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FORMULATION AND EVALUATION OF ORAL MEDICATED JELLIES OF DIMENHYDRINATE

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ABSTRACT
Dimenhydrinate is an antihistamine drug and it is approved for nausea, vomiting, motion sickness, vertigo and in this work the immediate release oral jellies of Dimenhydrinate were formulated as delivery systems for paediatric and geriatric patients who find swallowing of solid dosage forms to be difficult (dysphagia problem). Oral jelly can be chewed effortlessly & dissolves easily in saliva without any need of water for ingestion making it unique from other dosage forms. Further patients get fascinated by its appearance & soft texture resulting in high patient acceptance. In the present research work Dimenhydrinate jelly was formulated to provide faster relief from nausea, vomiting and especially motion sickness compared to other dosage forms. The oral medicated jellies of dimenhydrinate were prepared using gelling agents like Guar gum, Pectin, Agar and Gelatin by heating and congealing method. The drug and excipients compatibility study were performed using FT-IR and no interactions were found between drug and the polymers. Six formulations of dimenhydrinate jellies (F1-F6) were prepared using different concentrations of the gelling agents. The prepared oral jellies were evaluated for various parameters like Physical appearance, Weight variation, pH Determination, Stickiness and grittiness, Viscosity study, Syneresis, Content uniformity, In -Vitro Dissolution Study, Stability Study. All the physical Parameters and evaluation results of all the formulations were determined to be within the acceptable limit. The best formulation of the six formulations with the successful concentrations of the gelling agents was determined to be F5 with 98.5 % drug release in invitro dissolution study and also produced satisfying results in all the evaluation tests. It can be concluded that oral jelly of Dimenhydrinate can be successfully formulated.

KEYWORDS: *Oral medicated Jellies, Gelling agents, Anti-histamine, Heating & Congealing, Dysphagia, motion sickness, Physical appearance, Invitro dissolution test.*

I. INTRODUCTION
An optimal dosing regimen for treating any illness is one that quickly reaches the desired therapeutic drug concentration in the plasma (or at the target site) and maintains this level consistently throughout the treatment period. Oral administration is the most commonly used method for drug delivery. It is regarded as the most natural, straightforward, and convenient way to administer medications, offering greater flexibility in dosage form design, ease of production, low cost, the convenience of self-administration, compactness, and simple manufacturing.[19] As the oral drug delivery system is non-invasive and offers low cost of treatment, patients usually prefer this delivery system.[6] Pharmaceutical technologists have created a modern oral dosage form called Oral Medicated Jellies (OMJs). These jellies dissolve quickly in saliva, typically within seconds, without requiring water. This rapid dissolution and absorption can lead to faster onset of clinical effects and potentially higher drug bioavailability compared to traditional dosage forms.[19] Jellies are popular among children who enjoy chewing them. They offer a good alternative for drug delivery compared to solid and liquid forms.[6] These jellies are especially appreciated by populations who struggle with swallowing pills. Difficulty swallowing, or dysphagia, affects a wide range of age groups, with prevalence particularly high among children, the elderly, and patients in long-term care, psychiatric facilities, or those experiencing nausea, vomiting, or motion sickness.[11]

Dimenhydrinate is a salt of Diphenhydramine and Chlorotheophyllinate which shows the Antiemetic and Antivertigo action. Dimenhydrinate produces Antiemetic action by its central action on Chemoreceptor Trigger Zone (CTZ). It decreases the sensitivity of Labyrinth apparatus which transmit stimuli to the CTZ and stimulates the vomiting center. Dimenhydrinate is a potent H1 receptor antihistaminic agent. It has anticholinergic and central sedative action also. it is used in migraine due to its sedative as well as antiemetic actions.[14]

A. Oral drug delivery

The most common route for drug administration is oral intake. (Via oral mouth cavity).[13]

- Optimal dosage regimen: Rapidly achieves and maintains therapeutic drug concentration in the bloodstream or target site.
- Oral administration: Most natural, convenient, and cost-effective.
- Self-administration possible with flexibility in dosage forms.

