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FORMULATION AND EVALUATION OF MEDICATED ORAL JELLY OF TRAZADONE HYDROCHLORIDE

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Keywords:

Trazadone hydrochloride, Medicated oral jelly, Xanthan gum and gelatin

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ABSTRACT: The objectives of the present investigation were to formulate and evaluate of Medicated oral jelly containing Trazadone HCl for the treatment of depression. Many psychotic patients are medicinal phobic who are afraid of taking medicine, so this preparation is most beneficial over that type of fear. Trazadone HCl antidepressant drugs incorporate in jelly and give to those patients; in this way, we could administer medicine to them without bringing this to their attention. Jellies are prepared by heating and congealing methods by dispersing gelling agents in water and evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. All batches (F1-F8) of medicated jelly showed acceptable and comparable appearance, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. The viscosity range was found to be 53305 to 61731cps. The drug content of F1 to F8 formulations was found to be in the range of 88.42 to 98.95%. F7 batch prepared with gelatin + xanthan gum combination shows 98.95%. drug release.

INTRODUCTION: Definition: "Jelly can be defined as transparent or translucent non-greasy, semisolid preparations meant for external as well as the internal application". Or jellies are water-soluble bases prepared from natural substances such as tragacanth, pectin, alginates, and boro glycerin or from synthetic derivatives of natural substances such as cellulose and sodium carboxy methylcellulose or from synthetic derivatives of natural substances such as methylcellulose and sodium carboxymethylcellulose [1].

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The medicated jelly is mainly used for oral diseases as well as systemic diseases. It is useful for pediatric and psychotic patients because it's like candy, and they can easily take this medication as having attractive color and sweet taste, and they love chewing the jelly having different shapes and sizes [2]. Jellies are traditionally prepared using gelatin. The material is dissolved in hot water, and gelation occurs on cooling in the refrigerator. The gelatin molecules in solution undergo a coil-to-helix transition, which occurs at about 25 °C, and the helices aggregate to form a gel. The gels formed have high clarity and on heating melt at 37 °C, which corresponds to body temperature. The jelly, therefore, melts in the mouth, providing rapid flavor release and smooth texture, but they are prone to toughening on storage. Jellies can also be prepared using gums such as pectin, alginates, xanthan gum [3].

Trazodone is serotonin-2 receptor antagonist that also decreases extracellular gamma-amino-butyric acid (GABA) levels in the cerebral cortex, through the blockade of 5-hydroxytryptamine*2A* receptors. Trazodone, therefore, a psychoactive compound with sedative and anti-depressant properties [4, 5].

Many psychotic patients are medicinal phobic who are afraid of taking medicine, so this preparation is most beneficial over that type of fear, and moreover, it is attractive in appearance for those patients as well as pediatrics and geriatric patients. Trazodone HCl antidepressant drugs incorporate in jelly and give to that patient; in this way, we could administer medicine to them without bringing this to their attention; this is how we can treat psychotic patients.

MATERIALS AND METHODS: Trazodone HCl was received as a gift sample from the FDC Pvt. Ltd. Aurangabad. Xanthan gum and gelatin are received from Kandhar College of Pharmacy, Nanded. All other chemicals and solvents used are of analytical grade and used as procured.

Determination of Maximum Absorption in 6.8 Phosphate Buffer:

Preparation of Stock Solution: A stock solution containing 100 ug/ml, was prepared by dissolving 100 mg drug in 100ml volumetric flask with 6.8 phosphate buffer, and then from this solution, 1ml further diluted to100 ml volumetric flask with 6.8 phosphate buffer. The solution was prepared by dissolving Trazodone HCl in a 6.8 buffer solution. Ultraviolet absorption in the range 200-400 nm in 6.8 buffer solution as a blank and measured using UV Spectrophotometer. It is found to be 246.40 nm.

Standard Curve of Trazodone HCl in 6.8 Phosphate Buffer: Weighed quantity of Trazodone HCl (100 mg) was dissolved in 100 ml of 6.8 phosphate buffer, and volume was made up with the same up to 100 ml of 6.8 phosphate buffer. It was further diluted with 6.8 phosphate buffer to get solutions of concentrations 2, 4, 6, 8, 10, 12 µg/ml.

The absorbance of these solutions was determined by UV-spectrophotometer at 246.40 nm, and the calibration curve was plotted by taking absorbance on Y-axis and concentrations on X-axis [6].

