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MEDICATED CHOCOLATE DEVELOPMENT AND ESTIMATION FOR ORAL DRUG DELIVERY IN TRIBAL PEDIATRICS

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ABSTRACT:

Background*: This formulation aims to address the fact that traditional oral drug delivery systems were poorly tolerated, children disliked the taste of the drug administration, with swallowing difficulty and other problems*

Objective*: The study aimed to develop a palatable and stable formulation of medicated chocolate containing a selected drug suitable for pediatric use in tribal communities and assess the palatability.*

Methods*: The selected methods are maceration and Soxhlet extraction which are used for extracting active compounds from plant material. The moringa oleifera powder is extracted and dried for formulation. Qualitative phytochemical screening and viscosity determination were performed to achieve a stable and effective medicated chocolate formulation. The evaluation parameters for the medicated chocolate formulation included assessments of shape, size, taste, texture, dimensions, moisture content, bloom test, viscosity, weight change, hardness, and stability*

Result*: The study revealed the presence of all bioactive chemical constituents, Moringa Oleifera leaves, and green tea. The RF values are 0.44 and 0.72 for gallic acid and caffeine within moringa and green tea extract. The dimension value is 1.86, the Viscosity determination value is 0.56 kg/ms, Bloom strength in this sample heated for 8 hrs., the Weight Variation Value is 6.0+/0.001, the physical Evaluation is 3.1+/-0.01 and Melting Point is 35°C.*

Conclusion*: The conclusion highlights the development and estimation of medicated chocolate for oral drug delivery in tribal pediatrics and presents a novel approach to addressing the unique challenges faced by this population.*

Keywords: Moringa, Tribal Health, Medicated Chocolate, Mahapatra, Oral Drug Delivery.

INTRODUCTION:

Tribal Health in India:

Studies reveal a tribe's sociocultural customs and beliefs are closely linked to its health maintenance system, with tribal health seen as a cultural construct and dynamic social structure (1).

Fig.1

Difficulties that this population typically faces when receiving health care(2).

Prospective remedies for the present issues that tribal healthcare in India is facing(6):

(1) Invest in improving tribal communities' healthcare infrastructure, including modern clinics, hospitals, and primary facilities, to ensure quality services and access to their settlements.

(2) Implement health education programs focusing on sanitation, illness prevention, and culturally appropriate practices for tribal populations, promoting health literacy and decision-making for healthier lives.

(3) Research and data collection on tribal health are crucial for understanding health concerns, diseases, and medical needs, enabling the creation of effective treatments and policies.

Challenges in Pediatrics Medication (1, 4-6):

- **Taste Masking and Palatability**
- **Dose Administration Flexibility**
- **Size of Tablet**

Drug Delivery System (DDS):

Drug delivery systems are highly developed technological devices intended to precisely and/or precisely release medicinal medicines. Drugs have long been used to enhance health and extend life. Drug delivery systems are highly developed technological devices intended to precisely and/or precisely release medicinal medicines. Drugs have long been used to enhance health and extend life (7).

Types of drug delivery system(8)

a) Oral delivery system
b) Parenteral (injected) delivery system
c) Sublingual delivery system
d) Transdermal delivery system
e) Nasal delivery system
f) Ocular delivery system
g) Rectal delivery system

Suitable Dosage Forms for Pediatrics:

Medical experts suggest that most pediatric children should take liquid and Oro dispersible dose forms for oral administration. Oro-dispersible pills are ideal for children, while solid dose forms are suitable for those who can swallow complete tablets and capsules. The choice between these forms is believed to be personal.

Advantages:

a) The medication is protected against internal intestinal metabolism.

b) Liver level filtration is being reduced.
c) Increasing the biodistribution of a drug when taken orally.

Disadvantages:

(1) People interviewed may not remember dates and other important information
(2) more prone to misunderstandings or misinterpretations
(3) Oral traditions may not give information very far in the past.

