A REVIEW ARTICLE ON FORMULATION AND EVALUATION OF EDIBLE JELLY OF ENALAPRIL

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ABSTRACT

The present investigation's goals were to develop and evaluate medicated oral jelly containing enalapril for the treatment of hypertension. Since many patients have a dread of taking medicine, this preparation is particularly helpful for those who suffer from that kind of phobia. Enalapril antihypertensive medications are mixed with jelly and given to patients in order to help them take medication Jellies are prepared by heating and congealing methods by dispersing gelling agents in water and evaluated for their physicochemical parameters such appearance, stickiness, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity.

Keywords: ***Enalapril, Edible, Jelly, Hypertensive***

1.0 INTRODUCTION

JELLY

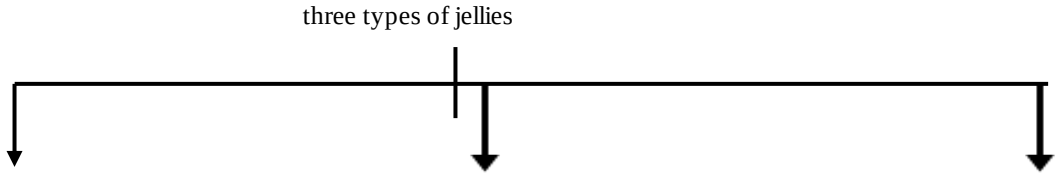
Jelly is a common term for semisolid medicines that are transparent or translucent in appearance, do not contain any oil, and can be applied topically as well as consumed internally.They are made to deliver the active substance for either systemic or local effects.[1]

Despite the significant advancements in medication delivery, the oral route continues to be the most favoured method for administering active components. The main drawback of solid dose forms is swallowing problems, particularly for children, the elderly, and other populations who experience nausea and vomiting. As a result of this, a number of different types of solid medication, including orodispersible, buccal, sublingual, and, more recently, oroslippery tablets, have been developed to assist people who have trouble swallowing. Unfortunately, these formulations have some drawbacks, such as restrictions on drugs or doses, issues with flavour masking, and other formulation issues like friability and hygroscopicity. Conversely, oral liquids such syrups and suspensions were thought to be a good substitute in these circumstances. Problems with stability, dispersibility, flavour masking, dose waste, and dumping plagued the liquid medicines' formulation .[1]

In response, oral jellies were created as a unique, quickly disintegrating oral dose form that could be easily ingested without the need for water. Additionally, it improves drug bioavailability, clinical effect onset, and solubility and absorption. Additionally, the choice of the patient who enjoys the flavour and chewability of the flavoured jellies.[2]

1.1.Types of jellies:

There are three types of jellies



Medicate jellies **Lubricating Jellies** **Miscellaneous jellies:**

Medicated jellies :Due to their spermicidal, local anaesthetic, and antiseptic qualities, they are primarily employed on skin and mucous membranes. These jellies have an adequate amount of water. Jellies have a local cooling effect once water has evaporated, and any remaining layer offers protection. As an illustration, vasoconstrictors include ephedrine sulphate jelly (to arrest the bleeding of nose). As a spermicidal contraceptive, phenyl mercuric nitrate jelly is utilised.[2]

Lubricating jellies: These jellies are used to lubricate diagnostic tools such gloves, catheters, fingerstalls, cystoscopes, and rectal thermometers. These jellies must be translucent, water-soluble, and thin. Because they are employed as lubricants for objects to be placed into sterile bodily parts like the urine bladder, etc., these jellies should be sterile.[2]

Miscellaneous jellies:

i)Patch testing: On evaluate sensitivity, allergens are applied to these jellies and then removed. The leftover coating that forms after drying helps to keep the patches apart and prevents unclear outcomes.[2]

ii) Electrocardiography: To lower the electrical resistance between the patient's skin and the electrode, jelly is placed on the electrode. Pumice powder, glycerin, and sodium chloride are all ingredients in the jelly. Glycerine serves as a humectant when sodium chloride serves as an excellent electrical conductor.[2]

1.2. ADVANTAGEOF JELLY

It's easy to give wherever you are because it doesn't need water and can be handled with minimal effort.