Preparation of Medicated Oral Jelly: Sugar base jellies are prepared by heating and congealing method. Weighed all the ingredients accurately. Prepared all formulations using freshly boiled and cooled distilled water. Prepared sugar syrup base by dissolving 66.7 gm of sugar in a beaker, then added water up to 10 0ml heated, stirred at 80 °C for about 30 min accurately. Dispersed weighed polymers powder to that solution maintaining at 90 °C throughout the preparation. Stirred the dispersion using a magnetic stirrer for 20 min to facilitate the hydration of the gelating agent. When the gelling agent is completely dissolved, Stabilizer and citric acid added and again stirred to enhance the softness of jelly maintaining pH respectively and then boiled for a few minutes. After boiling the above solution, preservatives were added to that solution, mixed thoroughly and uniformly. And then, Trazodone HCl was weighted accurately, dissolved in distilled water, and added before jellies were allowed to set, mixed thoroughly. Then the whole solution was transferred into molds and then allowed it for cooling and settling undisturbed by proper covering the molds to avoid exposure to outer environment t[7, 16].

Evaluation Parameters:

Physical Appearance: The medicated jelly was examined for physical appearance in terms of color, texture, clarity, and consistency. These tests are important regarding patients' compliance and acceptance.

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 [10].

pH: pH of the final jelly have 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 [8, 15].

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) [9].

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 ± 1 °C. [11]

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 50 ml of phosphate buffer pH 6.8 to give a 100 ug/ml solution. From the above solutions 1, 1.5, 2 ml taken and made up to 10 ml with pH 6.8 phosphate buffer to give 10, 15, 20 ug/ml solutions respectively. The absorbance of each solution will measure at 246.40 nm using UV-visible spectrophotometer [12, 13].

Spreadability: The Spreadability of the formulations was determined by the apparatus suggested by Multimer, which was fabricated and used for the study. It consists of wooden blocks provided with two glass slides. Lower slide fixed on wooden blocks and upper slide with a one end tide to a glass slide and other end tied to weight pan. Jelly quantity 2.5 gm was placed between two slides, and 100 gm weight was placed over it for 5 min. to press the sample to a uniform thickness. Weight 80 gm was added to the pan. The time in the second required to separate two slides was taken as a measure of Spreadability. Spreadability was calculated by using the following formula;

$$S = M \times L/T$$

Where, S = spread ability, M = weight tide to upper slide, L = length of glass slide (7.5 cm), T = time taken to separate two slides [13].

***In-vitro* Dissolution Study:** An *in-vitro* dissolution study was performed with USP paddle-type apparatus using pH 6.8 phosphate buffer as dissolution medium (90 0ml) 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} 246.40 nm. And absorbance was taken, and then % drug release was calculated [14].

Stability Study: Stability studies of prepared jelly at room temperature (25 °C ± 5 °C, - 35 °C the stability studies are carried out for 3 week and the formulations were analyzed for the changes in the physical parameters like appearance and pH [17].

RESULTS AND DISCUSSION: Trazodone HCl is an antidepressant chemically unrelated to tricyclic, tetracyclic, or other known antidepressant agents. Trazodone is used primarily in the treatment of mental depression or depression/anxiety disorders. It is freely soluble in water, so we could use it in jelly formulation for best absorption. Psychotic patients behave either violent or childish, so we make them greedy about jelly; due to the attraction of jelly, they easily eat it. While mastication drug release and absorbed though saliva and goes directly into the systemic circulation, so it shows the onset of action fast that calms down patients and induce sleep. Once the patient gets to sleep, his/her anxiety, fear, or any cause of depression reduced. Anti-depression drugs like this used in the jelly formulation. Therefore, an attempt was made to formulate medicated oral jelly by using various polymers with different concentrations.

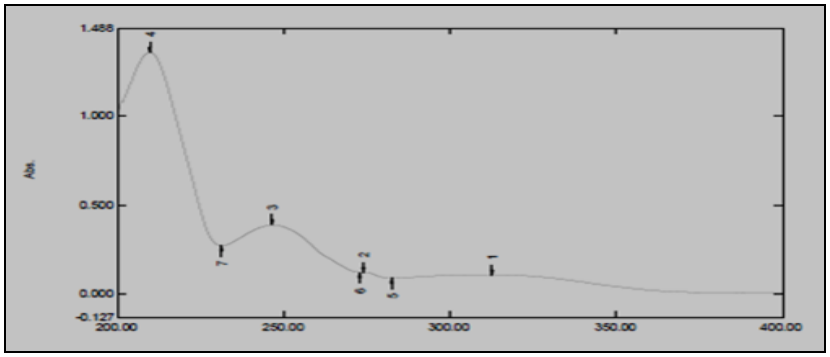

FIG. 1: ABSORPTION MAXIMA OF TRAZODONE HCl IN 6.8 PHOSPHATE BUFFER SOL

Calibration Curve of Trazadone HCl in 6.8 Phosphate Buffer Solution:

