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Formulation and characterization of paracetamol, diclofenac sodium and domperidone lozenges

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ABSTRACT

A combination of paracetamol, diclofenac and domperidone were formulated in the lozenge form to make available the immediate release of the drugs in fever, pain and nausea conditions. Lozenges are a form of dosage forms that deliver the drug in the oral cavity. They dissolve slowly in the mouth to release the medicament. A number of dosage forms like tablets, syrups, capsules are available for the above stated drugs but none acts locally and effectually. The aim of current investigation is to prepare the medicated lozenges of paracetamol, diclofenac and domperidone and to evaluate the same to meet the needs of increased bioavailability and reduced hepatic toxicity and gastric irritation. Lozenges were prepared by heat congealing method with varying concentrations of sugar base and polymer. Formulated lozenges were evaluated for various physicochemical parameters like hardness, weight variation, moisture content, friability and invitro dissolution. The results obtained were compared with pharmacopoeial limits. FTIR studies revealed no signs of incompatibility between the drugs and its excipients. Hardness, friability, moisture content of the prepared lozenges were found within the limits. Invitro dissolution studies showed the drug release of 90% at the end of 30 minutes. Thus, it can be concluded that medicated lozenges are suitable for large doses and immediate drug release requirements with improved bioavailability.

Keywords: Heat congealing, Nausea, Anti-pyretic, Bioavailability, Antiemetic.

INTRODUCTION

Lozenges are solid preparations with one or more medicaments usually in a flavored and sweetened base. Lozenges are meant to be held in the oral cavity to release the medicaments for localized actions [1]. They have become popular because of their ease of administration and possibility of incorporating large doses. Further,

they provide rapid onset of action with improved bioavailability. They are given for the patients who cannot swallow the solid pills as well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bathe the throat tissues in a solution of the drug. More amount of the drug will be absorbed from the buccal cavity and less will be swallowed and lost in GI tract [2, 3].

Paracetamol, diclofenac and domperidone are used for anti-pyretic, analgesic and antiemetic actions. Usually, these three conditions are associated with each other. Lozenges provide a possibility of including the large doses in a single dosage form without the need of administering repeated doses [4]. This combination of drugs in lozenges benefits the patients who are in multiple therapies having in need of antiemetic, antipyretic and analgesic actions. Lozenges dissolve slowly in the oral cavity and release the drugs [5]. Thus the drugs get protected against the acidic environment of stomach and avoids first pass metabolism in the liver. Lozenges increase the bioavailability of the drugs together while reducing the frequent dosing. The other reasons for the preference of lozenges over other solid dosage forms are their wide acceptability by the pediatrics and geriatrics, no water uptake along with the lozenge formulation [6].

The current investigation deals with the formulation and evaluation of the most common antipyretic, analgesic and antiemetic drugs in a hard candy lozenge formulation. Lozenges were

prepared by heat congealing method using varying concentrations of candy base and polymer. Prepared lozenges were evaluated for their physicochemical parameters like hardness, thickness, weight variation, moisture content and invitro dissolution studies etc.

MATERIALS AND METHODS

Paracetamol, Diclofenac and Domperidone were procured from Yarrow chemicals, Mumbai. Sucrose and Dextrose were obtained Finar chemicals Ltd., Ahmedabad. Methyl cellulose was procured from Merck specialties Pvt Ltd. Ahmedabad

Identification of drug

Drugs Paracetamol, Diclofenac and Domperidone were identified by infrared absorption spectral analysis on IR spectrophotometer in the range of 4000 to 400 cm^{-1} using potassium bromide. Obtained peaks were compared with standard spectra of Paracetamol, Diclofenac and Domperidone.