Potential of Medicated Chocolate (9, 10):

Chocolate is a popular food due to its nutritional value and ease of digestion. Premade drugged chocolates are popular among children. Chocolate contains saturated fat, polyphones, sterols, di- and triterpenes, aliphatic alcohols, and methylxanthines. Cocoa, the main component, contains polyphenols, which may reduce coronary heart disease risk.

OBJECTIVE OF THE STUDY:

(1) To develop and stable formulation of medicated chocolate for pediatrics.
(2) To estimate pharmacokinetic parameters of the drug delivery via the medicated chocolate formulation in pediatrics.
(3) To conduct a safety assessment to ensure the absence of adverse effects.
(4) It fulfills every requirement of the oral drug delivery system while providing a more thorough evaluation of the therapeutic impact.

MATERIALS AND METHODS:

Materials:

Procurement of Chemicals and Reagents: The research utilized chemicals, reagents, biomarkers, and solvents from approved suppliers like Merck, Loba Chemie Pvt. Ltd., Yucca Enterprise, Yarrow Chem products, Hi-media, and Generic, and analytical grade chemicals and reagents from Ayushakti Ayurved, Pvt. Ltd., Maharashtra.

METHOD FOR EXTRACTION:

Extraction of Crude Drugs and Polyherbal Formulation:

The method selected is Maceration:

Maceration is a method for extracting active compounds from plant materials, primarily phenolic compounds, by covering, filtering, and letting it stand for at least three days(20).

The method selected is Soxhlet extraction:

Plant material, either dried or fresh, can be crushed to increase surface area. In experiments, 14g of thyme was used in a 25x80mm thimble to fill a porous cellulose thimble. A solvent (250ml) was used in an anisomantle-mounted Soxhlet extractor and condenser.(21).

Extraction of Moringa oleifera (M. oleifera) powder:

M. oleifera powder was weighed, dissolved in 80mL of ethanol solvent, heated, filtered, and dried before use.(22).

Qualitative Phytochemical Screening of Polyherbal Formulation(25-27):

Thin Layer Chromatography (TLC) Profiling:

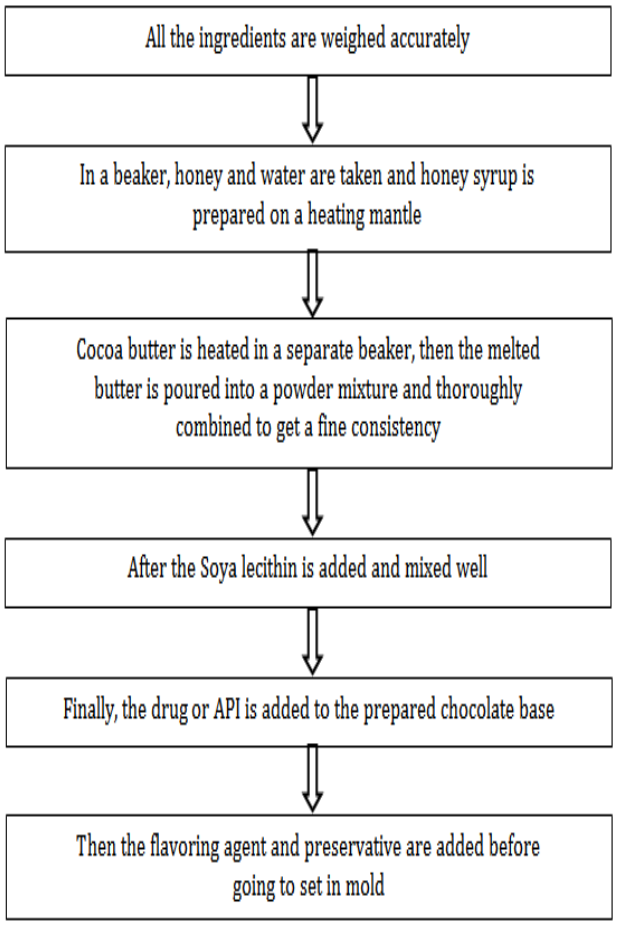
The study utilized an extract in methanol solution for TLC on a 60 F254 silica gel plate, observing spots 0.45 and 0.46 in UV Chromatograms, and determining their travel distance using the retention factor formula:

$$\text{Retention Factor } (R_f) = \frac{\text{Distance travelled by the solute (cm)}}{\text{Distance travelled by the solvent (cm)}}$$

