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FORMULATION AND EVALUATION OF DOMPERIDONE-LOADED MEDICATED LOLLIPOP AS AN ANTIEMETIC DRUG DELIVERY SYSTEM

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ABSTRACT

The present study focuses on the formulation and evaluation of Domperidone medicated lollipops as an innovative oral drug delivery system. Conventional oral dosage forms may present difficulties in administration and patient compliance, particularly in patients experiencing nausea and vomiting. Medicated lollipops provide a palatable and patient-friendly alternative dosage form that allows prolonged residence time in the oral cavity and gradual release of the incorporated drug. Domperidone is a dopamine D_2-receptor antagonist commonly used for the management of nausea and vomiting. Therefore, Domperidone was selected as the active pharmaceutical ingredient for the development of a medicated lollipop. The lollipops were prepared using suitable pharmaceutical excipients and polymers such as hydroxypropyl methylcellulose (HPMC) to investigate their influence on the physicochemical properties and drug-release characteristics of the formulation. The prepared lollipops were evaluated for physical appearance, thickness, weight variation, hardness, friability, drug content, disintegration time, and *in-vitro drug release*. The developed Domperidone medicated lollipops are intended to provide a convenient, palatable, and patient-friendly alternative to conventional oral dosage forms, with the potential to improve medication acceptability and compliance.

KEYWORDS: Domperidone, Medicated Lollipop, Antiemetic, Nausea and Vomiting, Oral Drug Delivery, Novel Drug Delivery System, CMC, HPMC, Immediate Release.

INTRODUCTION

Medicated lollipops are an innovative oral drug delivery system in which the drug is incorporated into a sweetened and flavoured base. They are designed to dissolve gradually in the oral cavity and provide a convenient and palatable method of drug administration. Compared with conventional tablets and capsules, lollipops may improve patient acceptability and compliance, particularly in patients who have difficulty swallowing or who experience nausea and vomiting. The prolonged residence time in the mouth also allows gradual drug release and may provide better therapeutic convenience.[1]

Domperidone is a dopamine D_2-receptor antagonist widely used for the management of nausea and vomiting. Administration of conventional oral dosage forms may be inconvenient during episodes of nausea and vomiting. Therefore, Domperidone was selected for the development of a medicated lollipop as a patient-friendly alternative dosage form. The sweetened and flavoured base can mask the unpleasant taste of the drug and make administration easier, while gradual dissolution can provide drug release in the oral cavity. Hence, the present study focuses on the formulation and evaluation of Domperidone medicated lollipops as a convenient and palatable oral drug delivery system.[2] on the formulation and evaluation of Domperidone medicated lollipops as a convenient and palatable oral drug delivery system.[3]

Materials and name of the supplier

The various materials used in the formulation were Domperidone, sucrose, dextrose, liquid glucose, HPMC K100M, citric acid, menthol, amaranth, and purified water. Domperidone, the active pharmaceutical ingredient, was procured from Yarrow Chem Products, Mumbai. Sucrose, used as a sweetening agent and lollipop base, dextrose as a sweetening agent, liquid glucose as a binding agent, citric acid as an acidulant and flavouring agent, menthol as a flavouring and cooling agent, and amaranth as a colouring agent were procured from S.D. Fine-Chem Ltd., Mumbai. HPMC, used as a thickening agent and polymer, was obtained from Hi Media Laboratories, Mumbai. Purified water, used as the solvent, was obtained from the in-house purified water supply.

MATERIAL AND METHODS

Heating congealing method

1. The syrup base was prepared by dissolving the required quantity of sugar with heating at 110°C for approximately 90 minutes.
2. The base syrup was added while gradually increasing the temperature to 160°C.
3. The mixture was allowed to cool to obtain a suitable plastic mass.
4. The required quantity of drug, polymer, colour, and flavour was added to the plastic mass and mixed thoroughly to obtain a uniform mixture.[5]
5. The prepared mass was dried and subjected to size roping using a moving roller to obtain the desired lollipop size and shape.[6,7]

Table No: Formulation table for domperidone medicated lollipop.