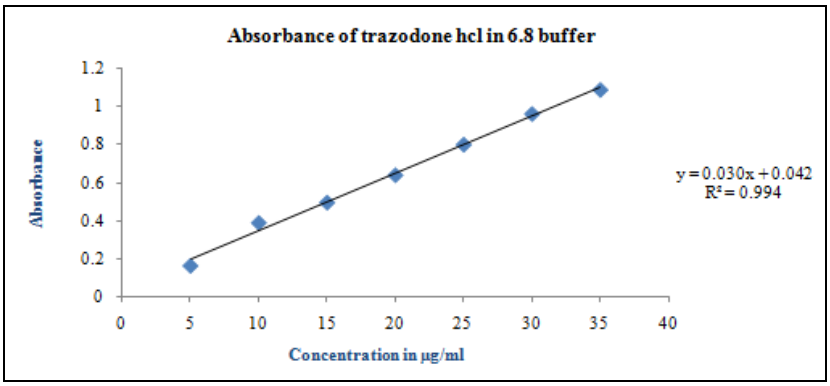

FIG 2: CALIBRATION CURVE OF TRAZODONE HCl IN 6.8 PHOSPHATE BUFFER

TABLE 1: CALIBRATION CURVE OF TRAZODONE HCl IN 6.8 PHOSPHATE BUFFER

S. no.	Concentration (µg/ml)	Absorbance
1	5	0.161
2	10	0.388
3	15	0.495
4	20	0.64
5	25	0.801
6	30	0.963
7	35	1.09

TABLE 2: FORMULATION OF TRAZODONE HCl BATCHES

Qty in %	F1	F2	F3	F4	F5	F6	F7	F8
Drug	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Gelatin	2	2.5	3					
Xanthan gum				0.5	1	1.5		
Gelatin + xanthan gum							1:1	
Gelatin + xanthan gum								0.5:1.5
Citric acid	0.3	0.3	0.3	0.3				
Methyl paraben	0.01	0.01	0.01	0.01				
Propyl paraben	0.01	0.01	0.01	0.01				
Propylene glycol	0.3	0.3	0.3	0.3				
Sucrose	50	50	50	50				
Distilled water	Qs	Qs	Qs	Qs				
Colour	Qs	Qs	Qs	Qs				
Flavour	Qs	Qs	Qs	Qs				

Each jelly contains 0.5 mg of drug. Each jelly weighs 10 gm.

Drug-Polymer Compatibility Study FTIR: The IR spectrum of the pure drug Trazodone HCl and its excipient shows as below.