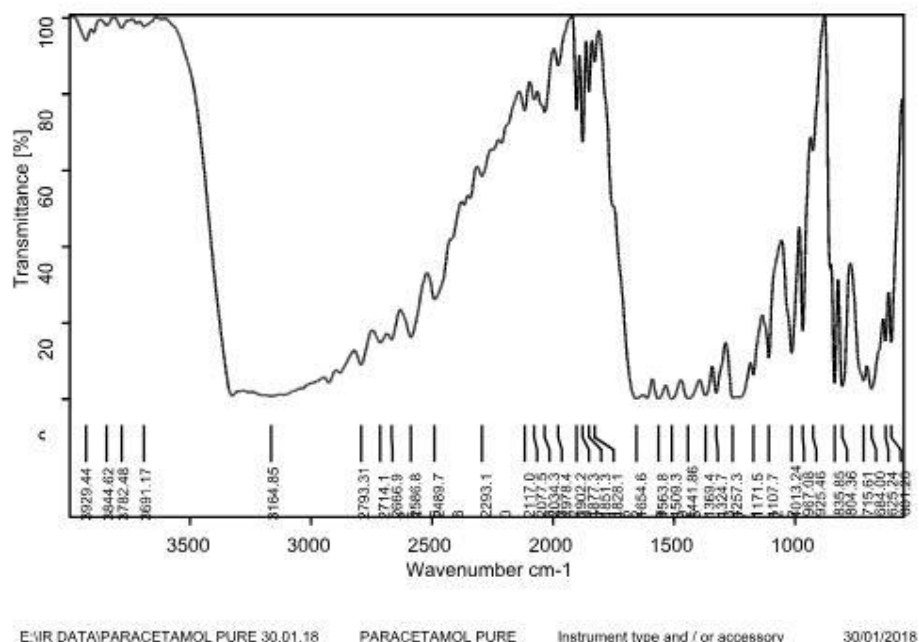
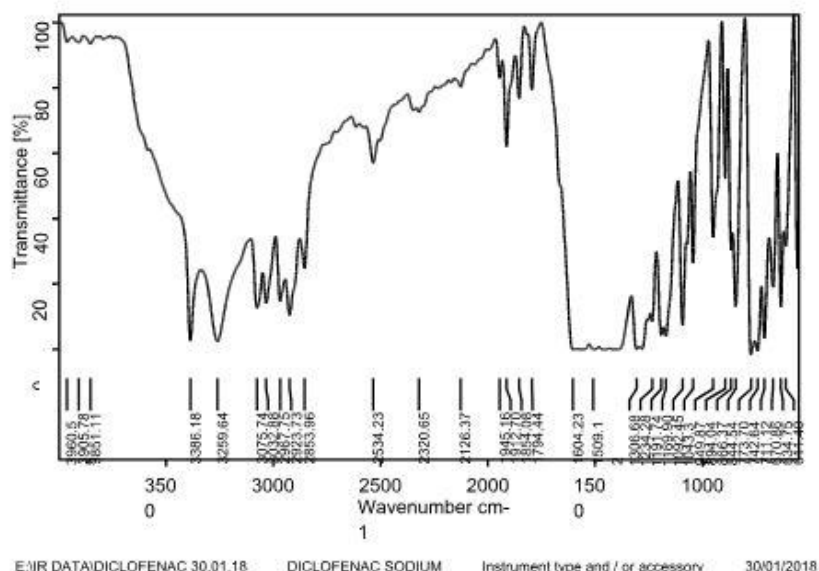
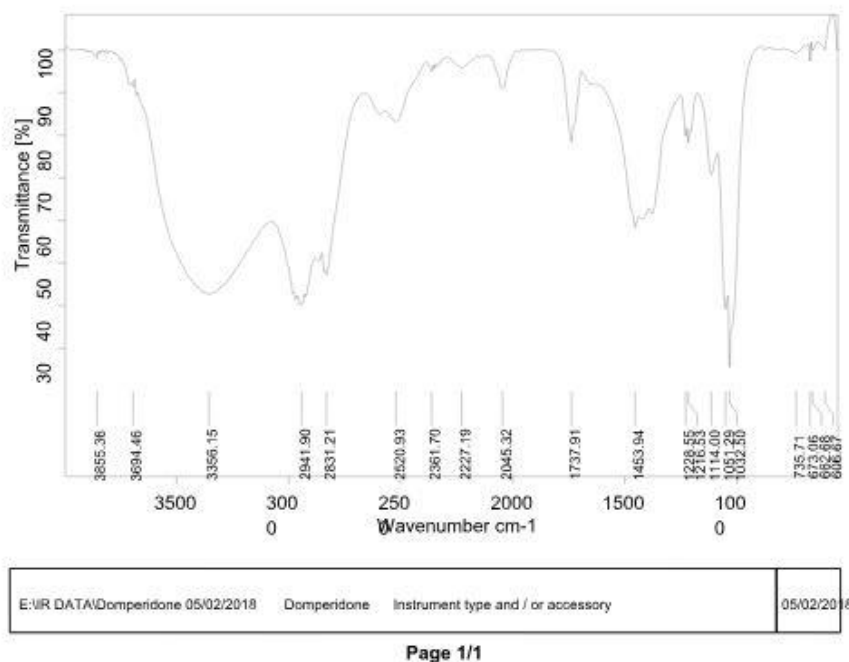


Figure 1: FT-IR spectrum of Paracetamol



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Figure 2: FT-IR spectrum of Diclofenac



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Figure 3: FT-IR spectrum of Domperidone

Compatibility studies for drug and polymers

Compatibility between the drugs, polymer and its excipients under experimental conditions is important prerequisite before formulation. Any kind of incompatibility between the drugs, polymer

and its excipients can alter the stability, safety, bioavailability and efficacy of drugs. Drug – Excipient compatibility is recorded on IR spectrophotometer.