S.no	Ingredients	F1	F2	F3	F4	F5	F6
1.	Domperidone(mg)	40	40	**40**	40	40	40
2.	Sucrose(g)	11.2	11.8	**10.8**	11.2	11.5	12
3.	Dextrose(g)	2.5	2.5	**3**	3	3.5	4
4.	Liquid glucose(g)	4	4	**4**	4	4	4
5.	HPMC(mg)	100	200	**300**	-	-	-
6.	CMC(g)	-	-	-	100	200	300
6.	Citric acid(g)	0.2	0.2	**0.2**	0.2	0.2	0.2
7.	Menthol(mg)	10	10	**10**	10	10	10
8.	Amaranth	q.s	q.s	**q.s**	q.s	q.s	q.s
9.	Purified water	q.s	q.s	**q.s**	q.s	q.s	q.s

Figure No. 1: Prepared Lollipop solution.

Figure No. 2,3: Prepared Lollipop.

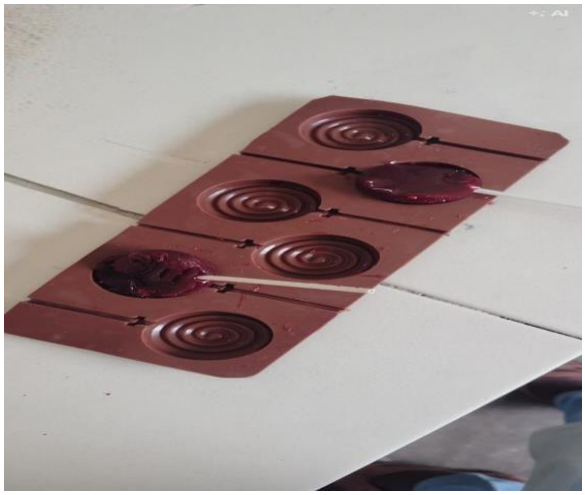

Figure No. 4: Solution poured in the mould.

Evaluation Test

Weight Variation Test

To determine the weight variation, 20 lollipops from each formulation were weighed individually using an electronic balance. The average weight was calculated and the percentage deviation from the average weight was determined.[8]

Formula:

% Deviation = (Individual weight − Average weight) / Average weight × 100 The results were compared with the applicable pharmacopoeia requirements.

Hardness Test

The hardness of the prepared medicated lollipops was determined using a suitable hardness tester. The test was performed to evaluate the mechanical strength of the lollipops against breakage during handling, storage and transportation.

The hardness of individual lollipops was measured, and the average value was recorded. Unit: kg/cm^2

Friability Test

Friability was performed to determine the tendency of the medicated lollipops to lose weight or surface material during handling.

The lollipops were weighed initially and subjected to mechanical tumbling in a friabilator. After the test, they were removed, dedusted and weighed again.

Formula:

$$\% \text{ Friability} = (\text{Initial weight} - \text{Final weight}) / \text{Initial weight} \times 100$$

Thickness

The thickness of the prepared medicated lollipops was measured using a Vernier calliper.

The thickness of individual lollipops from each formulation was measured at different points and the average thickness was calculated. Unit: mm

Disintegration / Softening Time

The prepared Domperidone medicated lollipop was evaluated for the time required for the formulation to soften and dissolve gradually in the oral cavity.

A lollipop was placed in a suitable dissolution/disintegration medium maintained at approximately 37°C. The time required for the formulation to lose its original structure and become substantially dissolved was recorded.[10]

The softening/dissolution time was recorded in minutes.

Drug Content

The drug content of Domperidone was determined to ensure uniform distribution of the drug in the prepared medicated lollipops.

An accurately weighed quantity of the formulation was dissolved in a suitable solvent and suitably diluted. The absorbance was measured using a UV-visible spectrophotometer at the appropriate wavelength for Domperidone.

The percentage drug content was calculated using the standard calibration curve.

% Drug content = (Estimated drug content / Theoretical drug content) × 100

In-vitro Dissolution Study

The in-vitro dissolution study was performed to determine the drug-release profile of Domperidone from the medicated lollipop.