The drawbacks of oral administration are swallowing difficulty (dysphagia) impacts compliance, especially in paediatrics, elderly, bedridden, or individuals without access to water.[11]

B. *Jellies*

According to the 17th edition of the Japanese Pharmacopoeia, jellies are thick, non-flowing preparations with a defined size and shape for oral use. They can be described as clear or slightly cloudy, non-greasy, semi-solid forms for both external and internal applications. Medicated jellies release the drug in the mouth, allowing absorption through the oral tissues and along the gastrointestinal tract. Nowadays, jellies are popular among children who enjoy chewing them. They offer a good alternative for drug delivery compared to solid and liquid forms.[6]

C. Features of oral medicated jellies (Omjs)

- Rapid disintegration in the mouth without water.
- Faster drug absorption and onset of action with improved bioavailability.
- Pleasant taste enhances patient compliance.
- **Target Groups:** Beneficial for patients with dysphagia (e.g., children, elderly, long-term care patients). 35% of the general population experiences dysphagia; rates are higher among the elderly (60%).[13][4]

II. MATERIALS AND METHODOLOGY

A. Materials and Manufacturers

Dimenhydrinate – Triveni chem, PVT. LTD. Gujarat, Citric acid - S d fine- CHEM limited, Sodium Citrate - LOBA Chemie PVT. LTD.Mumbai, Agar- LOBA Chemie PVT. LTD.Mumbai, Guar Gum - LOBA Chemie PVT. LTD.Mumbai, Pectin - LOBA Chemie PVT. LTD.Mumbai, Methyl Paraben - LOBA Chemie PVT. LTD.Mumbai, Propyl Paraben - LOBA Chemie PVT. LTD.Mumbai, colouring agent -The central drug house PVT. LTD, Delhi, Flavouring Agent - Scientific chemicals PVT.LTD, Chennai. All the chemicals were of analytical grade.

B. METHODOLOGY

1. *Pre-formulation studies*

a. Solubility test

The solubility of dimenhydrinate API was determined in various solvents like ethanol, DMSO, water, and phosphate buffer. This test is important to find the right solvent to dissolve the drug for the formulation. This test is also required to choose the right dissolution medium for the dissolution test.

b. Melting point test

The melting point determination for the API dimenhydrinate was carried out.

2. FT-IR analysis

The drug polymer compatibility study was carried out by FT-IR analysis. The IR spectrum peaks of pure dimenhydrinate and the polymer mixtures were compared and observed for the similar peaks to ensure there is no unnecessary interactions or incompatibility among the drug and polymers in the formulation.[2]

3. Spectrophotometric analysis

a. *Determination of Dimenhydrinate λ_{max} in Phosphate buffer pH 6.8*

Absorbances of standard solution of Dimenhydrinate solution was scanned between 200nm-400nm using 1cm quartz cell. and showed maximum absorption at 278 nm by UV in phosphate buffer.[3]

b. *Determination of Dimenhydrinate standard curve in phosphate buffer pH 6.8*

27.77 mg of dimenhydrinate was accurately weighed and taken in 10 ml clean and dry volumetric flask. Drug was dissolved and diluted upto the mark using phosphate buffer of pH 6.8. From that solution 1 ml pipetted out and taken in a 100 ml volumetric flask and made up to 100 ml volume with the same buffer. This was considered as the standard stock solution (27.77 µg/ml). 5 ml of the stock solution was pipetted out and made upto 10ml to get a concentration (13.88 µg/ml) and was treated with working standard.