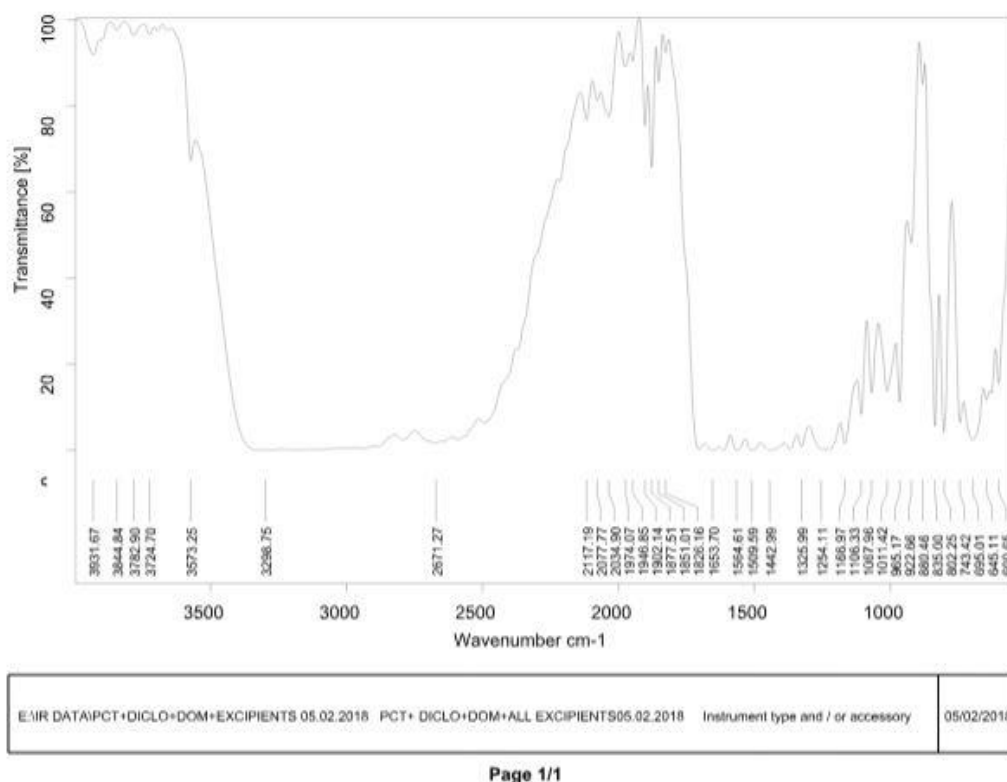


Figure 4: FT-IR spectrum of Paracetamol+Diclofenac+Domperidone+All excipients

Table 1: functional groups of infrared spectroscopy

Ingredients	Groups assigned			
	C-H stretch	C=O stretch	N-H stretch	C-C stretch
Paracetamol	3164.85	1877.3	1563.81	825.4
		1851.3	1654.69	835.8
		1828.1		
Diclofenac	3259.64	1854.0	1604.23	894.0
		1794.44	1509.12	866.3
				949.8
Domperidone	3022.65	1871.0	1621.84	968.2
		1834.22		928.7
		1721.10		898.8
Drugs+Excipients	3298.75	1877.5	16653.70	965.1
		1851.0	1564.61	922.6
		1828.1		880.4

Estimation of paracetamol, diclofenac, domperidone

Construction of calibration curve for Paracetamol

Accurately weighed Paracetamol (100mg) was made to dissolve and made to 100ml in pH 6.8 phosphate buffer in a volumetric flask, labeled as

stock solution-I. 10ml of the above solution was made up to 100 ml in another volumetric flask, labeled as stock solution-II. From the stock-II, a series of dilutions were prepared with concentrations ranging from 4 to 12µg/ml and absorbance was measured against the blank.

Table 2: Calibration curve data for Paracetamol

Sl.No.	Concentration (µg/ml)	Absorbance at 243nm
1	0	0
2	4	0.079
3	6	0.158
4	8	0.24
5	10	0.334
6	12	0.422

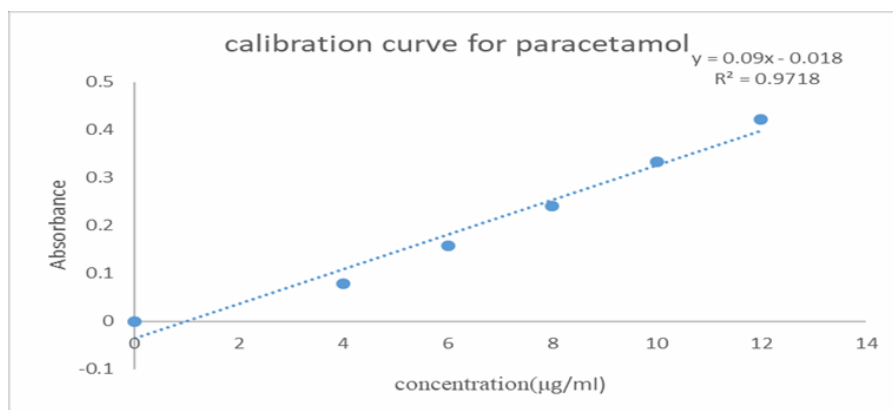


Figure5: Calibration curve forparacetamol

Construction of calibration curve of Diclofenac

Accurately weighed Diclofenac (100mg) was made to dissolve and made to 100ml in pH6.8 phosphate buffer in a volumetric flask, labeled as

stock solution-I. 10ml of the above solution was made up to 100 ml in another volumetric flask, labeled as stock solution-II. From the stock- II, a series of dilutions were prepared with concentrations ranging from 8 to 16µg/ml and absorbance was measured against the blank.