KEY INGREDIENTS USED IN THE PREPARATION OF CHOCOLATE:

Ingredients	Uses
Cocoa Powder	Principal Ingredient
Cocoa Butter	Solidifying Agent
Soya Lecithin	Emulsifying Agent
Honey	Sweetening Agent
Potassium Sorbate	Preservative

METHOD OF PREPARATION:



FORMULATION TABLE:

Sr. No.	Ingredients	Number of Trials			
		F1	**F2**	**F3**	**F4**
1.	Cocoa powder	1200mg	1300mg	1400mg	1500mg
2.	Cocoa butter	550mg	600mg	500mg	500mg
3.	Moringa oleifera	250mg	250mg	250mg	250mg
4.	Honey	2ml	4ml	3ml	3ml
5.	Soya lecithin	30mg	45mg	45mg	50mg
6.	Potassium sorbate	100mg	100mg	100mg	100mg
7.	Flavoring agent	q.s.	q.s.	q.s.	q.s.

Evaluation parameters of medicated chocolate(28, 29):

- General Appearance
- Dimension
- Viscosity determination of chocolate base
- Weight variation test
- Hardness
- Melting point of Medicated chocolate
- Bloom test
- Fat bloom test
- Sugar Bloom test
- Drug content determination

RESULT AND DISCUSSION:

Preliminary Phytochemical Screening:

The phytochemical analysis revealed significant active phytochemicals in green tea, moringa ethanolic, and chocolate extracts, including high concentrations of tannins, terpenoids, and glycosides.

Phytochemical Class	Tests	GreenTea	Moringa Oleifera leaves	Medicated Chocolate
1. Tannins	Ferric chloride	+	+	+
Phenolics	Lead acetate	+	+	+
2. Glycosides	Keller Kiliani	+	+	+
3. Flavonoids	Alkaline reagent	+	+	+
	Lead acetate	+	+	+
4. Alkaloids	Dragendorff's	+	+	+
	Hager's	+	+	+
	Wagner's	+	+	+
	Mayer's	+	+	+
5. Saponins	Liebermann-Burchard	+	+	+
6. Carbohydrates	Fehling	+	+	+
7. Tri-terpenes and sterols	Salkowski's	+	+	+

Thin Layer Chromatography (TLC)(16, 30-32):

Optimized TLC solvent system and visualizing agent for detection of plant-based chemicals:

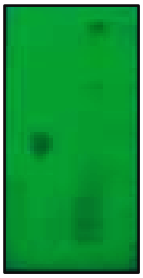
Biomarker	Solvent System	Visualizing agent
Caffeine	Toluene: Ethyl acetate: Methanol: Formic acid (2.1: 1.7: 0.8: 0.2)	UV and FeCl3
Gallic acid	Chloroform: Ethyl acetate: Formic acid (2.5:2.:0.2)	UV and FeCl3

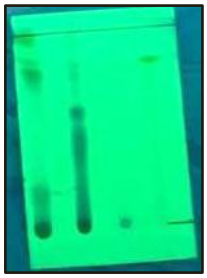
TLC for Gallic acid and caffeine within Moringa and Green tea extract(33):

The study examined the phytochemical screening of caffeine in green tea and gallic acid in moringa using various solvent systems. The ethanolic extract of Moringa solidified after exposure to UV wavelengths, while green tea showed caffeine with matching Rf values.

