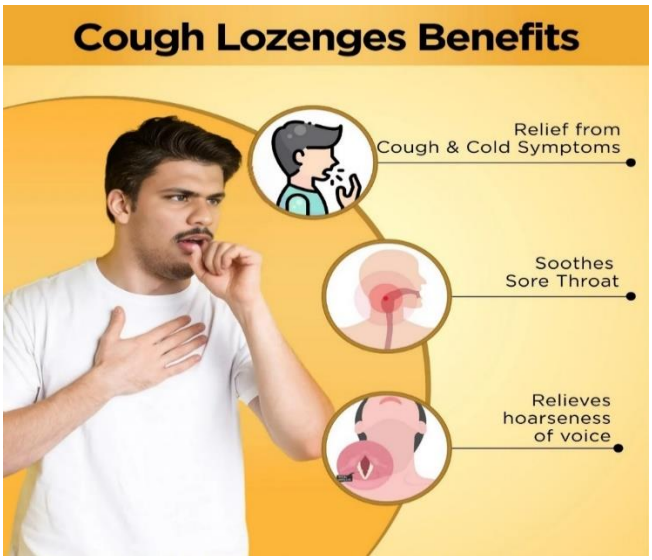

Fig: 3 Lozenges Benefits

1.2 MEDICATED CHOCOLATES:

Chocolate is a highly versatile and sophisticated food medium capable of delivering varied taste and texture experiences. Its anhydrous nature makes it an excellent carrier for water-sensitive active pharmaceutical ingredients, offering resistance to microbial growth and hydrolysis. Rich in compounds such as saturated fats, polyphenols, sterols, flavonoids, antioxidants, and methyl xanthines, chocolate not only enhances palatability but may also contribute additional health benefits. Medicated chocolate refers to chocolate formulations containing therapeutic agents in appropriate doses. Cocoa, the primary ingredient, is notably high in polyphenols, enhancing both taste and potential pharmacological value. Given the variation in taste preferences between adults and children—particularly children's natural inclination toward sweet flavors—chocolate serves as a highly acceptable and effective medium for pediatric drug delivery, improving compliance through taste masking and sensory appeal.

Fig: 4 Chocolate

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Types Of Chocolate:

1. Sweet Chocolate: Sweet Chocolate shall contain, on a dry matter basis, not less than 30% total cocoa solids, of which at least 18% shall be cocoa butter and at least 12% fat-free cocoa solids.

2. Couverture Chocolate: Couverture Chocolate shall contain, on a dry matter basis, not less than 35% total cocoa solids of which not less than 31% shall been cocoa butter and not less than 2.5% of fat-free cocoa solids.

3. Milk Chocolate: Milk Chocolate shall contain, on a dry matter bas, not less than 25% cocoa solid (including a minimum of 2.5% fat-free cocoa solids) and a specified minimum of milk solids between 12% and 14% (including a minimum of milk fat between 2.5% and 3.5%).

4. Family Milk Chocolate: Family Milk Chocolate shall contain on a dry matter basis, not less than 20% cocoa solids (including a minimum of 2.5% fat-free cocoa solids) and not less than 20% milk solids (including a minimum of 5% milk fat). "Milk solids" refers to the addition of milk ingredients in their natural proportions.

5. Milk Chocolate Couverture: Milk Chocolate Couverture shall contain, on a dry matter basis, not less than 25% cocoa solids, not less than 14% milk, and a total fat of not less than 31%.

6. White Chocolate: White Chocolate shall contain, on a dry matter basis, not less than 20% cocoa butter and not less than 14%milk solid.

7. Family Milk Chocolate: Family Milk Chocolate shall contain on a dry matter basis, not less than 20% cocoa solids (including a minimum of 2.5% fat-free cocoa solids) and not less than 20% milk solids (including a minimum of 5% milk fat). "

8. Milk Chocolate Couverture: Milk Chocolate Couverture shall contain, on a dry matter basis, not less than 25% cocoa solids, not less than 14% milk, and a total fat of not less than 31%.

9. High-quality Semisweet Chocolate: The use of predominantly West African stock is advised for its cocoa character and slightly nutty undertones (light to medium roast) to heighten desirable notes and limit burnt/bitter notes.

10. Bittersweet Chocolate: This product is mainly designed for use on very sweet and highly flavoured cream centres as it produces very bitter coatings.

11. Semisweet Cookie Drop: The use the dominant West African beans is advised in this product to provide a good cocoa impact. The strong profiles of the Brazilian and Sanchez components complement and contrast the West African component. In this application, a robust flavour is desirable for contrast in the baked cookies.

Fig: 5 Types Of Chocolates

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2. DRUG PROFILE:

2.1 PARACETAMOL:

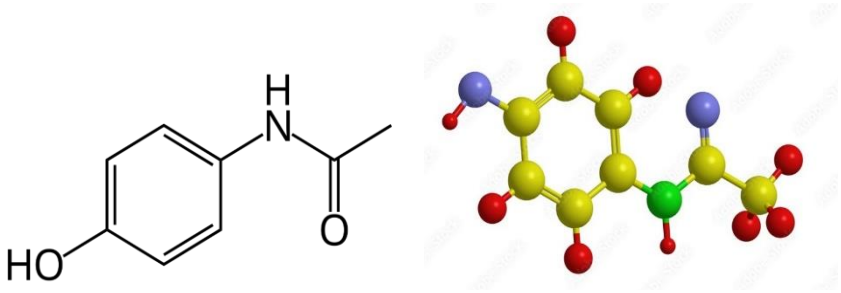

Fig: 6 Structure Of Paracetamol (Acetaminophen)