Table 3: Calibration curve data for Diclofenac

Sl.no	Concentration (µg/ml)	Absorbance at 276 nm
1	0	0

2	8	0.082
3	10	0.169
4	12	0.258
5	14	0.346
6	16	0.439

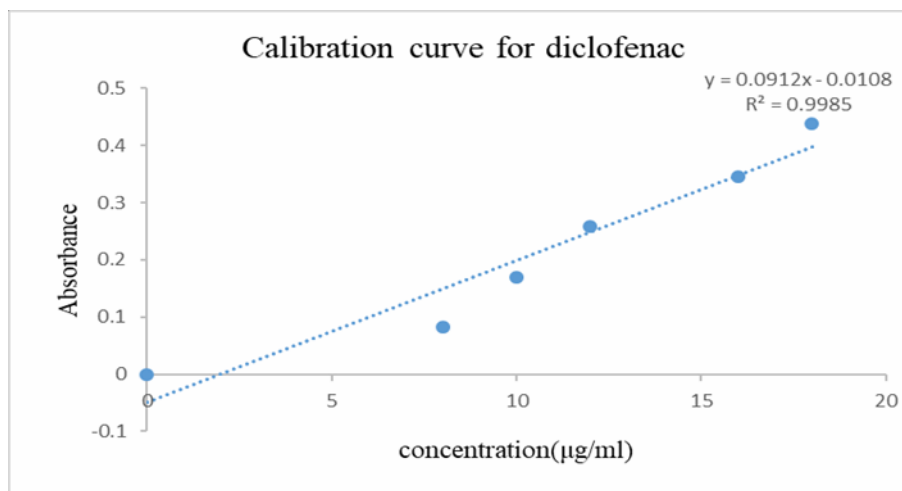


Figure 6: Calibration curve for Diclofenac

Construction of calibration curve of Domperidone

Accurately weighed Domperidone (100mg) was made to dissolve and made to 100ml in pH 6.8 phosphate buffer in a volumetric flask, labeled as stock solution-I. 10ml of the above solution was

made up to 100 ml in another volumetric flask, labeled as stock solution-II. From the stock-II, a series of dilutions were prepared with concentrations ranging from 2 to 10 µg/ml and absorbance was measured against the blank.

Table 4: Calibration curve data for Domperidone

SL.NO	Concentration (µg/ml)	Absorbance at 284 nm
1	0	0
2	2	0.05
3	4	0.12
4	6	0.19
5	8	0.26
6	10	0.34

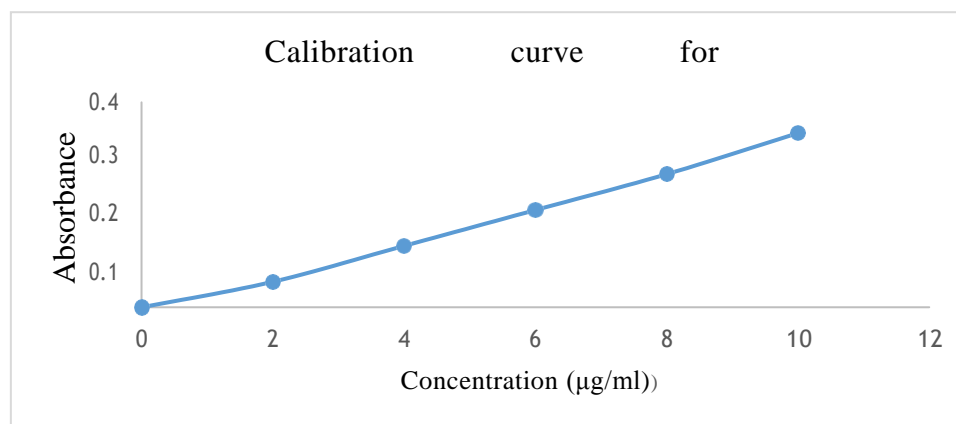


Figure 7: Calibration plot for Domperidone

Method of preparation

Paracetamol-Diclofenac-Domeperidone hard candy lozenges were prepared by Heat Congealing method. The method of preparation involves the following steps:

Sugar syrup was prepared by mixing required quantity of sugar with water in a beaker. In another beaker, dextrose was dissolved in a small quantity of water and heated to 110°C till clear viscous

syrup was formed. The dextrose syrup was added to previously prepared sugar syrup and heated to 160°C till the color changes to golden yellow. Drugs, polymer and other ingredients were added once the temperature reaches 90°C. The final solution was poured into the mold to fabricate them to lozenges. Prepared lozenges were wrapped in aluminium foils and stored in desiccators to prevent moisture uptake.