From this stock solution appropriate dilution were made to get final concentration of 6.94, 13.88, 20.82, 27.76, 34.70 µg/ml and absorbance was taken at λmax 278nm. The calibration curve was plotted taking an absorbance on a Y- axis against concentration of standard solution X-axis.[3][9]

4. Preparation of oral medicated jellies

The jellies are prepared by heating and congealing method using the following procedure :

1. Weighed all ingredients accurately.

2. Dispersed agar, gelatin, guar gum powder, and pectin in 50 ml of distilled water at 95°C.
3. Stirred the mixture for 20 minutes at 95°C using a magnetic stirrer.
4. Added propylene glycol to the gelling agent solution and maintained the temperature at 80-85°C with continuous stirring.
5. Dimenhydrinate was dissolved in ethanol separately and added to the solution.
6. Added sucrose solution, citric acid, and preservatives with stirring.
7. Dissolved sodium citrate in 5 ml of distilled water and added to the mixture.
8. Added flavouring and colouring agents.
9. Poured the mixture into polyethylene moulds of desired shape with an airtight seal.
10. Allowed the mixture to cool to room temperature to form jelly.

The formulation was prepared with different concentrations of guar gum, gelatin, and pectin to find the best formulation.[6][8][11][12][5]

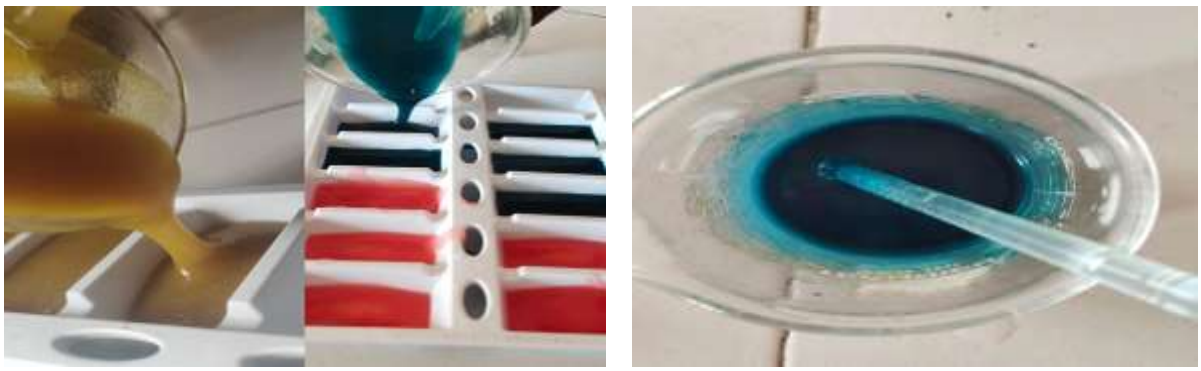

Figure 1: Formulation of jellies.

Table 1: Formulation table.[13][4][1]

S. no	Ingredients	F1	F2	F3	F4	F5	F6
1.	Dimenhydrinate	25mg	25mg	25mg	25mg	25mg	25mg
2.	Agar	0.5g	0.5g	0.5g	0.5g	0.5g	0.5g
3.	Guar gum	1g	1.5 g	1g	-	0.75g	1g
4.	Gelatin	-	-	-	0.75g	-	0.5g
5.	Pectin	0.5g	-	0.5g	0.75g	0.75g	-
6.	Sucrose	0.6g	0.6g	0.6g	0.6g	0.6g	0.6g
7.	Citric acid	0.2g	0.2g	0.2g	0.2g	0.2g	0.2g
8.	Sodium citrate	0.5g	0.5g	0.5g	0.5g	0.5g	0.5g
9.	Propylene glycol	1ml	1ml	1ml	1ml	1ml	1ml
10.	Methyl paraben	0.1g	0.1g	0.1g	0.1g	0.1g	0.1g
11.	Propyl paraben	0.1g	0.1g	0.1g	0.1g	0.1g	0.1g
12.	Colouring agent	QS	QS	QS	QS	QS	QS
13.	Flavouring agent	2 drops	2 drops	2 drops	2 drops	2 drops	2 drops
14.	Distilled water	QS	QS	QS	QS	QS	QS

5. Evaluation of dimenhydrinate oral medicated jellies

Following studies were carried out for evaluation of oral jelly of dimenhydrinate.