Table: 1 Physio-Chemical Properties Of Paracetamol

Property	Details
IUPAC Name	N-(4-hydroxyphenyl)acetamide
Molecular Formula	$C_8H_9NO_2$
Molecular Weight	151.16 g/mol
Appearance	White to off-white crystalline powder
Odor	Odorless
Taste	Slightly bitter
Melting Point	169 – 172 °C
Boiling Point	Decomposes before boiling
Solubility in Water	14 mg/mL at 25°C (sparingly soluble)
Solubility in Alcohol	Freely soluble in ethanol, methanol, acetone
pKa	9.5 (phenolic OH group)
Partition Coefficient (Log P)	0.46 (indicates low lipophilicity)
UV Absorption (λmax)	~243 nm in aqueous solution
Stability	Stable under normal conditions; light and heat-sensitive; degrades in strong oxidizing conditions

2.2 IBUPROFEN:

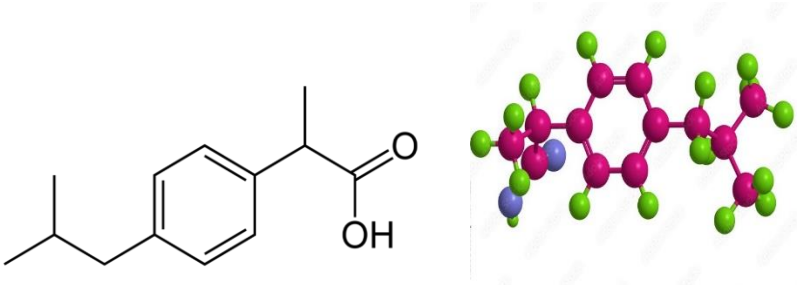

Fig: 7 Structure Of Ibuprofen

Table: 2 Physio-Chemical Properties Of Ibuprofen

Property	Details
IUPAC Name	(RS)-2-(4-isobutylphenyl)propanoic acid
Molecular Formula	$C_{13}H_{18}O_2$
Molecular Weight	206.28 g/mol
Appearance	White or almost white crystalline powder
Odor	Odorless
Melting Point	75 – 78 °C
Boiling Point	157 °C at 5 mmHg

Solubility in Water	Poor (21 mg/L at 25 °C)
Solubility in Alcohol	Freely soluble in ethanol, methanol, acetone
pKa	4.4 (carboxylic acid group)
Log P (Partition Coefficient)	~3.5 (lipophilic)
UV Absorption (λmax)	~264 nm
Chirality	Racemic mixture (S-enantiomer is active)
Stability	Stable under normal conditions; sensitive to light and oxidation

2.3 CAFFEINE:

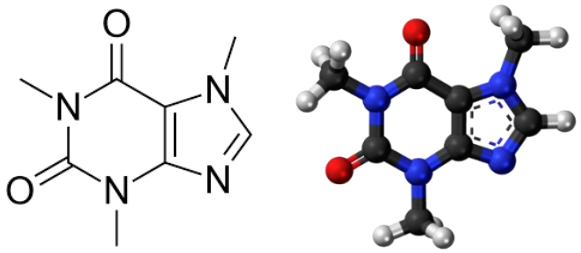

Fig: 8 Structure Of Caffeine

Table: 3 Physio-Chemical Properties Of Caffeine

Property	Details
IUPAC Name	1,3,7-trimethylxanthine
Molecular Formula	$C_8H_{10}N_4O_2$
Molecular Weight	194.19 g/mol
Appearance	White crystalline powder
Melting Point	235–238 °C
Solubility in Water	~20 mg/mL at 25°C (freely soluble)
Solubility in Alcohol	Slightly soluble
pKa	~14 (very weakly acidic nitrogen)
Log P (Partition Coefficient)	~−0.07 (moderately hydrophilic)
UV Absorption (λmax)	272 nm

3. MATERIALS AND METHODS:

3.1 RAW MATERIAL ANALYSIS:

3.1.1 Melting Point Determination

3.1.2 Solubility Test

3.2 FORMULATION OF MEDICATED SOFT LOZENGES:

Table: 4 Medicated Soft Lozenges

S.No	Ingredient	MSL 1	MSL 2	MSL 3
1	Paracetamol	250 mg	250 mg	250 mg
2	Ibuprofen	200 mg	200 mg	200 mg
3	Caffeine Anhydrous	50 mg	50 mg	50 mg
4	PEG 1450	3.5 g	3 g	2.5 g
5	Xanthan gum	200 mg	200 mg	200 mg
6	Sucrose	2g	2.5g	3g
7	Flavor (mint)	Q.S.	Q.S.	Q.S.
8	Color	Q.S.	Q.S.	Q.S.

Procedure: To prepare medicated lozenges containing Paracetamol, Ibuprofen, Caffeine Anhydrous, PEG 1450, Xanthan Gum, and Sucrose, begin by gently melting PEG 1450 using a water bath, maintaining the temperature between 50–55°C to avoid degradation of any components. Separately, sieve and weigh the active ingredients—Paracetamol, Ibuprofen, and Caffeine—and mix them uniformly in a dry blender or mortar to ensure even drug distribution. In another container, dry blend xanthan gum with sucrose to prevent clumping, and optionally pre-wet the xanthan gum with a small quantity of PEG or alcohol to aid dispersion. Combine the drug blend with the gum-sugar mixture and gradually incorporate this powder mix into the molten PEG 1450 with continuous stirring to form a uniform suspension. Once fully blended, add the desired quantities of mint flavor and color while the mixture is still warm, ensuring homogeneous distribution. While the mass remains pourable, transfer it into pre-cleaned lozenge molds, gently tapping the molds to remove air bubbles. Allow the lozenges to cool and solidify at room temperature or under refrigeration at 4–8°C. Once hardened, carefully demold the lozenges and package them individually in moisture-resistant blister packs or foil pouches to maintain stability and hygiene.