Table 5: Composition of Hard Candy Lozenges

INGREDIENTS	F1	F2	F3	F4	F5	F6
PARACETAMOL(mg)	120	120	120	120	120	120
DICLOFENAC (mg)	60	60	60	60	60	60
DOMPERIDONE(mg)	20	20	20	20	20	20
SUCROSE(mg)	3375	3350	3325	3300	3275	3250
DEXTROSE(mg)	1320	1320	1320	1320	1320	1320
METHYL CELLULOSE	250	500	750	1000	1250	1500
CITRIC ACID(mg)	50	50	50	50	50	50
SORBITOL SOLUTION	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
MENTHOL(mg)	30	30	30	30	30	30
AMARANTH	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
TOTAL(mg)	5000	5000	5000	5000	5000	5000

EVALUATION OF HARD CANDY LOZENGES

Average weight and Weight variation test

For weight variation test, 10 lozenges were selected randomly. All the lozenges were individually weighed on an electronic balance and an average weight was obtained. The individual

weight of each lozenge weight was compared with average weight. This assures if the formulated lozenges are within permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage [7].

$$\% \text{Weight variation} = \frac{\text{Average weight of lozenges} - \text{individual weight of each lozenge}}{\text{Average weight of lozenges}}$$

Thickness and Diameter

Thickness and diameter of the prepared lozenges were measured by Vernier Calipers. Ten lozenges of each formulation were tested for their thickness and diameter. The extent to which the thickness of each lozenge deviated from $\pm 5\%$ of the standard value was determined. [43]

Friability test

Friability of the prepared 20 lozenges was tested from each formulation using a Friabilator at 25rpm speed for duration of 4 minutes. Lozenges were then dedusted, reweighed and percentage weight loss was calculated by the equation [7].

$$\% \text{Friability} = \frac{\text{initial weight of lozenge} - \text{weight of lozenge after friability}}{\text{Initial weight of lozenge}}$$

Hardness test

Hardness of lozenge is defined as the force applied across the diameter of the lozenge to break it. The resistance of the prepared lozenge to chipping and breakage upon storage conditions and its transformation and handling before usage depends on its hardness. The hardness of each tablet was determined using Monsanto hardness tester and the average was calculated and presented with standard deviation.⁴⁵

$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

Moisture content analysis

Lozenge formulation was weighed and crushed in a mortar. One gram of the crushed lozenge was placed in a dessicator for a period of 24 hours and the sample was reweighed after 24 hours. Moisture content was analyzed by subtracting the final weight from initial weight of lozenge formulation.

$$\% \text{ moisture content} = \frac{\text{Initial weight of lozenge} - \text{final weight of lozenge}}{\text{Initial weight of lozenge}} \times 100$$

Drug Content

Drug content of paracetamol, diclofenac and domperidone lozenges was carried using UV spectrophotometer. Lozenges were powdered and dissolved in methanol and made to 50ml with phosphate buffer of pH 6.8 in a 50ml volumetric flask. 1ml of the prepared stock was diluted to 50ml using the same buffer, sonicated for 30 minutes, filtered and absorbance was measured at 243, 276 and 284 nm respectively using appropriate blank.

In-vitro drug release

In vitro release studies of paracetamol, diclofenac and domperidone lozenges were carried using USP Apparatus II (Paddle type). Lozenge formulations were placed in the dissolution basket containing 900 ml of phosphate buffer (pH 6.8), maintained at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. Samples (5 ml) were collected at predetermined time intervals and replaced with equal volume of fresh medium and analyzed using UV-Visible spectrophotometer at 243, 276 and 284nm. Drug concentration was calculated from a standard calibration plot and expressed as cumulative % drug release [8].

RESULTS AND DISCUSSION

Organoleptic examination of prepared candy lozenges

Prepared lozenges were examined for organoleptic properties such as shape, color, texture and taste. The results of the observation are tabulated below:

Table 6: General Appearance

Parameters	Observation
Shape	Oval
Color	Red
Texture	Smooth
Taste	Sweet

On physical observation, the color and shape of the lozenges were observed to be red and oval respectively. Taste and texture characteristics of hard candy lozenges were performed on healthy human volunteers. The results were found complimentary.

Weight variation

In weight variation, the lozenges are estimated based on their weight. It is performed to determine the content uniformity i.e. uniformity of Lozenges. The results of the weight variation are presented below in the table no. 7.

Table 7: Weight variation of formulation F1-F6

SL.NO	F1	F2	F3	F4	F5	F6
1	4.22	4.73	4.71	4.11	4.82	4.28
2	4.25	4.67	4.83	4.75	4.75	4.61
3	4.11	4.91	4.09	4.25	4.52	4.72
4	4.21	4.82	4.55	4.49	3.91	4.83
5	4.75	4.73	4.71	4.01	4.63	4.67
6	4.31	4.28	4.67	4.29	4.72	4.12
7	4.29	3.71	4.21	4.36	4.125	4.33
8	4.83	4.99	4.91	4.71	3.999	4.51
9	4.61	4.27	4.33	4.31	4.23	4.78
10	4.44	4.13	4.23	4.24	4.143	4.125

For the prepared lozenges, the deviation of individual net weight should not exceed the limits 1.5 to 5 gm. From the results, we can see clearly that lozenges weighed in the range 4.01gm to 4.99gm with not exceeding the standard limits.