a. ***Physical appearance:*** The medicated jellies were examined for physical appearance in terms of colour, texture, clarity, and consistency. These tests were important regarding patient's compliance and acceptance.[17]

b. ***Weight variation:*** The medicated jellies from each formulation were taken and weight of the individual jellies was determined by using digital Weighing Balance of Analytical Grade and the weight variation of the jellies and standard deviation was determined.[8]

c. ***pH:*** pH of the final jelly has an influence on not only stability but also on the taste. The pH of the jelly was measured using Digital pH meter at room temperature. For this, 0.5 gm of jelly was dispersed in 50 ml of distilled water to make 1% solution, and the pH was noted.[7]

d. ***Stickiness and Grittiness:*** Texture of medicated jelly in terms of stickiness and grittiness had been evaluated by visual inspections of the product after mildly rubbing the jelly sample between two fingers.[1]

e. ***Viscosity study:*** Viscosity of jelly was carried out using (LV) Brookfield viscometer. As the system is non-Newtonian spindle no. 63 was used. Viscosity

was measured for fixed time 2 min at 50 rpm at room temperature (25 °C ± 5 °C).[16]

f. ***Content uniformity:*** The content uniformity test is to ensure that every dosage form contains an equal amount of drug substances, i.e., active pharmaceutical ingredients within the batch. One medicated jelly from each formulation was taken and dissolved in 900 ml of phosphate buffer pH 6.8 to give a 100 µg/ml solution. From the above solution of six formulations, 5 ml was taken and made up to 10 ml with pH 6.8 phosphate buffer to give 13.8 µg/ml solution respectively. The absorbance of each solution will measure at 278 nm using UV-Spectrophotometer.[6]

g. ***In-vitro dissolution study:*** An in-vitro dissolution study was performed with USP paddle-type II apparatus using pH 6.8 phosphate buffer as dissolution medium (900ml) was kept at (37 °C ± 0.5 °C) and 100 rpm. The sample 5 ml withdrawn and diluted up to 10 ml in a volumetric flask with the same and 5 ml sample withdrawn after 5, 10, 15, 20, 25 min, and sink condition is maintained by replacing with 6.8 phosphate buffer solution. The samples were determined for the drug content using UV- spectrophotometer at λ_{max} 278 nm. And absorbance was taken, and then % drug release was calculated.[16]

h. ***Stability study:*** Stability studies of prepared jelly at room temperature (25 °C ± 5 °C, - 35 °C) the stability studies are carried out for 60 days and the formulations were analysed for the changes in the physical parameters like appearance and pH.[7]

i. ***Syneresis:*** Syneresis is a contraction of the gel upon storage and separation of water from the gel. It is more pronounced in the gels, where lower concentrations of gelling agents are employed. All jellies were observed for sign of Syneresis at room temperature (25 °C ± 5 °C) and 8 °C.[15]

III. RESULTS

The present study was undertaken to formulate ORAL MEDICATED JELLIES OF DIMENHYDRINATE by using various excipients. The pre-formulation studies for the drug- dimenhydrinate were done. Totally six formulations (F1 to F6) were prepared. The prepared jelly formulations were evaluated for their pharmaceutical parameters. The pre formulation results and evaluation results are as following:

1. Pre-formulation results

a. ***Solubility tests:*** Dimenhydrinate was found to be freely soluble in ethanol, DMSO, sparingly soluble in water and soluble in phosphate buffer of 6.8 pH. So the solvent chosen to dissolve the drug in the formulation was ethanol.

b. ***Melting point:*** The melting point of the dimenhydrinate drug was found to be 104°C which is as per the IP range.

2. Calibration curve

Calibration curve of the pure drug dimenhydrinate was prepared in the concentration range of 6.944 to 34.70 µg/ml and absorbance was determined at the wavelength of 278 nm. It followed Beer's and Lambert's law in the above concentration range. The calibration curve showed good linearity and the regression coefficient was 0.998 (R^2 value) which is shown in figure no. 3.