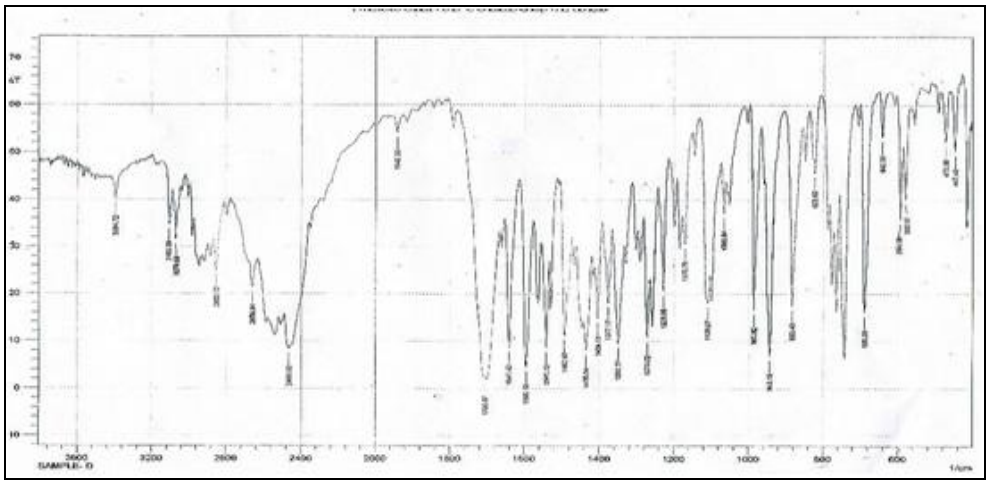

FIG. 3: FTIR SPECTRUM OF TRAZODONE HCl

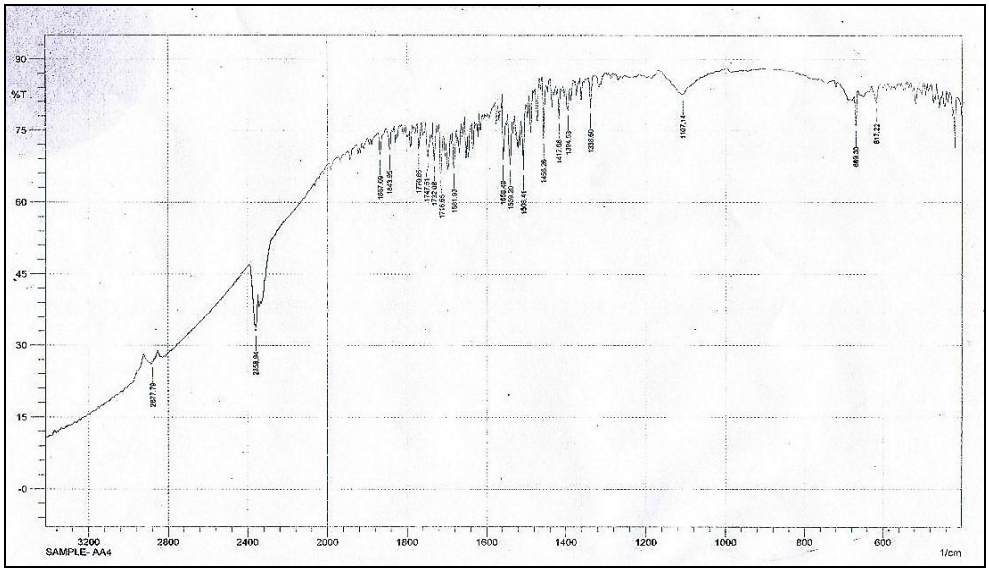

FIG. 4: FTIR SPECTRUM OF THE GELATIN

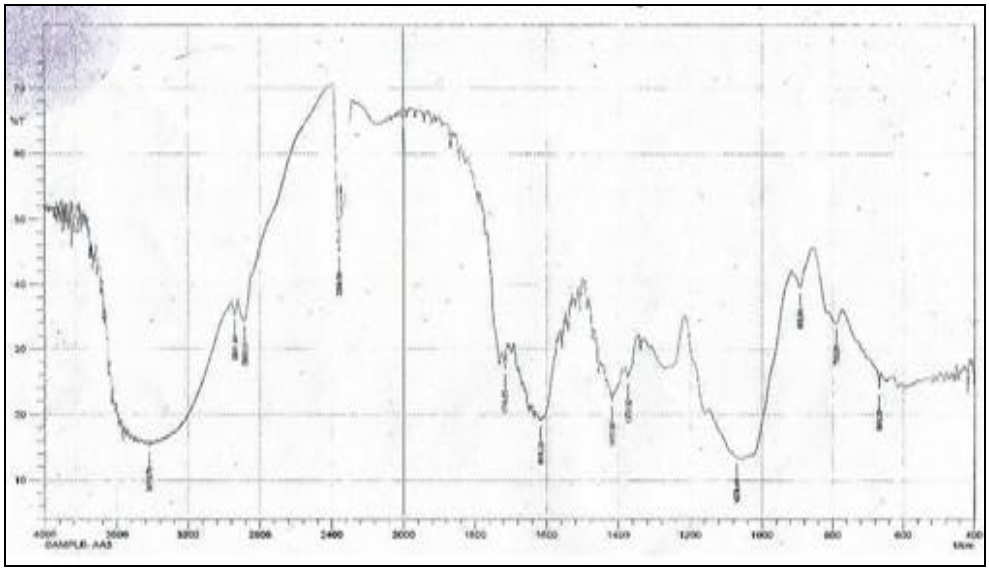

FIG 5: FTIR SPECTRUM OF THE XANTHAN GUM

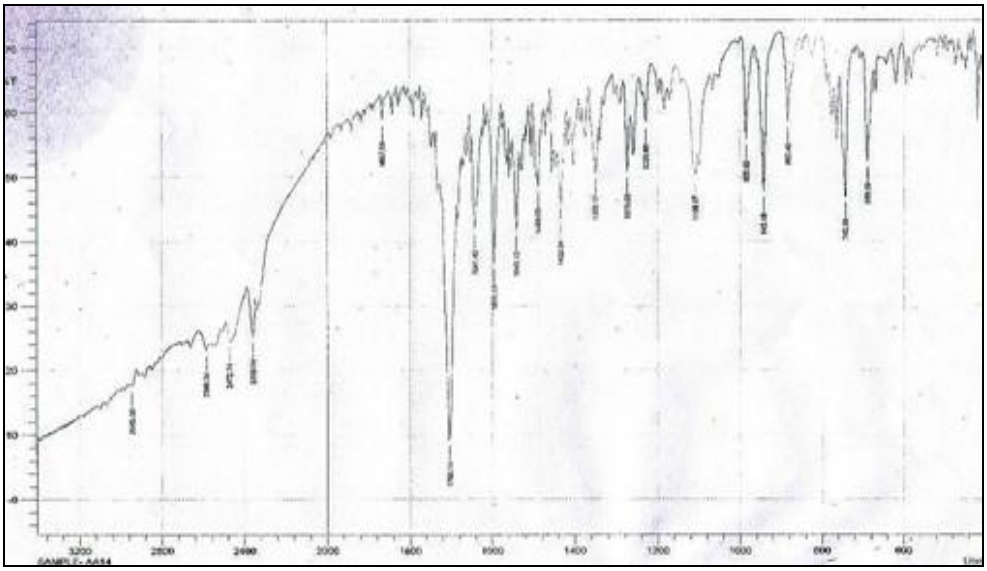

FIG. 6: FTIR SPECTRUM OF THE GELATIN +TRAZODONE HCl

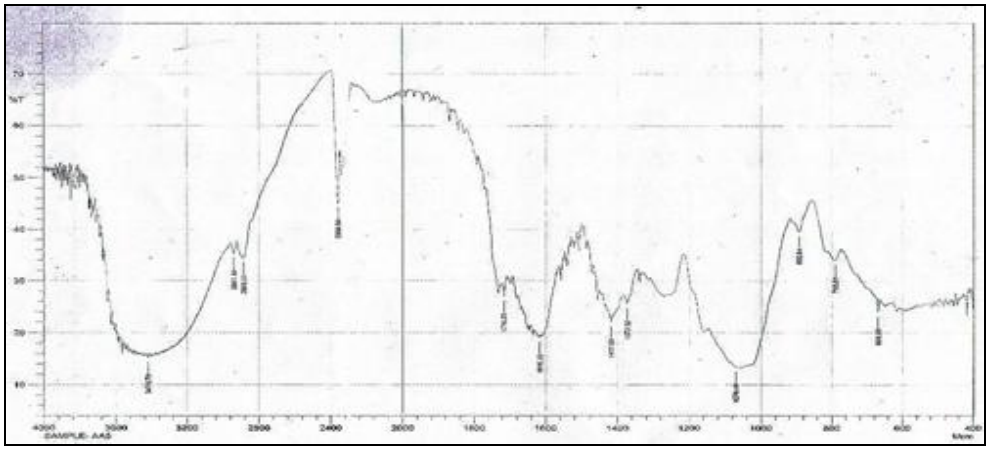

FIG. 7: FTIR SPECTRUM OF THE XANTHAN GUM+ TRAZODONE HCl

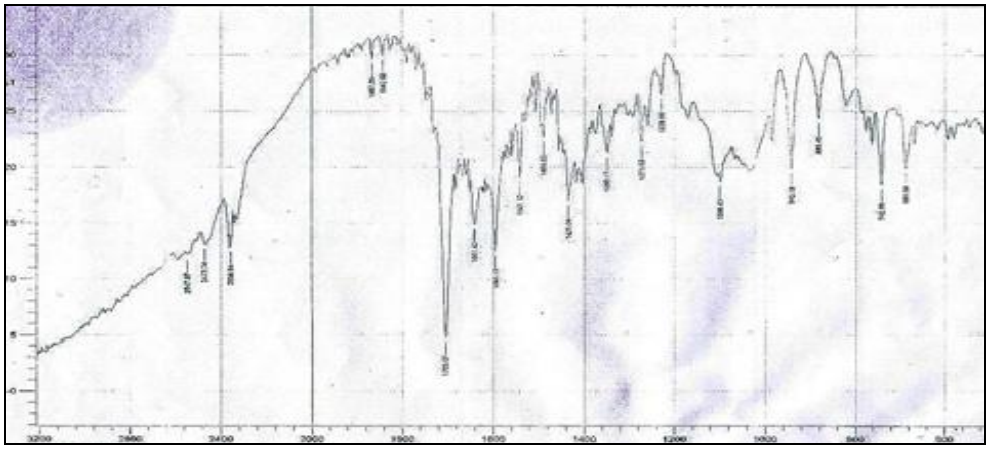

FIG. 8: FTIR SPECTRUM OF COMBINATION

TABLE 3: INTERPRETATION OF IR SPECTRUM

S. no.	Functional group	Vibration	Range	Peak	Intensity
1	Ether	C-O	1300-1000	1099	Strong
2	Aromatic benzene	C=C	1650-1475	1541	Medium
3	Alkane halide	H-CL	750-730	740	Weak
4	Amine	N-H	3500 -3100	3200	Medium
5	Alkane	C-H	3000-2500	2547	Medium