Issues with pharmaceutical release and retention times can be mitigated by oral mucosal delivery of a medicinal agent.

Pharmaceutical jellies are helpful for patients who have difficulty swallowing, or who are resistant to doing so, including the elderly, stroke victims, bedridden patients, and patients with esophageal issues. As a result, patients are more likely to stick to their treatment plans.

Saliva aids in the rapid absorption and increases the bioavailability of drugs by pre-gastric absorption in the mouth, throat, and oesophagus.

For those who don't always have access to water, such as the disabled, bedridden patients, travellers, and busy people, jelly is the most practical option.[4]

1.3.JELLY DISADVANTAGE

An issue with stability and deterioration exists.

Challenges in Dose Calculation.

Oral medicinal jellies should have the following qualities.

After oral administration, it should leave little to no tongue residue that is compatible with a pleasant mouth feel.

Work well with flavour masking.

Technologies that effectively masked tastes should be used for medications with a bitter taste.

Travel well without posing a fragility risk.

Avoid leaving the mouth feeling sticky after usage.

Adaptations to shifting environmental conditions could stand to be enhanced.

Permit heavy drug loading.

Convenient for traditional processing and adaptable and packaging tools for a little fee.

The excipients' properties shouldn't be impacted by the drug's the tablet that dissolves in the mouth.[5]

2. General Prepreation of edible jelly

Medicated edible jelly is prepared by heating and congealing method

The jellies were made using several polymers in varying amounts.

The sugar syrup is going to be made.

The gelling ingredient is heated and stirred continuously into the sugar syrup.

Stabilizers and solubilizers are added as the gelling agent completely dissolves, and the mixture is then heated for a short time while being thoroughly mixed.

Preservatives are added to the mixture after it has entirely dissolved while being continuously stirred.[6]

2.1Preparation of edible jelly

The drug is first dissolved in water, then brought to a boil, and finally allowed to cool and harden. Heating the medicine results in the production of jelly that contains enalapril.

After the individual components have been accurately measured out, the gelling agent is dissolved in a certain volume of distilled water at a temperature of 95 degrees Celsius while the mixture is stirred for a period of thirty minutes. After that, the polymer dispersion was heated to a temperature between 80 and 85 degrees Celsius while the sugar syrup was added gradually while being stirred. It is necessary for the active substance to be dissolved in a solvent, and some examples of such solvents include ethanol, glycerin, and propylene glycol. Additionally, propylene glycol was utilised in the preparation step that was carried out here. After the polymer and combination have attained temperatures between 50 and 65 degrees Celsius and have become stable, the medicine solution is gradually added while the mixture is continually stirred. After that, propylene glycol and methyl paraben are added to the mixture while it is constantly stirred for a few minutes in order to regulate the pH in order to form a soft jelly and to destroy any germs that could be present. After stirring the previously indicated mixture for a few minutes, a flavouring and colouring component (sunset yellow) should be added to the mixture. After that, I transferred the medicated jelly to a polyethylene mould that was airtight and allowed it to cool at room temperature .[7]

Fig 1: Formulation of jelly

2.2 Preformulation

Preformulation investigations are described as the examination of the drug's physicochemical characteristics. Once the new molecule is planted, the phase in question begins. It is consistent with research on the physical, chemical, analytical, and medicinal properties of molecules and offers suggestions for how to modify molecules to improve their performance. The preformulation

study's goal is to create and build a stable, efficient, and safe dosage form by determining the novel medication substance's physicochemical properties, compatibility with other constituents, and kinetic rate profile.[8]

Investigate the drugs physical, chemical and medicinal property & helps to formulate safe and effective formulation.

Provides suggestion regarding the modification in the molecule to improve its modification.

Gives significant data regarding the compatibility of drug and excipients.