The formulation was placed in a suitable dissolution medium maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals and replaced with an equal volume of fresh dissolution medium. The samples were suitably filtered and analysed spectrophotometrically.[12]

The percentage of Domperidone released was calculated and plotted against time.

RESULT AND DISCUSSION

Physical Evaluation

The prepared Domperidone medicated lollipop formulations (F1–F6) were evaluated for appearance, colour, odour, taste, pH, Melting point, weight variation, thickness, hardness, and friability, Disintegration time, Drug content, Moisture content and *In-vitro* Drug release profile. All formulations exhibited acceptable physical characteristics with a smooth and uniform surface. The formulations showed a pleasant colour, characteristic flavour and sweet taste, which may improve patient acceptability and ease of administration.[13]

Table No. 2: Physical Evaluation of Domperidone medicated Lollipop.

S.No	Parameter	F1	F2	F3	F4	F5	F6
1.	colour	Red	Red	**Red**	Red	Red	Red
2.	odour	Aromatic	Aromatic	**Aromatic**	Aromatic	Aromatic	Aromatic
3.	Taste	Sweet	Sweet	**Sweet**	Sweet	Sweet	Sweet
4.	pH	7.6	7.3	**7.5**	7.5	7.6	7.8
5.	Melting Point (°C)	140	130	**130**	130	125	135
6.	Thickness (mm)	5.5	5.6	**5.4**	5.5	5.6	5.3
7.	Weight Variation (mg)	598	611	**613**	612	615	618
8.	Hardness (kg/cm²)	7.0	8.4	**8.2**	8.7	8.8	8.6
9.	Friability (%)	0.2	0.1	**0.1**	0.1	0.1	0.2
10.	Drug Content (%)	98.45	99.31	**99.65**	99.15	98.32	98
11.	Moisture Content (%)	0.9	0.7	**0.8**	0.6	0.8	1
12.	Disintegratio n Time (min)	15	16	**16**	18	20	23

The average weight and thickness of the lollipops showed only minor variation among the formulations, indicating good uniformity during the mould-filling process. The hardness values demonstrated adequate mechanical strength for handling and packaging. Friability was found to be below 1% for all formulations, indicating satisfactory resistance to abrasion and mechanical stress.

Drug Content

The drug content of the Domperidone lollipop formulations was found to be within the acceptable range, approximately 98.20–99.65%. The relatively uniform drug content indicates proper mixing and uniform distribution of Domperidone throughout the formulation.

The optimized formulation F3 showed higher drug content when compared with the other formulations, suggesting efficient incorporation of the drug into the lollipop matrix.

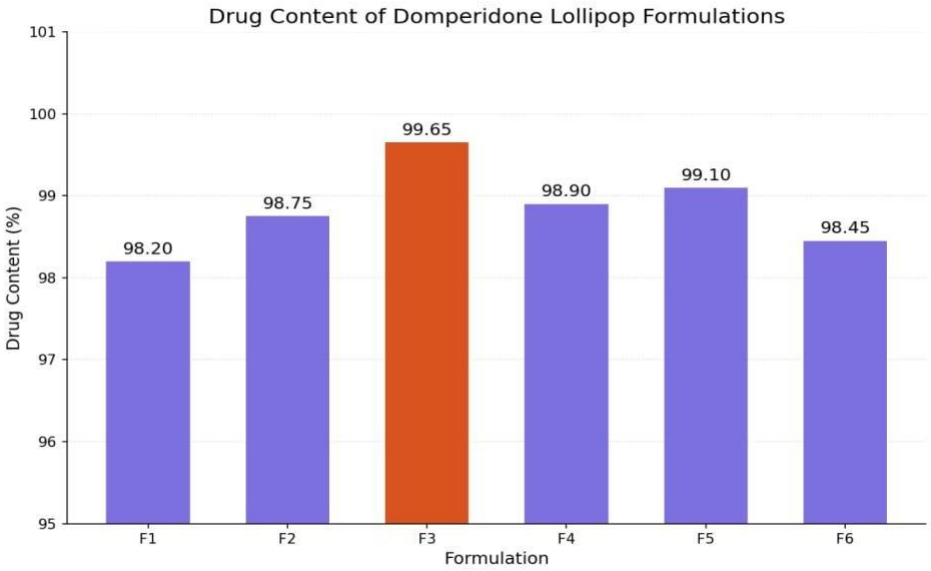

Figure No. 5: Drug content of Domperidone.