3.3 FORMULATION OF MEDICATED CHOCOLATE:

Table: 5 Medicated Chocolate

S.No	Ingredient	MC 1	MC 2	MC 3
1	Paracetamol	250 mg	250 mg	250 mg
2	Ibuprofen	200 mg	200 mg	200 mg
3	Caffeine Anhydrous	50 mg	50 mg	50 mg
4	Cocoa Butter	7 g	6.5 g	6 g
5	Cocoa Powder	0.3 g	0.4 g	0.5 g
6	Milk Powder	0.5 g	0.5 g	0.5 g
7	Lecithin (Emulsifier)	0.1 g	0.2 g	0.3 g
8	Sucrose	Q.S.	Q.S.	Q.S.
9	Vanilla Flavor	Q.S.	Q.S.	Q.S.

Procedure: To prepare the medicated chocolate, begin by melting the compound chocolate base (or a mixture of cocoa butter, sugar, and cocoa powder) using a water bath at 40–45°C, ensuring the temperature does not exceed 45°C to prevent degradation of active ingredients. While the chocolate is melting, accurately weigh and pass Paracetamol, Ibuprofen, and Caffeine through a fine sieve to break up agglomerates and ensure uniform particle size. Separately, prepare a dry blend of cocoa powder, milk powder, and sweetener to enhance taste and mask bitterness. Once the chocolate base is completely melted, gradually add the sieved active drug blend into it with continuous stirring to ensure even dispersion. Then incorporate the dry excipient blend (milk powder, cocoa powder, sweetener) into the mixture.

Add lecithin to improve texture and emulsification, followed by flavoring agents such as vanilla or mint to enhance palatability. Mix thoroughly until a smooth, homogenous mass is obtained. Pour the final molten chocolate into pre-sterilized silicone or plastic molds suitable for dosing. Tap the molds gently to eliminate air bubbles and ensure uniformity. Allow the filled molds to cool and solidify at room temperature or in a refrigerator. Once fully set, demold the medicated chocolates and package them individually using food-grade foil wrappers or blister packs to protect them from moisture and contamination.

3.4 EVALUATION PARAMETERS:

3.4.1 Weight Variation:

Purpose: To ensure uniformity in dosage.

Procedure:

- Weigh 20 individual chocolate units.
- Calculate the average weight**.**
- Determine the percentage deviation of each unit from the average.

3.4.2 Content Uniformity (Assay):

Purpose: To ensure each unit contains the correct amount of active drug.

Procedure:

- Crush randomly selected units.
- Weigh a quantity equivalent to one unit.
- Dissolve in a suitable solvent (e.g., methanol).
- Filter and analyze using UV-Vis Spectrophotometry**,** HPLC & FT-IR.
- Repeat for each API (Paracetamol, Ibuprofen, Caffeine).

3.4.3 Melting Point / Softening Point:

Purpose: To determine the temperature at which the chocolate softens/melts.

Procedure:

- Use a melting point apparatus or capillary method**.**
- Record softening range of the formulation.

3.4.4 Disintegration Time:

Purpose: To evaluate the time it takes to soften or melt in the mouth.

Procedure:

- Place one unit in a petri dish containing simulated saliva (37°C).
- Observe and record time taken to fully disintegrate or melt.

3.4.5 Organoleptic Evaluation:

Purpose: To assess taste, appearance, and texture.

Procedure:

- Use a trained panel of 5–10 individuals.
- Rate taste**,** mouth feel**,** bitterness masking**,** appearance**,** and odor using a scoring scale (1–5).

3.4.6 Hardness / Texture Analysis:

Purpose: To assess mechanical strength or breakability.

Procedure:

- Use a Pfizer tester and observe.

- Record resistance to breaking.

3.4.7 Moisture Content:

Purpose: To check for excess water which could lead to microbial growth.

Procedure:

- Use Loss on Drying method.

3.4.8 Thickness:

The thickness and diameter of the formulated lozenges & chocolate were measured by using Vernier callipers.

3.4.9 Friability:

The Roche friability test apparatus was used to determine the friability of the lozenges & chocolate. 5 pre-weighed lozenges & chocolate were placed in the apparatus, which was subjected to 100 revolutions. Then the lozenges & chocolate were reweighed.

3.4.10 pH:

Determined the PH using PH meter apparatus.

3.4.11 Stability Testing:

Purpose: To evaluate the product under accelerated and long-term conditions.