Study of some physicochemical parameters: There are several parameters that are to be studied before development of any formulation.[9]

3. PREPARATION AND FORMULATION

Table1 : Formulation table

Formulation code.	Drug	Guar gum	Sodium alginate	Xanthan Gum	Propyl glycol	Methyl Paraben	Sweetning Agent (Saccharin)	Coloring agent	Flavouringa gednt	Water
F1	40	143	-	-	10	143	10	2	2	150
F2	40 mg	-	143	-	10	143	10	2	2	150
F3	40 mg	-	-	143	10	143	10	2	2	150
F4	40 mg	71.5	71.5		10	143	10	2	2	150
F5	40 mg	-	71.5	71.5	10	143	10	2	2	150
F6	40 mg	71.5	-	71.5	10	143	10	2	2	150

3.1.**PRE-FORMULATION STUDIES**

The enalapril that was obtained was a powder that was either completely white or nearly colourless, and it had a flavour that was extremely bitter. The melting values that were measured were 143 and 144.5 degrees Celsius. It was determined that there was a loss of 0.6% 0.02% due to the drying process. It dissolves well in water, as well as in ethanol and methanol, both of which are common solvents. In addition to the in vitro release testing, solubility investigations were carried out in both a buffer solution with a pH of 6.8 and one with a pH of 7.4 in order to establish which dissolving medium maintained sink conditions the most effectively. The medication is soluble in both of these buffers to a high degree.Organoleptic properties: [10]

Parameters	Interference
Colour	White
Odor	Slight Odor
State/Form	Smooth

Melting Point	143 and 144.5 ˚C

DISCUSSION: From table no 7 it is found that the drug sample was white in colour, with slight odor. This data matches with the standard.

3.2.MELTING POINT (˚C)

The temperature at which a solid transforms into a liquid under atmospheric pressure is known as the melting point or liquefaction point of the material.[11]

Enalapril's reported melting point (M.P.) is between 143 and 144.5 °C (289.4 and 292.1 °F).

Table 2: melting point

S.NO	OBSERVED M.P	AVERAGE M.P.	STANDARD M.P.
1	143°C	-	-
2	144°C	143.16	**143 to 144.5**
	142.5°C	-	

DISCUSSION: From table 8 it is found that the melting point of the sample drug is very close to the standard.

3.3. SOLUBILITY:

Table 3: Solubilitty

S.NO	**SOLVENTS**	**SOLUBILITY**	**OBSERVATION**
1.	WATER	25 mg/ml	Very Soluble
2.	ETHANOL	8 mg/ml	Sparingly Soluble
3.	PHOPHSTE BUFFER	10.0mg/ml	Soluble

DISCUSSION: From table: it is very clearly seen that the drug sample is highly soluble in water and sparingly soluble in alcohol.

3.4.Weight variation test

Jellies were tested for weight variation. Results have been tabulated below in table .

Table 4 : Results for Weight variation test

S.no.	Formulation code	Observed value (±S.D.)
1	F1	53.45 ±0.02
2	F2	53.45 ±0.02
3	F3	50.56 ±0.30
4	F4	54.86 ±0.20
5	F5	55.22 ±0.05
6	F6	54.32 ±0.06