This indicates the uniform weight of the prepared lozenges. At the same, this uniformity may also be covered by the usage of a good weighing balance. The weighing balance used for measuring the weight of lozenges is more accurate as it is a more advanced balance.

Hardness

The present work also evaluates for the uniformity in hardness of lozenges to determine the crushing strength of the lozenges. This is because, a lozenge requires a certain some amount of strength or hardness to withstand mechanical shocks of handling in manufacture, packaging and shipping.

Table 8: Hardness of Lozenge formulations F1-F6

SL.NO	F1	F2	F3	F4	F5	F6
1	7.3	8.9	8.04	9.3	8.82	8.51
2	8.1	8.3	8.3	8.19	8.42	8.27
3	8.5	7.1	9.25	9.2	8.78	8.96
4	8.2	9.1	8.66	8.9	8.3	9.17
5	8.6	8.6	8.32	8.3	8.25	9.39
6	7.2	7.3	8.70	8.6	9.17	8.53
7	7.9	8.21	9.12	8.75	9.03	9.58
8	8.3	8.3	8.66	8.25	9.8	8.02
9	8.0	9.3	8.86	8.47	8.35	8.64
10	7.26	8.6	8.35	8.91	8.28	8.27

The hardness of all formulated lozenges was found within the standard range up to 5.5 kg/cm² to 13.5 kg/cm². Among the six formulations of lozenges, the lowest value for hardness was noted for F2 (i.e., 7.1 kg/cm²) and highest i.e., 9.8 kg/cm² for F5. The hardness of the lozenges is due to the presence of methyl cellulose. Methyl cellulose binds all the formulation ingredients together and stands responsible for the hardness of the lozenge formulations. As the concentration of polymer i.e., methylcellulose increased, hardness of the lozenges also increases.

For the hardness of each lozenge, the result obtained proved that one lozenge will have its own

hardness which might be same or different to other lozenges. Commonly, the hardness of the individual lozenge will be slightly different compared to others. The average hardness is 8.6 kg/cm² which means that in an average of 8.6 kg/cm² force is needed to break a lozenge.

Friability

Friability testing of lozenges is to evaluate the ability of lozenges to withstand abrasion, packaging, handling and shipping. The results of the friability studies carried on using Roche friability are presented in the below table.

Table 9: Friability of Lozenge Formulation F1-F6

SL.NO	INITIAL WEIGHT	FINAL WEIGHT	%FRIABILITY
F1	44.02	43.99	0.070
F2	45.24	45.21	0.069
F3	45.42	45.39	0.066
F4	43.52	43.5	0.0459
F5	43.838	43.818	0.0456
F6	44.975	44.955	0.044

The loss due to abrasion in friability is a measurement of lozenge friability. The minimum weight loss of the lozenge on abrasion should not be more than 0.8%. As per the results obtained, the weight loss of lozenges is between or in the range of 0.04- 0.07% which means that the lozenges are

strong and hard enough to withstand from breaking easily packing, handling and also shipping.

Thickness

The thickness of the prepared lozenges is tabulated in the below table;

Table 10: Thickness of Lozenge formulation F1-F6

SL.NO	F1	F2	F3	F4	F5	F6
1	6.12	6.366	6.32	6.25	6.54	6.21
2	6.25	6.216	6.52	6.35	6.25	6.34
3	6.59	6.526	6.17	6.47	6.41	6.55
4	6.66	6.816	6.38	6.31	6.32	6.12
5	6.85	6.156	6.45	6.54	6.66	6.45
6	6.75	6.456	6.55	6.85	6.45	6.27
7	6.95	6.326	6.81	6.48	6.77	6.34
8	6.27	6.666	6.38	6.16	6.85	6.59
9	6.14	6.316	6.44	6.78	6.94	6.48
10	6.33	6.676	6.54	6.54	6.64	6.69

Thickness is an important quality control test for lozenge packaging. Lozenge thickness can vary without any change in its weight. This may depend on the mould and process employed in the preparation of lozenges.

From the results, the thickness of the lozenges was found to be in the range between 5 to 8 mm, ensuring uniformity in their thickness.

Moisture content determination

Moisture content determination is a critical parameter of lozenges quality. It influences lozenges manufacturing and packaging. The standard limits of moisture content should be in the range of 0.5 to 1.5 %.

As per the result obtained that moisture content in the prepared lozenges was found in the range 0.5 to 1.0 % which is within the standard limits.

Table 11: Moisture content of lozenge formulation F1-F6

SL.NO	FORMULATION CODE	% MOISTURE CONTENT
1	F1	0.6
2	F2	0.7
3	F3	0.5
4	F4	0.9
5	F5	1.0
6	F6	0.8

Drug content

Drug content studies were performed on the prepared lozenges for estimating the total amount

of drug i.e., paracetamol, diclofenac and domperidone respectively in the molded lozenges.