Procedure:

- Store samples at 25°C/60% RH and 40°C/75% RH**.**
- Analyze monthly for appearance, content, texture, and taste**.**

4. RESULTS AND DISCUSSION:

4.1 RAW MATERIAL ANALYSIS:

Table: 6 Raw Material Analysis

S.NO	DRUG	MELTING POINT	SOLUBILITY
1	Paracetamol	170°C	• **Water**: Slightly soluble • **Ethanol**: Freely soluble
2	Ibuprofen	70.5 °C	• **Water**: Practically insoluble • **Ethanol**: Soluble
3	Caffeine Anhydrous	231 °C	• **Water**: Moderately soluble • **Ethanol**: Slightly soluble

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4.2 SPECTRUM ANALYSIS:

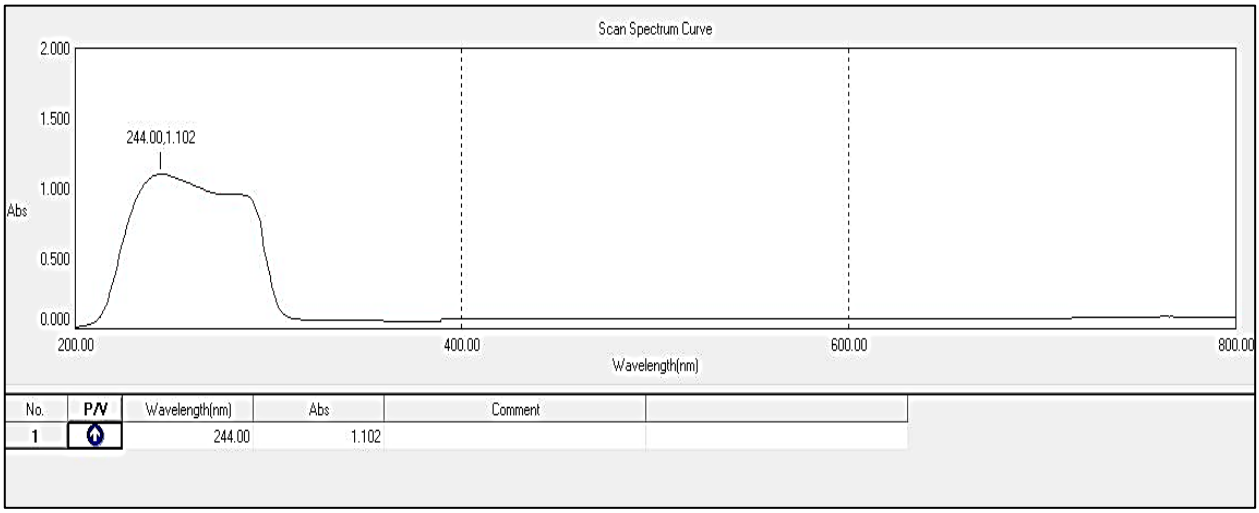

Fig: 9 UV Spectrum Of API

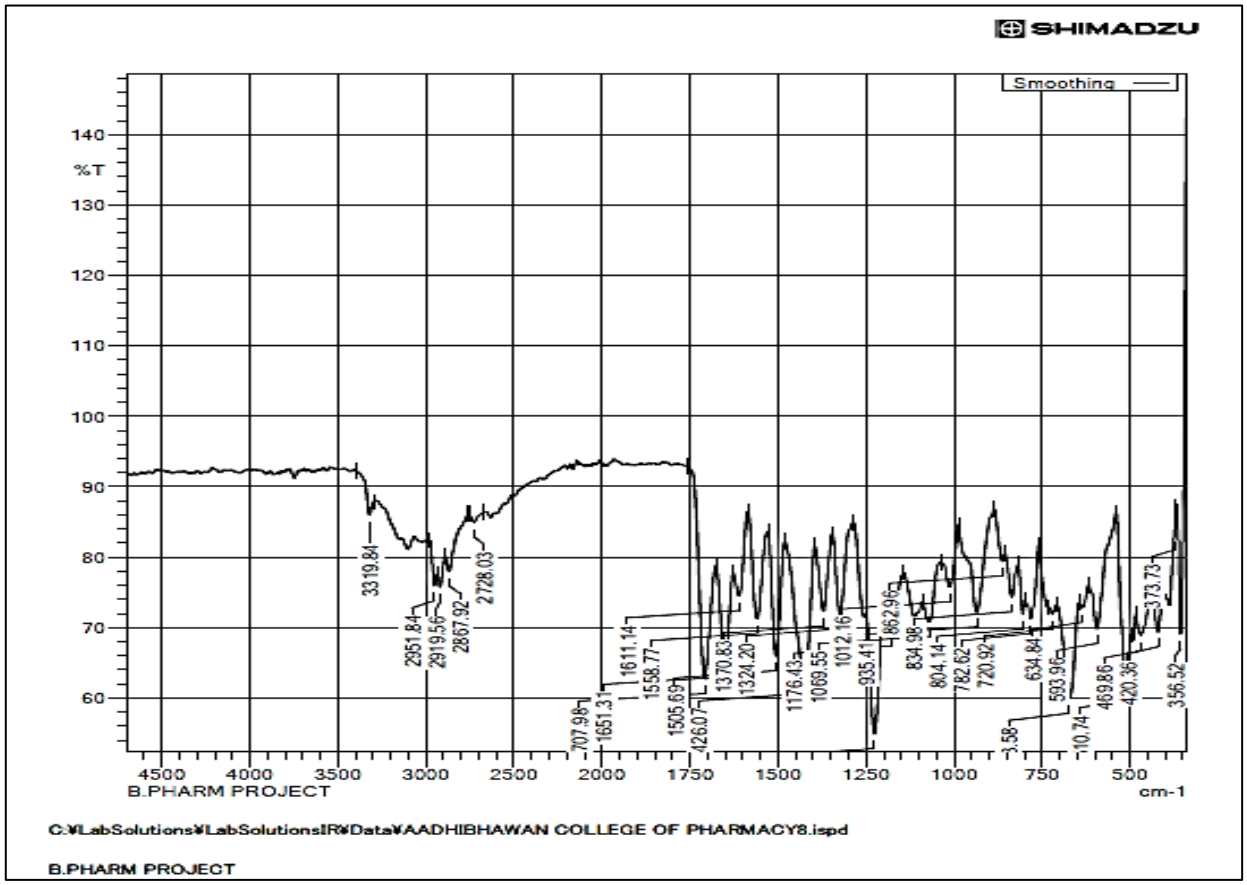

Fig: 10 IR Spectrum Of Paracetamol + Ibuprofen + Caffeine

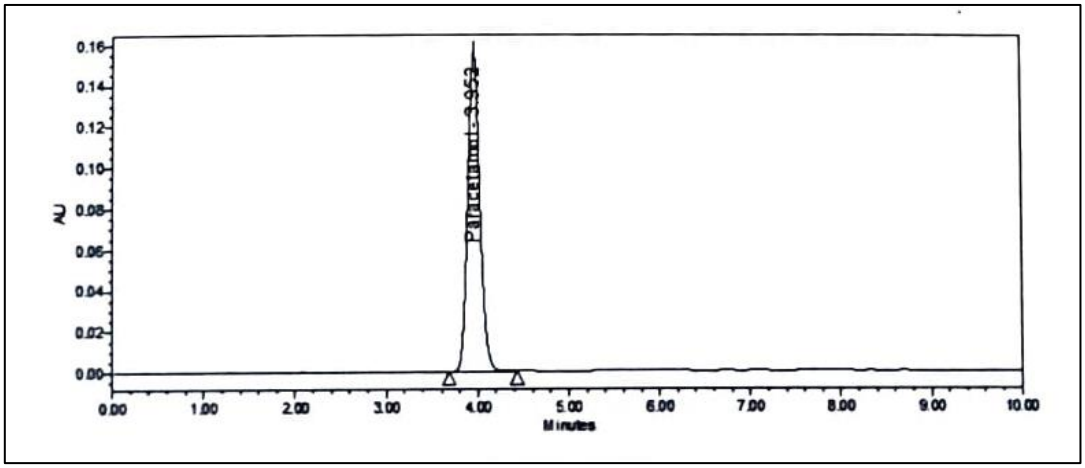

Fig: 11 HPLC Of Paracetamol

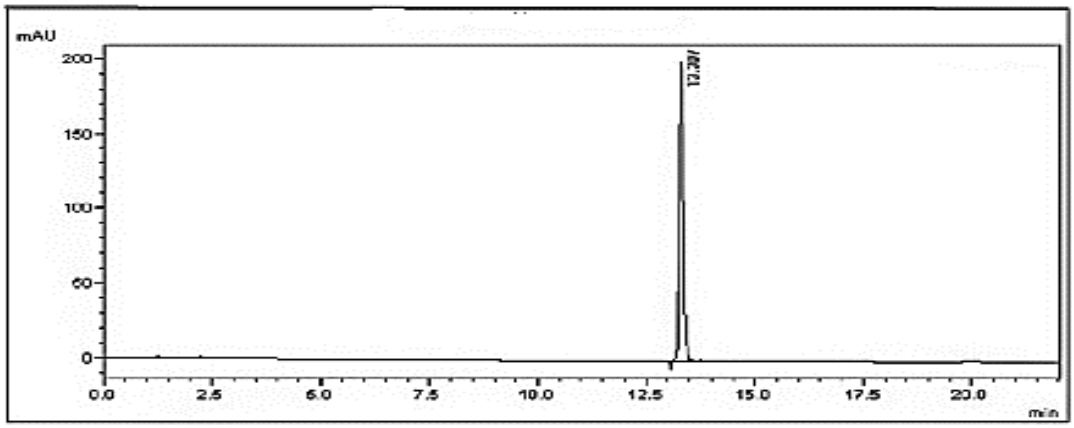

Fig: 12 HPLC Of Ibuprofen

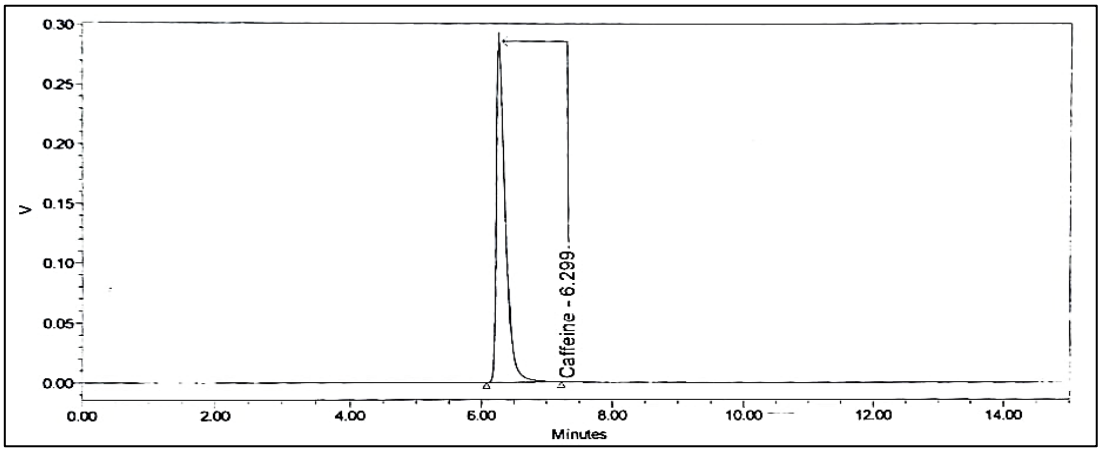

Fig: 13 HPLC Of Caffeine

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4.3 EVALUATION OF MEDICATED SOFT LOZENGES:

Table: 7 Evaluation Of Medicated Soft Lozenges

S.NO	PARAMETERS	MSL 1	MSL 2	MSL 3
1	Color	Red Color	Red Color	Red Color
2	Shape	Round	Round	Round
3	Weight Variation	5.12 gm	5.85 gm	5.45 gm
4	Melting Point	44°C	48°C	46°C
5	Disintegration	5 min	5 min	5 min
6	Organoleptic Evaluation	Taste: 4.3 Texture: 4.5 Odor: 4.6 Bitterness masking: 4.1	Taste: 4.5 Texture: 4.4 Odor: 4.4 Bitterness masking: 4.4	Taste: 4.1 Texture: 4.1 Odor: 3.9 Bitterness masking: 3.8
7	Moisture Content	1.4%	1.5%	1.4%
8	Hardness / Texture	Smooth, not brittle, stable on handling	Smooth, not brittle, stable on handling	Smooth, not brittle, stable on handling
9	Friability	0.107±0.001	0.101±0.001	0.102±0.001
10	pH	7.3	7.3	7.4
11	Stability (1 month, 40°C/75% RH)	No change in taste, appearance, disintegration, color, & Drug content	No change in taste, appearance, disintegration, color, & Drug content	No change in taste, appearance, disintegration, color, & Drug content

4.3.1 SPECTRUM ANALYSIS OF MEDICATED SOFT LOZENGES:

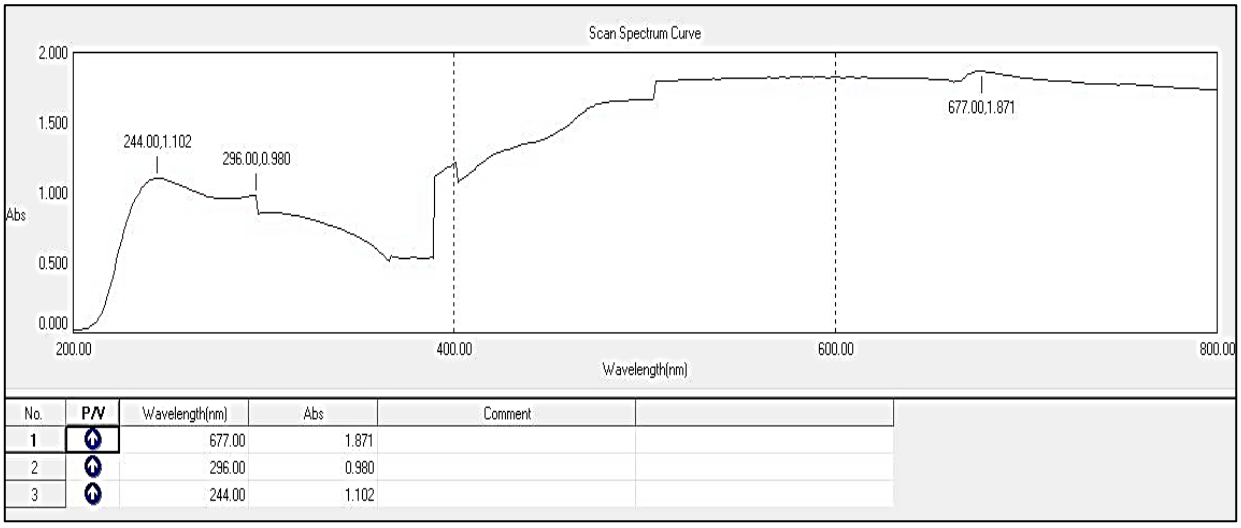

Fig: 14 UV Spectrum Of Medicated Soft Lozenges

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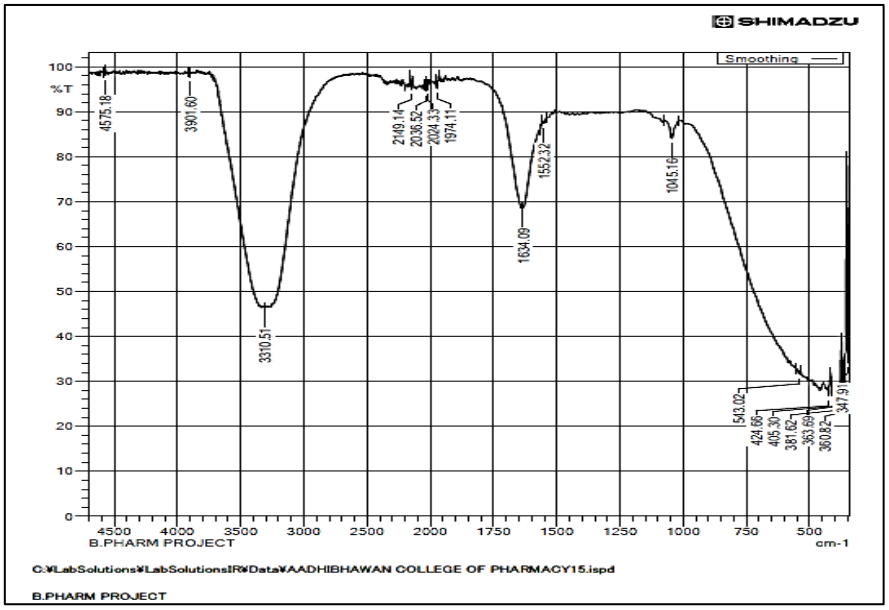