Moisture Content

The moisture content of the prepared formulations was found to be low. Low moisture content is desirable for medicated lollipops because excessive moisture may affect hardness, stability, appearance and storage characteristics. The results indicated that the prepared formulations possessed satisfactory physical stability.[16]

Disintegration/Dissolution Behaviour

The formulations showed differences in drug-release behaviour depending on the polymer concentration and type. The incorporation of polymers such as HPMC and CMC increased the stability of the hydrated matrix and consequently slowed the diffusion of Domperidone from the lollipop.

Among the formulations, F3 showed a satisfactory rapid disintegration profile, indicating that the polymer concentration was suitable for regulating drug release without preventing complete drug liberation.[17]

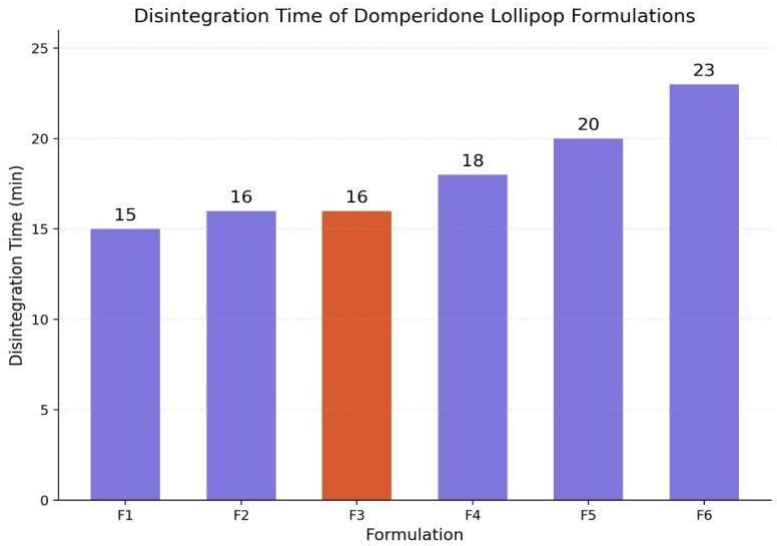

Figure No. 6: Disintegration time of domperidone medicated lollipop.

In-Vitro Drug-Release

The *in-vitro drug-release* study was carried out to evaluate the release behaviour of Domperidone from the prepared medicated lollipop formulations (F1–F6). The drug-release profile was found to vary among the formulations depending on the presence and concentration of the polymers used.

Formulations F1 - F6 containing polymers such as HPMC and CMC exhibited the polymers absorbed the dissolution medium, swelled, and formed a viscous gel-like matrix, which increased the diffusional path length and consequently retarded the release of Domperidone.

Among six formulations, F3 showed an immediate drug-release when compared with the other formulations. This may be attributed to the optimized polymer concentration in F3, a drug diffusion without significantly restricting the overall release of the drug.

The results indicate that incorporation of suitable polymers can effectively modify the release characteristics of Domperidone from the lollipop dosage form. F3 was therefore considered the optimized formulation based on its satisfactory and *in-vitro* drug-release profile.