Table 12: Drug content of lozenge formulation F1-F6

SL.NO	PARACETAMOL	DICLOFENAC	DOMPERIDONE
F1	99.2	98.4	98.5
F2	99.5	98.7	97.3
F3	99.7	99.1	98.1
F4	97.8	98.5	96.8
F5	97.6	98.2	97.5
F6	97.8	96.3	96.7

Drug content values ranged from 90% to 99 % for the drugs, Paracetamol, Diclofenac and Domperidone. Above results showed that the method for the preparation of lozenges produces reproducible results.

In vitro drug release

In vitro drug release of the hard candy lozenges containing drugs i.e. Paracetamol, Diclofenac, Domperidone was studied by varying the concentrations of methyl cellulose and the data of the same is listed in the following tables;

Table 13: Cumulative drug release for paracetamol F1-F6

		CUMULATIVE DRUG RELEASE					
SL.NO	TIME	F1	F2	F3	F4	F5	F6
1	0.5	14.788	11.390	12.036	11.475	11.840	12.384
2	1	20.42	20.773	19.512	20.451	20.724	21.142
3	2	26.660	31.476	32.188	32.243	32.997	32.372
4	3	38.807	42.396	40.976	43.696	42.546	41.441
5	5	49.712	53.311	53.862	55.601	55.373	53.891
6	7	61.308	67.681	66.983	69.893	68.439	67.257
7	9	73.206	73.814	73.321	75.575	74.458	72.799
8	11	80.30	80.113	79.716	82.215	81.555	78.845
9	13	88.24	85.798	86.279	86.075	83.707	81.421
10	15	93.23	91.085	89.779	87.693	85.872	83.903

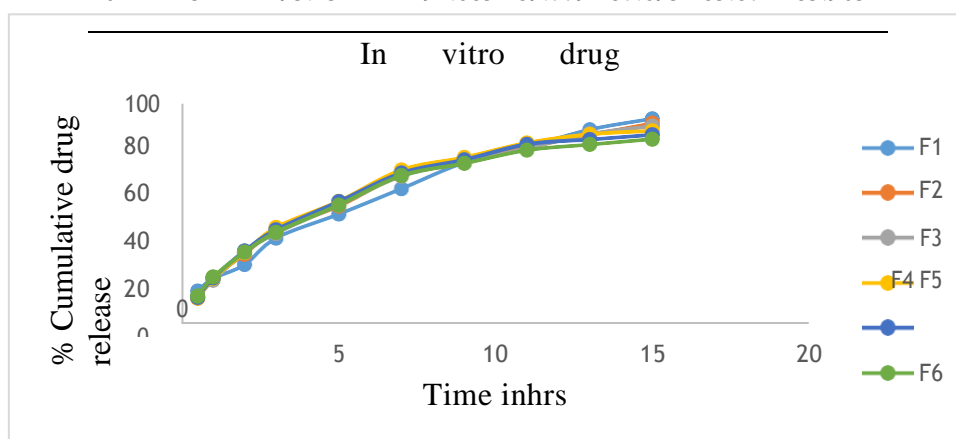
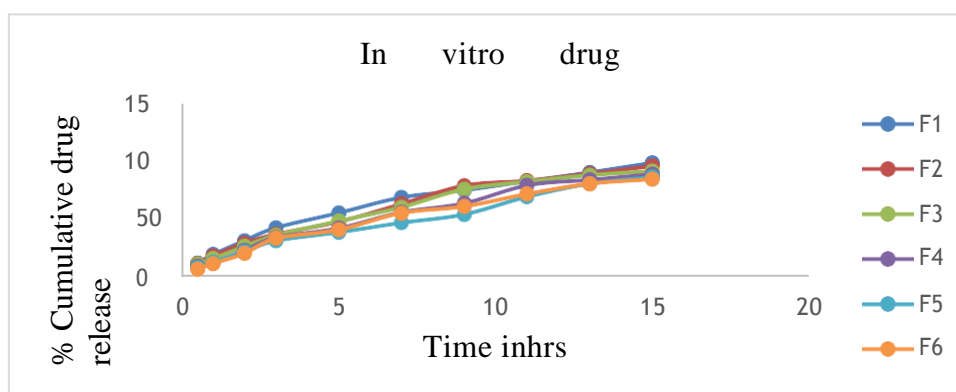


Figure 8: In vitro dissolution studies plot for Paracetamol (F1-F6)