Fig: 15 IR Spectrum Of Medicated Soft Lozenges

4.3.2 PROUCT & LABEL:

Fig: 16 Medicated Soft Lozenges

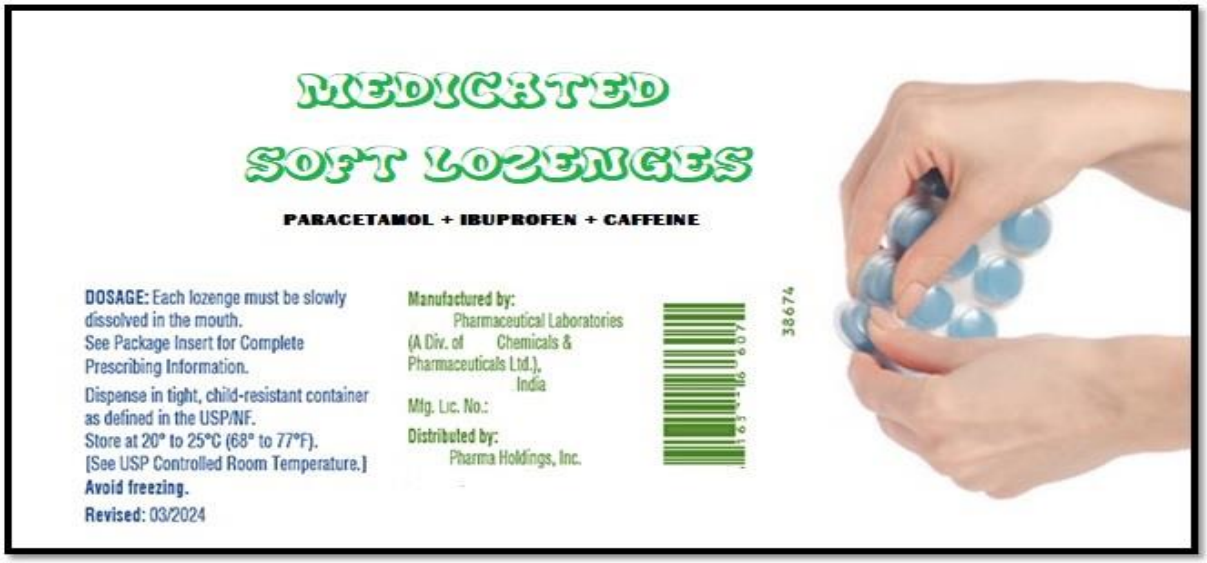

Fig: 17 Label

4.4 EVALUATION OF MEDICATED CHOCOLATES:

Table: 8 Evaluation Of Medicated Chocolates

S.NO	PARAMETERS	MC 1	MC 2	MC 3
1	Color	Brown Color	Brown Color	Brown Color
2	Shape	Round	Round	Round
3	Weight Variation	4.10 gm	4.15 gm	4.13 gm
4	Melting Point	43°C	43°C	45°C
5	Disintegration	5 min	4 min	4 min
6	Organoleptic Evaluation	Taste: 4.7 Texture: 4.7 Odor: 4.9 Bitterness masking: 4.7	Taste: 4.6 Texture: 4.7 Odor: 4.7 Bitterness masking: 4.8	Taste: 4.6 Texture: 4.5 Odor: 4.9 Bitterness masking: 4.8
7	Moisture Content	1.2%	1.2%	1.3%
8	Hardness / Texture	Smooth, not brittle, stable on handling	Smooth, not brittle, stable on handling	Smooth, not brittle, stable on handling
9	Friability	0.102±0.001	0.102±0.002	0.103±0.001
10	pH	6.3	6.3	6.4
11	Stability (1 month, 40°C/75% RH)	No change in taste, appearance, disintegration, color, & Drug content	No change in taste, appearance, disintegration, color, & Drug content	No change in taste, appearance, disintegration, color, & Drug content