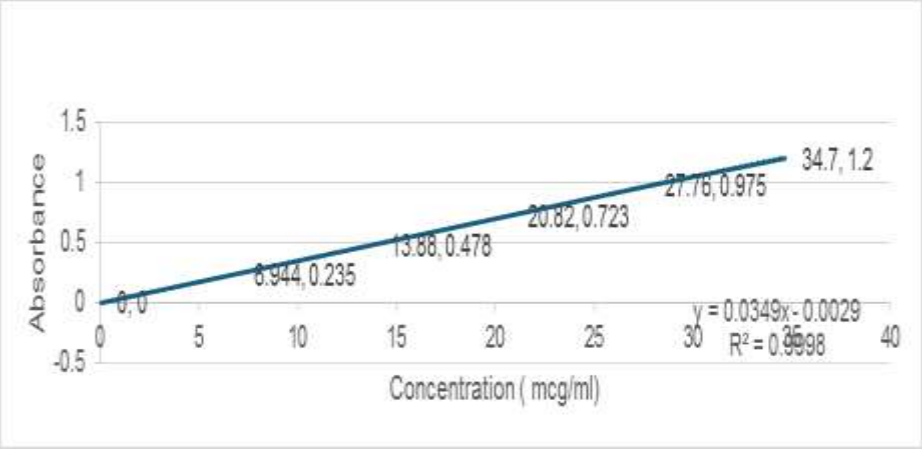

Figure 2: Standard calibration curve of dimenhydrinate.

3. FT-IR Analysis results

Pure drug was mixed with all the individual excipients separately and determined FT-IR spectrum. The FT-IR spectrum of the entire formulation mixture was also determined to find the compatibility of the drug and all the excipients in the formulation.

For the pure drug, the characteristic peaks were present for aromatic C-H stretching at 3022.47 cm^{-1}, aromatic C=C stretching at 1454.01 cm^{-1}, C=O stretching at 1684.24 cm^{-1}, R1,R2,R3,N stretching at 1241.48 cm^{-1} , =N-H stretching at 3420.42, amine salts at 1454.01 cm^{-1}, N=C at 1684.24 cm^{-1}, C-Cl at 749 cm^{-1}, C-O-C stretching at 1222.5 cm^{-1}.

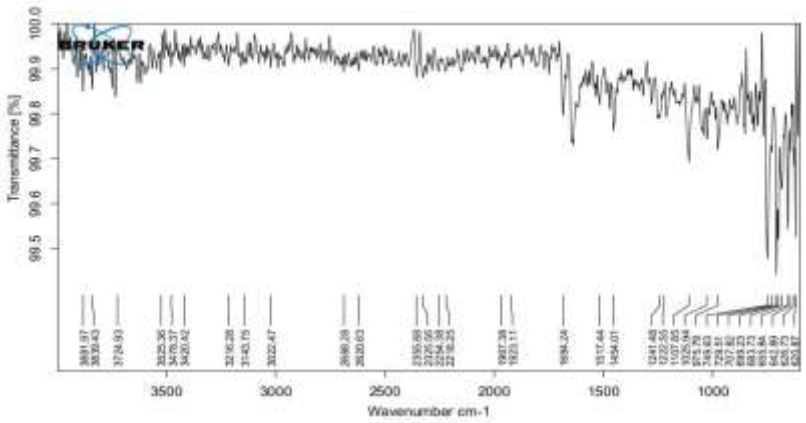

Figure 3: FT-IR spectrum of pure dimenhydrinate.

Similar peaks within the same ranges were observed in the spectrum of drug mixed with all gelling agents used separately and also the entire formulation mixture with all the excipients. This indicated that there was no interaction between the drug and excipients and determined the compatibility.