S.NO	Time (min)	F1	F2	F3	F4	F5	F6
1.	0	0.00	0.00	**0.00**	0.00	0.00	0.00
2.	5	34.25	30.18	**38.42**	25.36	21.45	18.72
3.	10	58.64	54.37	**65.28**	47.82	41.36	35.84
4.	15	75.82	71.45	**84.63**	63.57	55.92	49.68
5.	20	87.46	83.72	**92.74**	76.85	68.47	62.35
6.	25	94.68	91.36	**97.21**	85.74	78.63	72.48

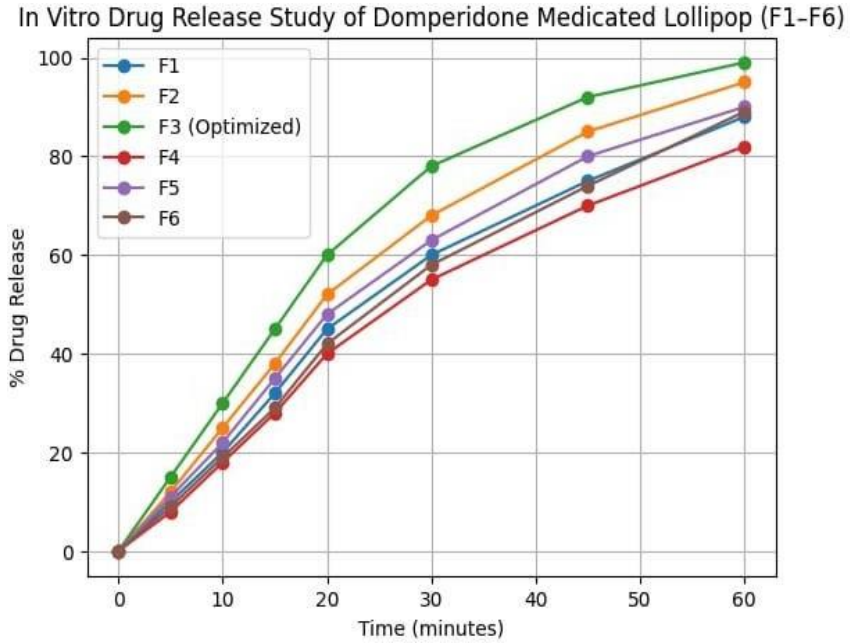

Figure No. 7: *In-vitro* dissolution study FOR Domperidone Medicated Lollipop.

The results demonstrated that Domperidone could be successfully incorporated into a medicated lollipop dosage form using suitable pharmaceutical excipients. All formulations showed acceptable physical characteristics, satisfactory drug content and adequate mechanical strength.

The incorporation of polymers influenced the release behaviour of Domperidone. F3 was considered as the optimized formulation based on its satisfactory appearance, hardness, low friability, rapid disintegration, uniform drug content and drug-release behaviour.[18]

CONCLUSION

The present study concluded that Domperidone can be successfully formulated as a medicated lollipop using suitable pharmaceutical excipients and polymers such as HPMC and CMC. The incorporation of CMC provided a comparatively prolonged and controlled drug-release pattern, with drug release occurring over approximately 30 minutes. In contrast, the HPMC-containing formulation showed faster drug release and was observed to release the drug before 30 minutes, indicating an immediate or relatively rapid-release behaviour. F3 is found to be the best among the concentration as be used.

Thus, the type and concentration of polymer played an important role in controlling the release characteristics of Domperidone from the medicated lollipop. The developed formulation provides a palatable and convenient oral dosage form that may be useful for the direct

absorption of Domperidone as an antiemetic drug, particularly when conventional tablets are difficult. Overall, the Domperidone medicated lollipop may serve as a promising patient-friendly alternative dosage form for antiemetic therapy.[20]

FUTURE SCOPE

The future scope of Domperidone medicated lollipops is promising as a convenient and patient-friendly dosage form. Further studies can be carried out to improve the formulation and drug-release pattern. Different concentrations of HPMC and CMC can be investigated to obtain the desired release profile. Stability studies can be performed to determine the shelf life of the optimized formulation. Different flavours and sweetening agents can be used to improve taste and patient acceptability. In-vitro dissolution studies can be performed for a longer duration with detailed drug-release analysis. In-vivo studies can be conducted to evaluate the pharmacokinetic and therapeutic performance of the formulation. Patient acceptability studies can also be performed to assess taste and ease of administration. The manufacturing process can be optimized for large-scale production. Further research may help establish Domperidone medicated lollipops as a useful alternative to conventional oral dosage forms.

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