Drug–Polymer Compatibility Studies by FTIR: The study of pure drug Trazodone and excipients was carried out by using FTIR in the range 500^{-1} to 3500^{-1}. It has been observed that there is no chemical interaction between drug and polymers used. FTIR spectra with a mixture of polymers, which show there were no physical interactions between drugs and polymers. The IR spectrum of the pure drug indicates prominent peaks shown in **Table 3**. These values compared with the references, so it confirmed the pure drug.

Differential Scanning Calorimetry of the Drug and Best Batch:

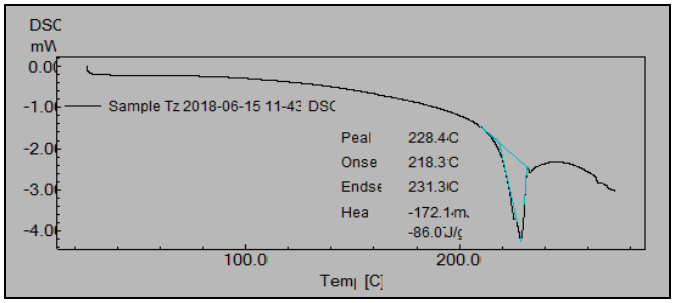

FIG. 9: DSC OF TRAZODONE HCl

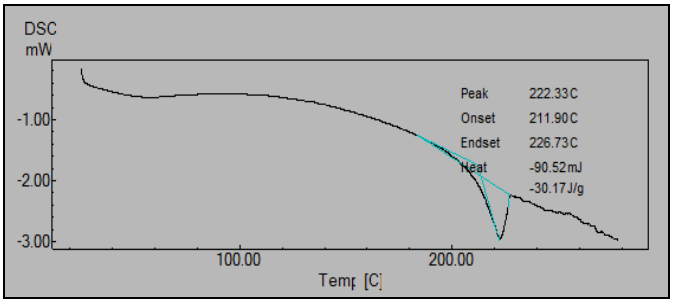

FIG. 10: DSC OF TRAZODONE HCl + OPTIMIZED FORMULATION (F7)

DSC: Differential scanning Calorimetry Thermograms of pure Trazodone HCl and blends of polymer with the drug were determined. Pure Trazodone HCl showed a sharp peak at 228.44 °C, corresponding to its melting point. There was no appreciable change in melting endotherms of physical mixture compared to that of pure drug Trazodone HCl. Absence of any new endothermic peak or disappearance or shift of endothermic peak confirmed that here was no interaction and hence polymers were compatible with drug.

Physical Appearance:

TABLE 4: PHYSICAL APPEARANCE OF FORMULATED JELLY

Batch	Appearance	Colour	Texture
F1	Opaque	Reddish pink	Smooth
F2	Opaque	Reddish pink	Smooth
F3	Opaque	Reddish pink	Smooth
F4	Opaque	Reddish pink	Smooth
F5	Opaque	Reddish pink	Smooth
F6	Opaque	Reddish pink	Smooth
F7	Opaque	Reddish pink	Smooth
F8	Opaque	Reddish pink	Smooth

All the formulated batches are evaluated for physical appearance; the results are given above.

The texture of all jellies was found smooth. The medicated jellies of F1, F6 exhibit fluid-like consistency. Medicated jelly of batches F2, F3 F7, is thick in consistency. F5 is thin in consistency, F4 very thin, and F8 is very thick.