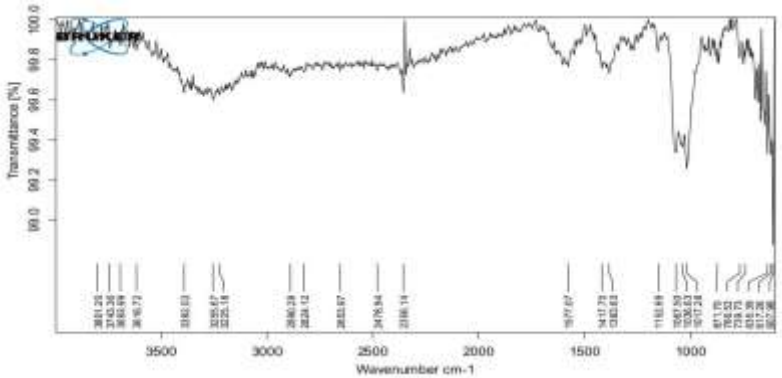

Figure 4: FT-IR spectrum of formulation mixture containing Dimenhydrinate and all excipients.

Table no. 2: FT-IR analysis of drug and formulation.

S. no.	Functional groups Vibration	Pure Drug Peaks (wavenumber cm^{-1})	Formulation mixture peaks (with all the gelling agents) (wavenumber cm^{-1})
1.	C=C	1454.01	1417.70
2.	C=O	1684.24	1577.07
3.	C-Cl	683	635
4.	R1,R2,R3,N	1241.48	1383.63
5.	R-O-R	1107.85	1152.69
6.	N=C	1684.24	1577.07

4. Evaluation of oral dimenhydrinate jelly

a. Physical appearance

All the formulated batches are evaluated for physical appearance. The results involving colour, appearance and texture of the jellies are given the table no. 3

Table no. 3: physical appearance observations.

Batch no	Appearance	Colour	Texture
F1	Opaque	Green colour	Smooth
F2	Opaque	Green colour	Smooth
F3	Opaque	Reddish pink colour	Smooth
F4	Opaque	Yellow colour	Smooth
F5	Opaque	Pink colour	Smooth
F6	Opaque	Blue colour	Smooth

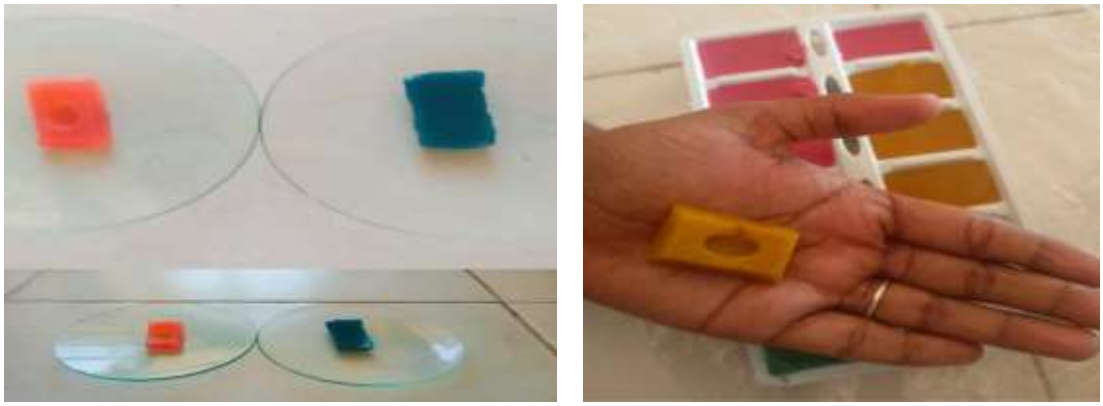

Figure 5: Prepared jellies.

b. Weight variation

Four jellies of each formulation were selected for weight variation test. The result showed that weight variation was ranging from 3.812 ± 0.06 to 4.169 ± 0.09. It was within the IP limit and all the jellies passed the weight variation test which is shown in the table no: 4.

Table no. 4: Weight variation test.

Formulation					
Code	**Jelly 1**	**Jelly 2**	**Jelly 3**	**Jelly 4**	**MEAN ± SD**
F1	3.980	4.154	3.905	3.892	3.982 ± 0.104
F2	4.185	4.020	4.231	4.241	4.169 ± 0.09
F3	3.990	3.801	3.885	4.026	3.925 ± 0.09
F4	3.815	3.739	3.798	3.899	3.812 ± 0.06
F5	3.870	3.741	3.821	3.905	3.834 ±0.06
F6	3.895	3.956	4.079	3.957	3..970 ±0.07

c. Determination of ph

The pH for F1 – F6 formulated jellies were measured by using digital pH Meter and the results are shown in the table no: 5. The pH value of the formulations range in between 6.8 to 7.25, So it shows that all the formulations have optimum pH range.