DISCUSSION: The variation in weight ranges between 53.45 ±0.02to 55.22 ±0.05

3.5..Infrared studies

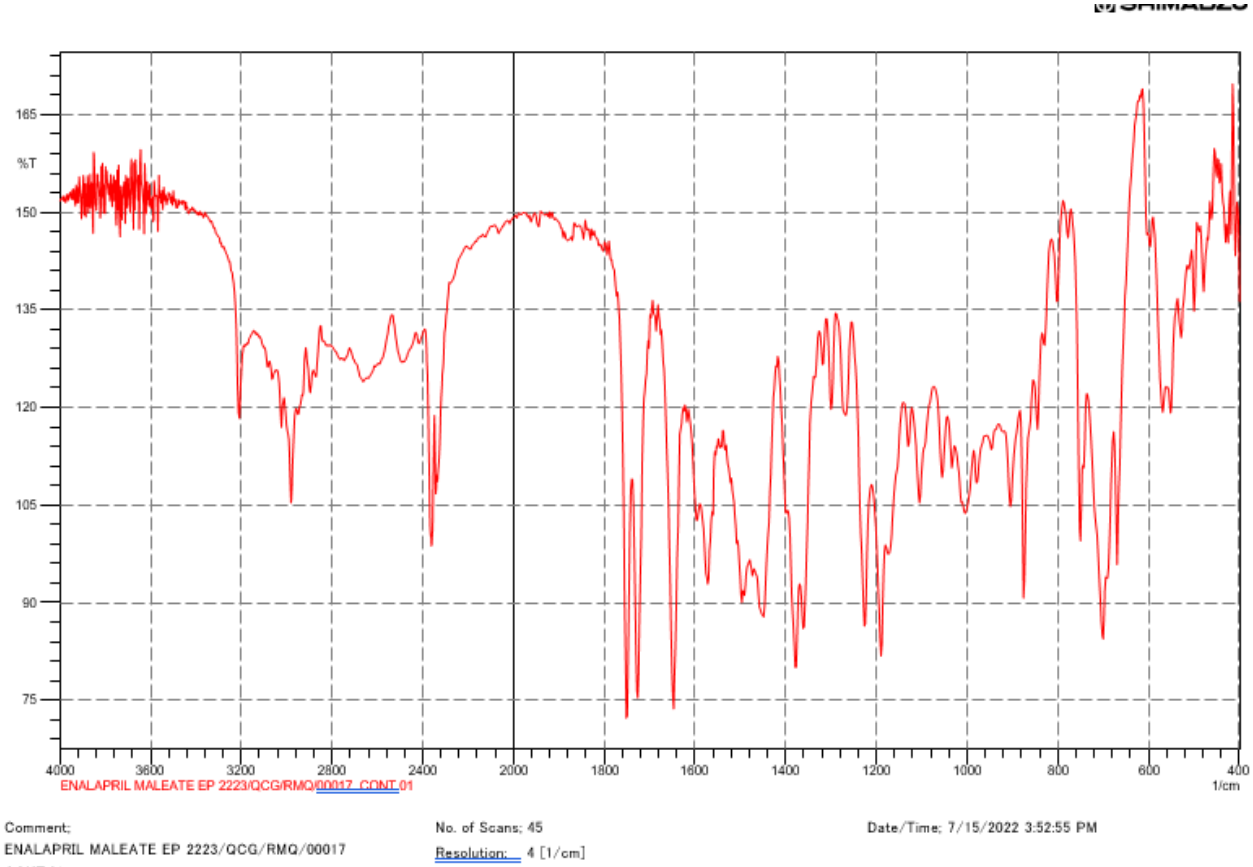


Fig 4: Observed FTIR of Enalapril