Stickiness and Grittiness:

TABLE 5: STICKINESS AND GRITTINESS OF FORMULATED JELLIES

Test	F1	F2	F3	F4
Stickiness	Sticky	Sticky	slightly sticky	Slightly sticky
Grittiness	Gritty	Gritty	Less gritty	Slightly gritty
Test	**F5**	**F6**	**F7**	**F8**
Stickiness	Slightly sticky	Non-sticky	Non-sticky	Slightly Sticky
Grittiness	Slightly gritty	More gritty	Non-gritty	Slightly gritty

The medicated jelly of batches F6, F7, is non sticky whereas F3, F4, F5, F8 are slightly sticky. Grittiness shown by f6 is more whereas F3, F7 is less Gritty F1, F2, F6 gritty F4, F5, F8 slightly gritty.

TABLE 6: % CUMULATIVE DRUG RELEASE OF BATCHES

Time in min	% Cumulative Drug release SD $^{n=3}$							
	F1	F2	F3	F4	F5	F6	F7	F8
5	27.52±01	27.55±04	2846±05	29.30±08	29.35±01	28.10±02	41.01±07	40.32±02
10	46.80±0.9	50±0.8	48.60±0.1	45.30±0.4	45±0.8	46.81±0.4	46.85±0.5	48.93±0.4
15	54.20±0.6	54.55±0.4	58.45±0.3	57.80±0.7	59±0.3	56.90±0.8	56.30±0.6	58.01±0.6
20	64.91±0.3	64.63±0.1	63.75±0.8	62.88±0.2	71.12±0.6	67.62±0.2	64.95±0.7	66.02±0.2
25	73.88±0.5	72.99±0.5	70.60±0.5	69.10±0.1	71.15±0.5	72.65±0.3	73.25±0.8	72.99±0.5
30	78.31±0.8	83.95±0.2	85.95±0.3	84.40±0.4	83.65±0.3	83±0.9	97.60±0.3	83.94±0.4

± SD N=3

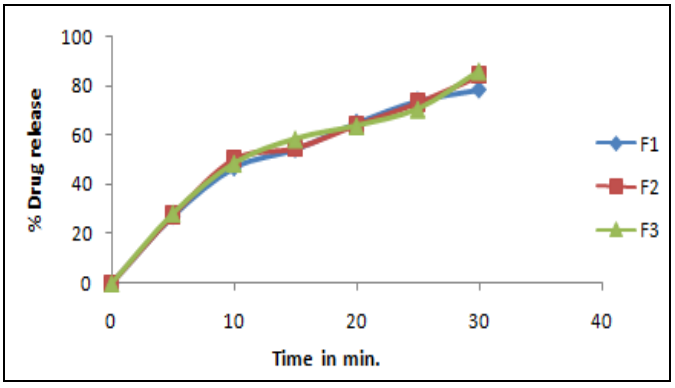

FIG. 11: % DRUG RELEASE OF BATCH F1, F2, F3

Dissolution was carried out with gelatin in different conc. The dissolution profile of F1, F2, F3 batches prepared with concentration 2%, 2.5% and 3%, respectively. The batch F1 show 78.35% release, batch F2 show 83.99% release, and F3 showed 85.99% release in 30 min.

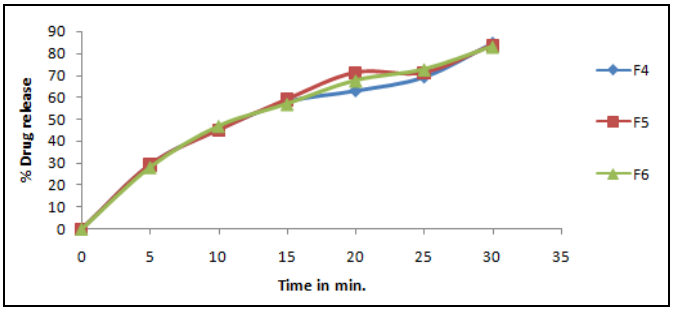

FIG. 12: % DRUG RELEASE OF BATCH F4, F5, F6

Dissolution was carried out with Xanthan Gum in different conc. The dissolution profile of batches F4, F5, F6 prepared with concentration 1%, 1.5%.