Table no. 5: mean pH of jellies of every formulation.

Formulation code	pH
F1	7.18 ± 0.2
F2	7.25 ± 0.1
F3	6.88 ± 0.3
F4	6.92 ± 0.3
F5	7.25 ± 0.2
F6	7.18 ± 0.2

d. Stickiness and grittiness

Except F3 no jelly had shown stickiness or grittiness under the physical evaluation. Results are shown in table no. 6.

Table no. 6: Stickiness and grittiness of jellies.

Batch no	Stickiness	Grittiness
F1	Non sticky	Non gritty
F2	Non sticky	Non gritty
F3	Less sticky	Non gritty
F4	Non sticky	Non gritty
F5	Non sticky	Non gritty
F6	Non sticky	Non gritty

e. Viscosity study

The viscosity of six formulation was found with the help of Brookfield Viscometer (LV), using spindle no: 63. The viscosity range was found to be 9870 cps to 12784 cps. It indicates all the formulation have good viscosity; the values are shown in the table no: 7.

Table no. 7: Viscosity study of oral medicated Dimenhydrinate Jelly.

S. No	Formulation code	Viscosity (cps)
1	F1	10030
2	F2	12784
3	F3	9875
4	F4	9894
5	F5	9870
6	F6	10024

f. Content uniformity

The drug content of the six formulations were found using UV Spectrometer at 278 nm. The values of the formulations were ranging from 85.3 % to 98.6 %, the results are shown in the table no: 8.

Table no. 8: Drug content assay in the formulated jellies.

Formulation code	Absorbance	Percentage
F1	0.413	87.8 ± 1 %
F2	0.401	85.3 ± 2 %
F3	0.437	92.9 ± 2 %
F4	0.425	90.2 ± 1 %
F5	0.441	93.8 ± 1 %
F6	0.421	89.5 ± 1%

g. In -vitro dissolution study

The dissolution study was carried out for all formulations using dissolution test apparatus, the batch F5 shows 98.60% of drug release in 30 minutes which is considered as the best, the results are shown in table no: 9. All the formulation shown maximum drug release in 30 minutes.

Table no. 9: Percentage drug release calculated in-vitro dissolution test.

	% Drug release					
Time (MIN)	F1	F2	F3	F4	F5	F6
5	36.01	20.16	48.96	51.84	51.86	55.44
10	43.20	31.68	64.08	59.04	64.10	64.08
15	49.68	46.80	72.72	64.96	72.71	72.01
20	72.01	51.86	81.36	82.24	84.96	77.76
25	77.76	59.76	82.80	88.01	88.99	80.64
30	84.24	73.44	95.11	91.44	98.61	88.99

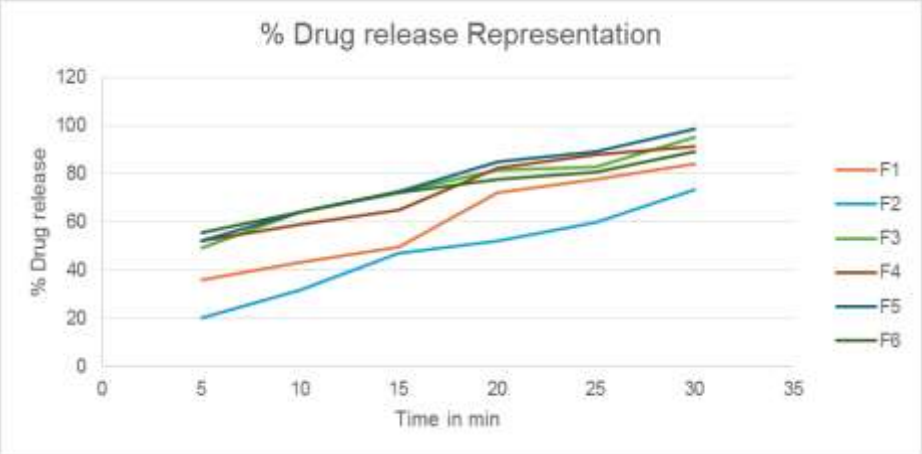

Figure 6: Graphical representation of percentage drug release in all formulations.