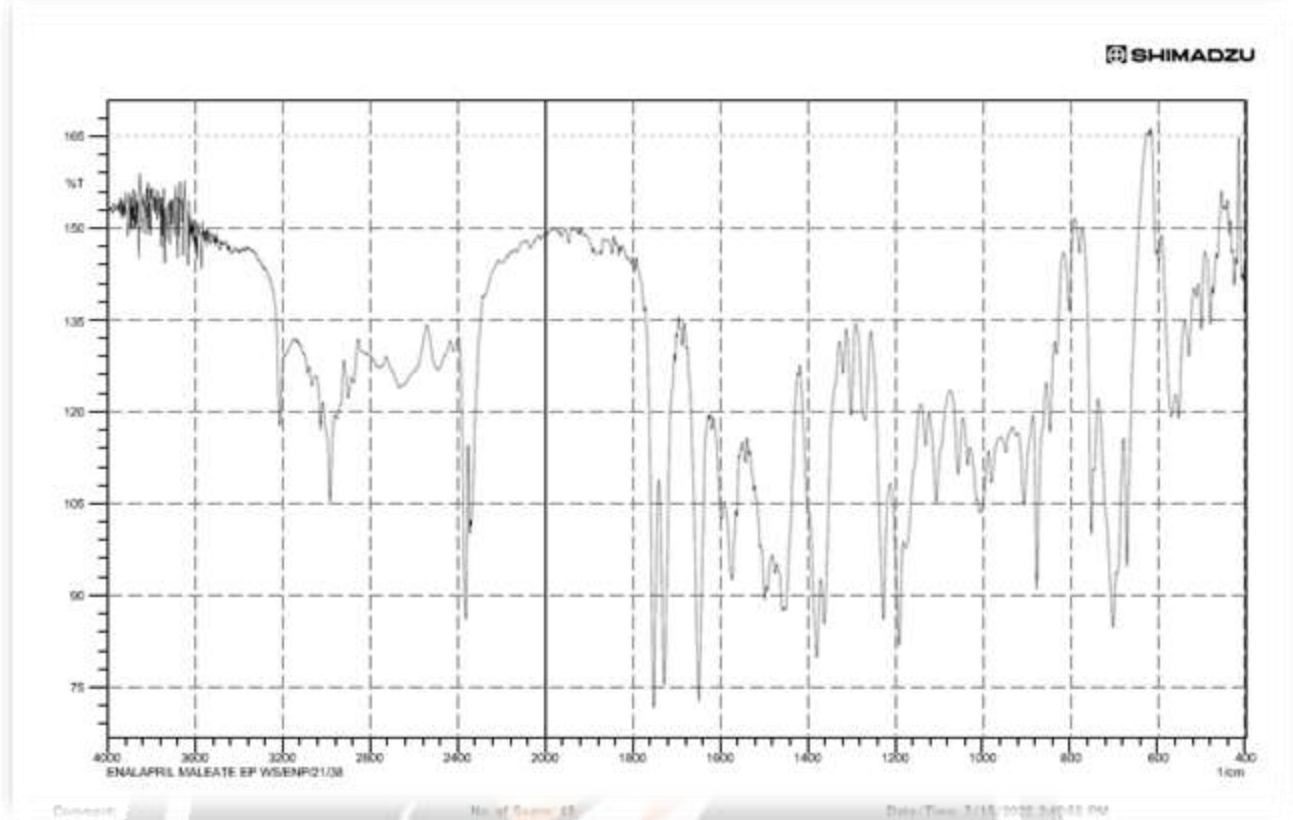


Fig 5 :Standard cure of Enalapril

3.6. FTIR Studies

Table 7:FTIR of pure form of the drug (Enalapril)