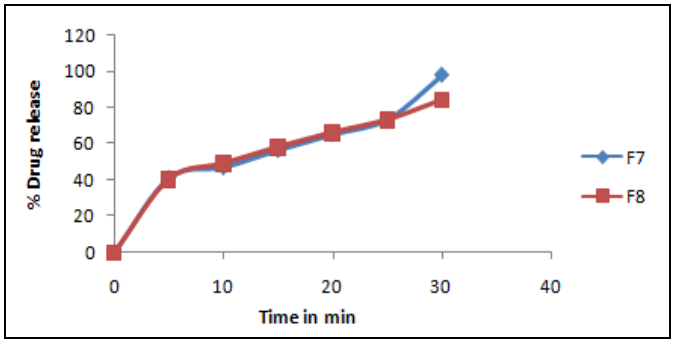

FIG. 13: % DRUG RELEASE OF BATCH F7 & F8

Dissolution was carried out with gelatin + Xanthan Gum in different conc. The dissolution profile of batches F7, F8 prepared with concentration 1:1%, 0.5:1.5% respectively. The batch F7 show 97.60% & batch F8 show 83.94% in 30 min.

Maximum drug releases in 30 min of all batches. In this formulation, the fast release provides an effective amount of trazodone for treating disorders for example, improving sleep architecture. Among the gelatin, xanthan gum, and gelatin + Xanthan gum, gelatin+ Xanthan gum had good polymer for preparation of fast release oral jelly of trazodone HCl. Batch 7 and 8 combinations of polymers were formulated, because plane polymer showed either high viscous or low viscous, where combination polymer shows good consistency (gelatin + xanthan gum). All the above experiments decided on various trial batches.

Drug Content Uniformity:

TABLE 7: STUDY OF % DRUG CONTENT IN ALL BATCHES

Formulation code	% content uniformity(%) ± S.D$^{n=3}$
F1	88.42±0.36
F2	90.95±0.15
F3	89.66±0.23
F4	98.13±0.02
F5	94.80±0.21
F6	96.09±0.52
F7	98.95±0.25

The drug content of F1 to F8 formulations was found to be in the range of 86.51 to 98.95%. It is within the acceptable limit, which shows all the formulations have uniformity of content

Viscosity, Spreadability, and pH:

TABLE 8: RESULTS OF VISCOSITY, SPREAD ABILITY AND pH

S. no.	Formulation code	Viscosity (cps)	Spredability	pH
1	F1	57047	30	6.3
2	F2	58111	27.6	6.2
3	F3	61731	26.8	6.5
4	F4	53498	22.4	6.7
5	F5	55161	21.2	8.1
6	F6	53305	20.4	6.4
7	F7	61595	21.3	7.5
8	F8	53773	20	5.1

The viscosity range was found to be 53305 to 61731cps.

Short Term Stability: The result of short term stability studies given in **Table 12** indicates insignificant changes in pH and appearance in the optimized formulation of batch 7 with time. Precipitation of the drug in the jellies was not observed. Also, insignificant syneresis was not observed in any of the samples at both temperatures. Therefore, it is recommended that jelly should be stored at about 25 °C.

TABLE 9: STABILITY STUDY OF BATCH F7

S. no.	Storage condition	Weeks	General appearance	Syneresis	pH
1	2-8 °C	Initial	Slightly sticky	+	6.51
		1	No change	+	6.45
		3	No change	+	6.87
2	25 ± 5 °C	Initial	Slightly sticky	+	6.09
		1	No change	+	6.32
		3	No change	+	6.78

Optimized batch formulation F7 was further evaluated for stability *i.e.*, stability study and syneresis.

Precipitation of the drug in the jellies was not observed. Syneresis was not observed at both temperatures (2-8 °C and 25 °C). Therefore, it is

recommended that jelly should be stored at about 25 °C.

CONCLUSION: In the present study, an attempt had been made on the formulation and evaluation of the Medicated oral jelly of Trazodone HCl. The melting point of the pure drug was measured and found to be 228 °C, which complied with the standard. The solubility reveals that Trazodone HCl freely soluble in water, sparingly soluble in ethanol, methanol, and chloroform. FTIR and DSC studies reveal that there was no additional peak observed, and hence drugs were compatible with excipients.

Jellies are prepared by heating and congealing methods by dispersing gelling agents in water and evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, spreadability, stability studies, drug release, and content uniformity. All batches (F1-F8) of medicated jelly showed acceptable and comparable appearance, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. The viscosity range was found to be 53305 to 61731 cps. The drug content of F1 to F8 formulations was found to be in the range of 88.42 to 98.95%. F7 batch prepared with gelatin + xanthan gum combination shows 98.95% drug release; hence, it can be concluded that jelly of Trazadone HCl having satisfactory result and induce sleep and also provide an increased therapeutic efficacy

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CONFLICTS OF INTEREST: None

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