4.4.1 SPECTRUM ANALYSIS OF MEDICATED CHOCOLATES:

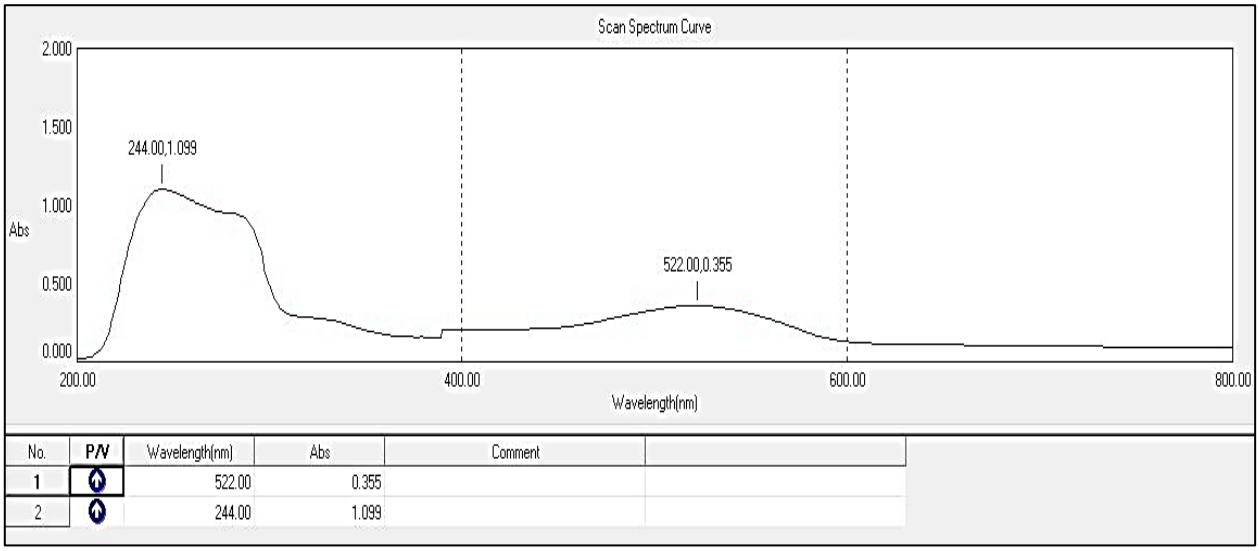

Fig: 18 UV Spectrum Of Medicated Chocolates

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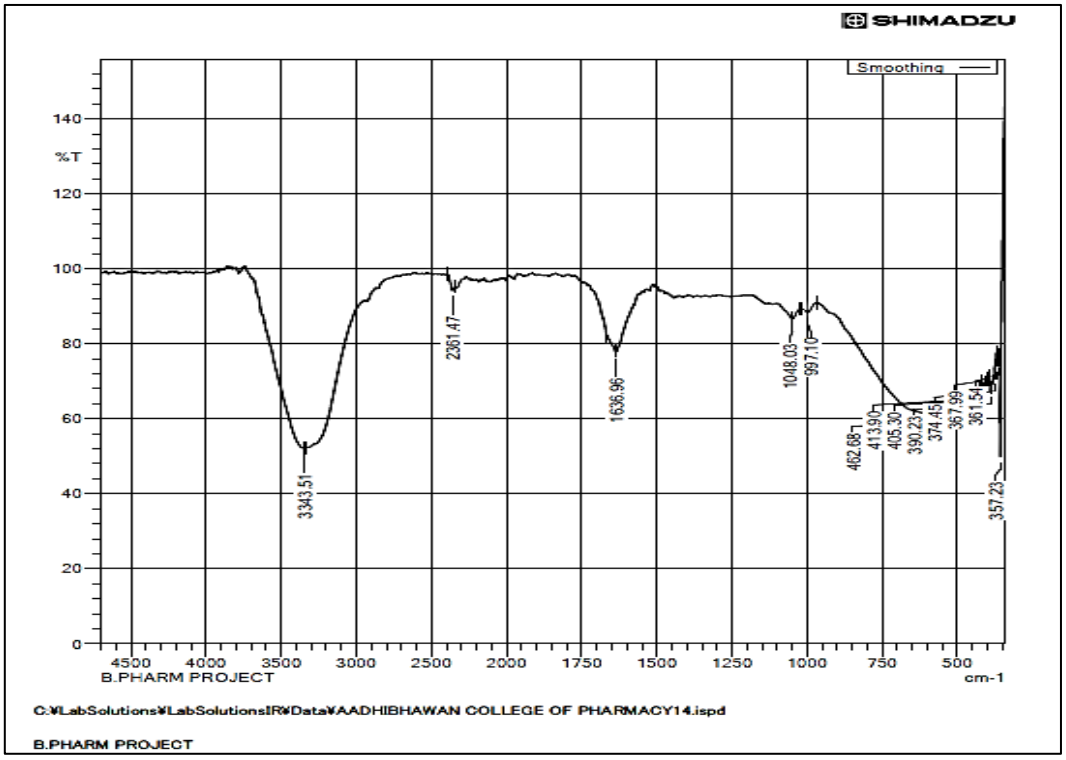

Fig: 19 IR Spectrum Of Medicated Chocolates

4.4.2 PROUCT & LABEL:

Fig: 20 Medicated Chocolates

Fig: 21 Label

DISCUSSION:

The study involved the formulation and evaluation of two novel dosage forms—Medicated Soft Lozenges (MSL) and Medicated Chocolates (MC)—incorporating Paracetamol, Ibuprofen, and Caffeine Anhydrous for their synergistic analgesic and antipyretic effects. Both dosage forms aimed to enhance patient compliance by offering palatable and non-traditional drug delivery alternatives.

Three formulations of each type (MSL1–3 and MC1–3) were prepared by varying the quantities of excipients like PEG 1450 and sucrose in lozenges, and cocoa butter**,** cocoa powder, and lecithin in chocolates. The manufacturing methods ensured proper dispersion and integration of active pharmaceutical ingredients (APIs) into the respective bases, utilizing low-temperature water baths to avoid degradation.

Evaluation parameters such as weight variation, melting point, disintegration time, moisture content, and organoleptic properties were assessed. Both lozenges and chocolates maintained acceptable physicochemical properties, stable texture, and appearance across all formulations. Notably, disintegration times were within 4–5 minutes for both dosage forms—suitable for oral administration.

Organoleptic scores were generally higher for medicated chocolates, with MC1 scoring highest in taste and bitterness masking (4.7), possibly due to better flavor masking by cocoa and vanilla. Stability studies conducted over one month at 40°C/75% RH showed no significant degradation or changes in any of the key quality attributes for either dosage form.

5. CONCLUSION:

Medicated soft lozenges and chocolates are promising alternative dosage forms for delivering a combination of analgesic and antipyretic agents. The formulations were stable, palatable, and easy to administer. Among all, MC1 (Medicated Chocolate) emerged as the most acceptable formulation due to its superior taste, texture, and bitterness masking. These innovative delivery systems can enhance patient compliance, especially in pediatric and geriatric populations, and warrant further clinical investigation.

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