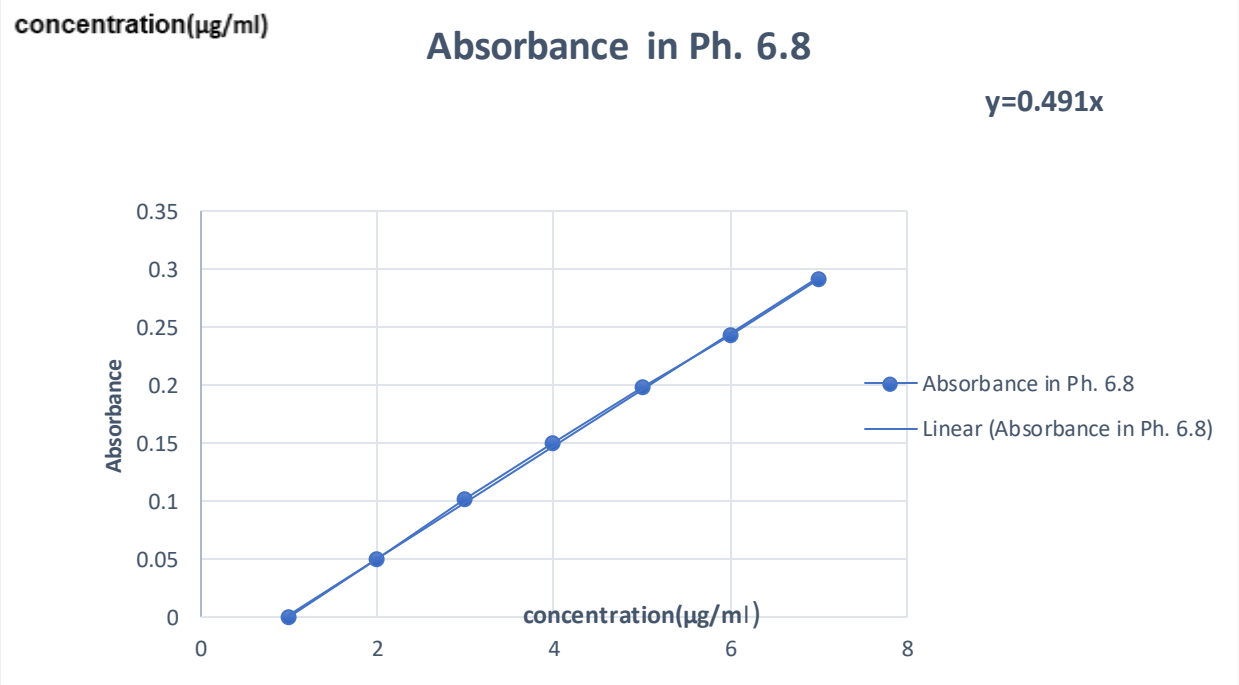
S.NO.	Functional Groups	Frequency	Reported value
1.	CH3	1450-1357	1376
2.	COOH	1440-1400	1445-34
3.	CH or C-H	3000	2978.08
4.	N-H	3400	3209.56
5.	COO	1765-1720 1290-1180	1746 1188.30

3.7. CALIBRATION CURVE:

Table 5: Enalapril calibration curve at a buffer pH of 6.8

S.NO	Concentration (µg/ml)	Absorbance in pH. 6.8
1.	0.0	0.00
2.	0.1	0.050
3.	0,2	0.102
4.	0.3	0.150
5.	0.4	0.199
6.	0.5	0.244
7.	0.6	0.292

Test parameter	Batch Code						
	F1	F2	F3	F4	F5	F6	F7



3.8. EVALUATION STUDIES

Table 6 : Evaluation Studies

Clearity	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent
Consistency	Thick	Thick	Thick	Thick	Thick	Thick	Thick
Texture	Non sticky Non gritty	Non sticky Non gritty	Non sticky Non gritty	Non sticky Non gritty	Non sticky Non gritty	Non sticky Non gritty	Non sticky Non gritty
Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
Viscosity (n=3)	1869	2569	4344	4582	5706	5797	6142
Syneresis at R.T	++	++	=	+++	+++	++	++

DISCUSSION:

3.9. Viscosity.

The viscosity is the most important single characteristic to consider when trying to optimise the soft jelly. The outcomes of our randomised, placebo-controlled, blinded, and double-blind investigation of lots F1 through F6 of enalapril edible jelly are presented in the following table.

The viscosities of enalapril jellies varied based on the kind of polymer and the concentration of the polymer, with values ranging from 1869 to 6142 cps. Both the consistency and the viscosity of the accompanying soft gels are influenced by the concentration of the gums guar gum, Xanthum gum, and sodium alginate. It was discovered that xanthumgum, sodium alginate, and guar gum jellies have the appropriate viscosity to be employed when coupled with gelatin to create jelly compositions. Jellies made using gelatin and xanthum gum on an individual basis revealed much higher viscosities. The amount of polymer present had a discernible effect on the consistency of the liquid.