Figure 7: In-vitro dissolution test.

h. Stability study

The results of 60 days short-term stability studies are given in table no: 10 which indicates insignificant changes in pH and appearance in the prepared formulations with that time. Syneresis was not observed in both temperature (2-8□C and 25□C).

Therefore, the jellies can be stored at 2-8□C and 25□C.

Table no. 10: Stability study.

S. no.	Storage condition	Weeks	General appearance	Syneresis	pH
		Initial	Non -sticky,	Not observed	7.18
			Non gritty		
1	2-8□C	4	No change	Not observed	7.02
		8	No change	Not observed	6.80
		Initial	Non-sticky, Non gritty	Not observed	7.25
2	25±5□C	4	No change	Not observed	6.81
		8	No change	Not observed	6.45

IV. SUMMARY AND CONCLUSION

The colourful, attractive and pleasant odour oral medicated jellies containing Dimenhydrinate drug to treat motion sickness, nausea and vomiting were formulated and evaluated. The jellies were formulated by heating and congealing technique. The poorly water soluble dimenhydrinate drug was dissolved in suitable solvent, ethanol and then mixed with the gelling agents solution while the formulation process which enhances the bioavailability of the drug. Guar gum, Gelatin, Agar and Pectin were served as the successful gelling agents in the successful formulation of oral medicated jellies. These jellies are administered orally to the pediatrics, geriatrics, adults and psychiatric patients who have difficulty in swallowing and mastication easily and conveniently as the jellies quickly disintegrate and dissolve in the saliva. These can be taken even without water. This increases the patient compliance and acceptance. Dimenhydrinate shown its solubility in phosphate buffer and ethanol in the pre- formulation solubility experiments. Dimenhydrinate's λmax was found to be 278nm and FTIR research revealed the presence of functional groups like carbonyl group, alkene, hydroxyl group, hydrocarbon and halogen group in the provided sample of the drug raw material. Except formulation F3 every formulation lacks stickiness and no presence of gritty particles in any formulation. The pH of the formulated jellies was found to be ranging from 6.88 to 7.25. The Dimenhydrinate jellies viscosities ranged from 9870 to 10030 cps. In all the prepared jelly formulations, the weight variation was observed to be ranging from 3.812 to 4.169 gm. The syneresis was not observed in any formulation in the specific temperature. The drug contents each formulation were determined to be ranging from 85.3% to 98.6 %, demonstrates a large amount of drug release due to low concentration of gelling agents and low viscosity, the formulation F5 to have higher drug content than the other formulations. The rate of dimenhydrinate drug dissolution from F5 was found to be greater consistent with the bio-pharmaceuticals categorization system (BCS) concept for the instant release formulations (98.6 % in 30 minutes), according to the in vitro dissolution investigation. All the evaluation tests of F5 jellies were found more acceptable and satisfactory compared to the other formulations. The improved drug release and physiochemical characteristics of formulation F5 were satisfactory. The prepared formulations were placed in plastic container covered with aluminium foil and stored at 25 ±2ºC and in 2-8ºC for 8 weeks (60 days) and has shown no significant changes during the time period. The prepared oral medicated jellies of dimenhydrinate have passed the short- term stability study. The best formulation with the

best concentrations of gelling agents was found to be F5. (agar-0.5g, gelatin-0.75g, guar gum-0.5g)

Hence the formulation and evaluation of oral medicated jellies of Dimenhydrinate drug to treat motion sickness, nausea and vomiting was done successfully.

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