Table 14: Cumulative drug release for Diclofenac F1-F6

SL.NO		TIME %Cumulative drug release					
		F1	F2	F3	F4	F5	F6
1	0.5	11.631	11.370	10.876	8.911	7.807	6.231
2	1	19.199	17.900	15.581	12.046	12.298	11.254
3	2	31.134	28.886	26.163	22.544	21.585	20.020
4	3	42.282	36.714	35.728	33.822	30.964	33.141
5	5	55.120	47.432	48.077	41.826	38.285	40.507
6	7	68.533	62.870	59.985	55.660	46.581	54.981
7	9	74.736	78.794	75.708	63.425	53.824	60.712
8	11	82.575	83.052	82.164	78.932	69.056	71.571
9	13	90.259	89.033	87.780	83.759	80.362	80.457
10	15	98.576	95.741	91.314	88.513	86.230	84.232


Figure 9: In vitro dissolution studies plot for Diclofenac (F1-F6)
Table 15: Cumulative drug release for Domperidone F1-F6

SL.NO		TIME % Cumulative drug release					
		F1	F2	F3	F4	F5	F6
1	0.5	9.201	8.029	7.008	6.457	7.692	5.494
2	1	15.638	14.854	13.449	11.041	10.333	11.043
3	2	26.263	23.995	21.547	19.867	19.090	20.524
4	3	33.503	31.941	30.043	28.458	30.817	35.270
5	5	44.619	41.569	42.762	42.297	43.622	46.284
6	7	54.892	51.291	53.695	50.462	51.423	54.495
7	9	63.360	65.281	66.644	68.388	69.554	69.248
8	11	76.666	75.874	75.895	74.868	74.721	74.771
9	13	89.464	89.135	85.232	83.019	80.253	78.726
10	15	96.672	94.492	92.743	88.339	86.154	82.714

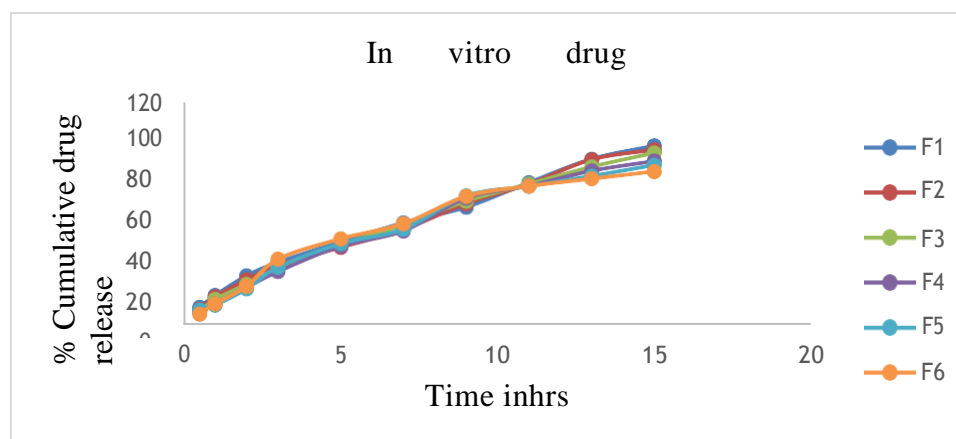


Figure 10: In vitro dissolution studies for Domperidone (F1-F6)

Based on the in vitro dissolution study results Hard candy lozenge formulation F1 containing 0.025gm was selected as the best formulation because, the cumulative drug release of the selected formulation at the end of 15 minutes was found to be 93.2%, 98.5% and 96.67% for all the three drugs i.e. Paracetamol, Diclofenac, Domperidone respectively which is better over the other formulations for all the 3 drugs. In the present study, methyl cellulose acts as thickening agent and binds the preparation together altering its release from the lozenge. Lower its concentration in the formulation better the drug release will be. Thus the F1 formulations showed better release over other formulations due to the low concentrations of methyl cellulose in those formulations. As the concentration of methyl cellulose increased the drug release from the formulations decreased linearly.

CONCLUSION

The current study Formulation and Characterization of Paracetamol, Diclofenac, Domperidone Lozenges was an attempt to formulate the Hard candy lozenges for the drugs like Paracetamol, Diclofenac, Domperidone for Analgesic, Anti-pyretic, Anti-emetic actions. The main interest for designing such a dosage form is to achieve maximum and rapid drug release from the formulations. Lozenges offer a simple and

practical approach to improve patient compliance, bioavailability, avoid first pass metabolism and modifies drug release profile for rapid localized and systemic drug actions. IR results of the drugs proved their identity. The IR data of drugs and its excipients did not show any compatibility. Organoleptic properties of the prepared lozenges were found complimentary. Hardness, Thickness, Weight variation and Moisture content of the prepared lozenges were found within the standard limits when examined. Drug content was found within the pharmacopoeial limits indicating uniform distribution of drug within the lozenges formulations. All the lozenges formulation showed good in vitro drug release indicating maximum therapeutic efficacy. Thus lozenges loaded with Paracetamol, Diclofenac, Domperidone used analgesic, anti-pyretic and anti-emetic actions produces rapid and maximum therapeutic action and are more effective and acceptable than the existing marketed formulations. The study conducted so far reveals a promising result suggesting scope for pharmacodynamics and pharmacodynamic and pharmacokinetic evaluation.

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