No. of Spots	Gallic acid (Rf value)
1-Moringa	0.45
2-Gallic acid	0.44
Standard (Rf value)	
2-Gallic acid	0.44 (Gallic acid)

No. of Spots	Caffeine (Rf value)
1-Green tea	0.73
2-Caffeine	0.72
Standard (Rf value)	
2-Caffeine	0.72 (Caffeine)





Organoleptic Characteristics:

Sr. No.	Characteristics	Result
1.	Color	Brown
2.	Odor	Pleasant with no burnt smell
3.	Taste	Sweet
4.	Surface	Smooth and even

Dimensions:

It was measured by Vernier's capillary Average width of 4 formulations: 1.85+1.86+1.901.85/4 = 1.86

Viscosity Determination:

It is determined by Brookfield viscometer and observed to be 560cp viscosity = 0.56kg/ms.

Physical Evaluation:

Formulation	Hardness (kg/cm)
F1	2.1+/-0.01
F2	2.4+/-0.01
F3	2.3+/-0.01
F4	3.1+/-0.01

Weight variation determination:

Formulation	Weight variation (gm)
F1	4.0+/-0.001
F2	4.15+/-0.001
F3	5.0+/-0.001
F4	6.0+/-0.001

Bloom test:

The sample was heated at 40 degrees for eight hours

Stability:

The study examined the stability of medicinal chocolate at room and refrigeration temperatures, revealing no significant changes in its physical appearance.

Melting Point:

Formulation	Melting point
F1	28°C
F2	29°C
F3	34°C
F4	35°C

CONCLUSION:

The creation and assessment of medicated chocolate for oral medication administration in tribal pediatrics offers a fresh strategy to deal with the particular difficulties this group faces. The project has shown that giving children in tribal communities their necessary medications through medicated chocolate may be a successful, tasty, and culturally acceptable method.

Tribal pediatricians' successful development and testing of medicated chocolate for oral medication delivery suggests that this novel strategy has the potential to enhance healthcare outcomes in marginalized groups. Large-scale clinical studies, investigating a wider variety of drugs and therapeutic areas, and further refining the formulation for mass manufacturing and distribution should be the main goals of future research. This initiative uses chocolate's universal appeal to improve medicine adherence and health outcomes, setting the stage for a new paradigm in pediatric drug administration.

In terms of smoothness, flavor, and patient compliance, we can state that medicated chocolate including components like honey, Coca powder, Coca butter, potassium sorbate, moringa, and soy lecithin is a good choice. The created chocolate was examined for its shape, size, taste, texture, dimensions, moisture content, bloom test, viscosity, weight change, hardness, and stability. The study's

findings led us to the conclusion that medicated chocolate enhances the formulation's smooth, creamy texture and effectively masks off taste while producing a stronger therapeutic impact.

LIST OF ABBREVIATIONS:

- TLC: Thin Layer Chromatography
- cp: Centipoise (a unit of viscosity)
- RF: Retention Factor
- kg/ms: Kilogram per meter per second (a unit of viscosity)
- °C: Degrees Celsius
- HPLC: High-Performance Liquid Chromatography
- GC: Gas Chromatography
- pH: Potential of Hydrogen (a measure of acidity or alkalinity)
- mg: Milligram (a unit of mass)
- g: Gram (a unit of mass)
- ml: Milliliter (a unit of volume)
- dL: Deciliter (a unit of volume)
- v/v: Volume/Volume (a concentration unit)
- w/v: Weight/Volume (a concentration unit

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AUTHOR CONTRIBUTIONS:

Conceptualization was done by Samiksha Mhatre, Methodology was done by Prerna Sharma, Formal Analysis done by Prerna Sharma, Himanshu prajapati, Samiksha Mhatre, Writing original draft preparation was done by Samiksha Mhatre, Prerna Sharma, Himanshu prajapati

Writing review and editing done by Samiksha Mhatre, Prerna Sharma, Himanshu prajapati, Ayesha Shaikh, Supervision was done by Samiksha Mhatre and Laboratory support from St. Wilfred's Institute of Pharmacy, Panvel.

CONFLICT OF INTEREST:

The authors declare they have no competing interests.

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