3.10.CHARACTERIZATION OF DRUG

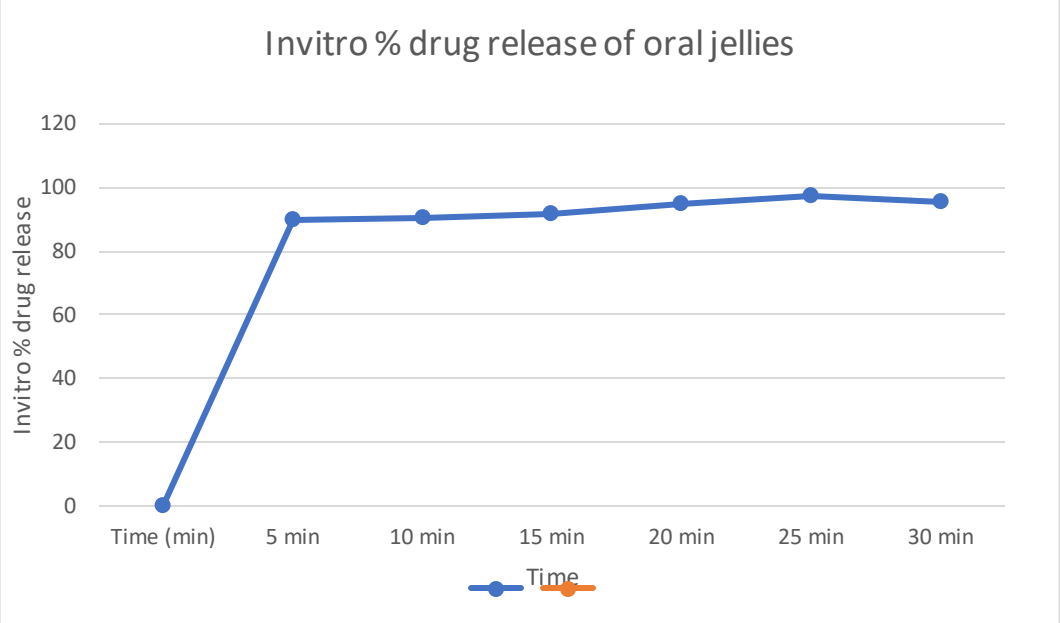
Table 10 : Characterization of drug

TEST	SPECIFICATIONS	OBSERVATION	REMARKS
Description	White, crystalline powder	White, crystalline powder.	Complies
Solubility	soluble in water, ethanol and methanol (95.5%).	soluble in water, ethanol and methanol (95.5%).	Complies
Odour	Slight odour	Slight odour	Complies
Melting point	143 and 144.5 ˚C	143 and 144.5 ˚C	Complies

3.11.In vitro dissolution rate

Table 11: In vitro dissolution rate

S.No	Time (min)	Formulation code	% Drug release after 30(min)
1	5 min	F1.	89.73
2	10 min	F2.	90.34
3	15 min	F3.	91.73
4	20 min	F4.	94.55
5	25 min	F5.	97.29
6	30 min	F6.	95.69



DISCUSSION: The F5 batch was determined to be the optimum formulation since it produced a cumulative% drug release graph that showed 97.30% of the medication was released after 30

minutes. This observation allows for the continuation of in vivo research. The best formulation F5 disintegrated faster and in line with the biopharmaceutics categorization systemidea for formulations intended for immediate release (>85% in 20 min).

CONCLUSION

Every edible jelly formulation was found to be acceptable. In the current study, the gelling agents xanthan gum, guar gum, and sodium alginate were employed to successfully manufacture the enalapril-loaded jellies. In conclusion, prepared medicinal jelly is better accepted on an organoleptic level, especially by patients who have hypertension, are unable to consume food or drink, or have difficulty chewing and swallowing.The creation of oral jelly ushers in a new era for the administration of medications containing various active components. It offers a conveniently oral dose type that can be administered having no need for water makes it a good.replace the easily accessible soliddosing regimens for use withpopulations with dysphagia, including children,elderly patients, especially when nausea or vomiting occurs inFurthermore, the travelling patient According to the results of the current experiment, enalapril-containing oral medicated jellies offer a great deal of promise for effective systemic circulation concentrations. The pre-made medicated jelly is a useful and patient-friendly product.

REFRENCE

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