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DESIGN AND EVALUATION OF PARACETAMOL CHEWABLE PAEDIATRIC ORAL JELLY

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ABSTRACT

This study aimed to formulate paracetamol in a new dosage form, jelly using gelatine and sucrose and to improve paediatric patient's compliance to achieve maximum drugefficacy. Paracetamol is an antipyretic and analgesic, used in the treatment of pain andreduce a high temperature (fever). This dosage form was selected because of sharing between both advantages of liquid and solid dosage forms. A few liquid oral formulations areavailable in market containing 250 mg/5 ml dose. However, as there is a chance of errorin dosage of liquid oral formulations hence, an alternate, unit packaged oral jelly dosagefrom can be a very good option to get accurate dose. The effect of jellifying agents and their concentration have been investigated. It also has a pleasant texture and look, making it easy to attract and administer to patients. The organoleptic properties and physicochemical parameters (Such as - stickiness, texture, grittiness, drug content and pH) of the formulations were determined. The drug excipient compatibility study was done by FT-IR and was found that there is no physicochemical interaction. Dissolution studies have shown that more than 90 % drug is released within 10 min.

Keywords: Jelly, Paracetamol, Paediatric, Antipyretic and Analgesic

1. INTRODUCTION

The oral route is the most desirable and convenient method of drug administration for administration of therapeutic agents, because of their patient compliance. It's also most economical and they have low cost of therapy. For oral administration we have various preparations like Tablets, Pills, Capsules, etc. Such dosages forms are not easily taken by childrenand sometimes geriatric patients, particularly patients with dysphagia. Children cannot easily taketablets due to their sizes (or) bitterness of effective components, etc. Jelly a popular form of nutraceutical, as they offer a convenient and palatable way to consume a wide range of beneficial compounds. The preparation of jelly in nutraceutical involves a combination of ingredients and processes that are designed to deliver the desired nutritional profileand physical characteristics. In this review article, we will discuss the various ingredients and equipment used in the preparation of jelly, as well as the different methods and techniques used tocreate these functional foods.[1]

The medicated jelly has through years gained increasing acceptance as a drug delivery system. They may be prepared from natural gums, such as tragacanth, pectin, sodium alginate or from synthetic derivatives of natural substance such as methyl cellulose and sodium Carboxymethyl cellulose. Children may consider jelly as more preferred method of drugs administration compared with oral liquid or tablets. The use of medicated jelly is feasible as local treatment of disease of oral cavity as well as treatment of systemic condition.

An ideal lozenge authority in the medicine remedy of any complaint is the one, which incontinentlyattains the asked remedial attention of medicine in tube (or at the point of action) and maintains itconstant for the entire duration of treatment. Medicines are more constantly taken by oral administration. It's considered most natural, uncomplicated, accessible, safe means of administering medicines, lesser inflexibility in lozenge form design, ease of product and low cost,convenience of tone administration, conciseness and easy manufacturing. The most apparent debitof the generally used oral lozenge forms like tablets is difficulty in swallowing, leading to case's incompliance particularly in case of children and senior cases, but it also applies to people who are ill in bed and to those active working cases who are busy or traveling, especially those who have no access to water. To fulfill these medical requirements, pharmaceutical technologists havedeveloped a new oral lozenge form known as Jelly which disintegrate fleetly in slaver, generally in a matter of seconds, without the need of water. Medicine dissolution and immersion as well asonset of clinical effect and medicine bioavailability may be significantly lesser than those observedfrom conventional lozenge forms. Over a few years, the demand for development of Jelly has tremendously increased as it has greater impact on the case compliance. Oral treated jelly are appreciated by a significant member of populations particularly who have difficulty in swallowing.It has been reported that Dysphasia (difficulty in swallowing) is common among all age groups and more specific with children, senior population along with institutionalized cases, psychiatric cases and cases with nausea, puking, and stir sickness complications. Common among all age groups, dysphasia is observed in about 35 of the general population, as

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well as over to 60 of the senior institutionalized population and 18- 22 of all cases in long- term care installations. Jelly with good taste and flavor increase the adequacy of bitter medicines by colorful groups of population.

The need for on-invasive delivery systems persists due to cases' poor acceptance of, and compliance with, being delivery administrations, limited request size for medicine companies andmedicine uses, coupled with high cost of complaint operation.[2-4]

2. METHOD OF PREPARATIONS OF JELLY

Jelly was prepared by heating and congealing method. Prepared using freshly boiled and cooled distilled water as per composition listed. Sucrose syrup prepared in water on heating and continuous stirring. Gelatine was added to the sucrose syrup prepared in water on heating and continuous stirring. Drug taken in the beaker and added with the above mixture. Mix the mixture till the drug gets dissolved completely at a temp 40-60 °C. Added flavouring agents and colouring agents to the above hot mixture and mix it well. Transfer the mixture to suitable moulds, sealed and allow to cool at room temperature toform a jelly like texture for 11 hrs. Finally, when jelly was set, wrap in the gelatine paper and store in a dry place.[5]

Evaluation Parameters

Physical appearance

The treated jelly was examined for physical appearance in terms of clarity, texture and thickness. Stickiness and grit Texture of the treated jelly in terms of stickiness and grithad been estimated by visual examination of the product after mildly rubbing the jelly sample between two fritters.

pH

The pH of all the jelly was determined using digital pH cadence 0.5 gm. of the counted expression was dispersed in 50 ml of distilled water and the pH was noted.

Content Uniformity

The content uniformity test is to ensure every lozenge form contains equal quantum of medicine substance. Jelly from every expression was taken, crushed and mixed. From the admixture medicine fellow of admixture was uprooted completely with suitable media. The quantum of medicine present in each excerpt was determined using suitable logical system.

Syneresis

Syneresis is the compression of the gel upon storehouse and separation of water from the gel. It's more pronounced in the gels, where lower attention of gelatinizing agent is employed. It's one of the major problems associated with low acylated guar goo gels.[6,7]

SPECTROSCOPIC STUDIES

Preparation of Potassium Buffer pH 5.8

Buffer solution was prepared by taking 250 ml of 0.2 M KH_2PO_4 in 1000 ml of volumetric flask and added 18 ml of 0.2 M NaOH and made the volume with water.

Determination of λ max

Standard stock solution was prepared by dissolving accurately weighed quantity of Paracetamol in suitable volume of distilled water. Dilutions were made and scanned in the rangeof 200-400 nm against pH 5.8 Phosphate buffer as blank. Wavelength of maximum absorption was determined for the drug. Paracetamol showed maximum absorption at 243 nm.

Fig. No:1 UV Visible spectrophotometer (Model No: UV 3200)

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Preparation of standard solutions and Calibration curve of Paracetamol

Take 100 mg of drug in 100 ml volumetric flask and make it up to the volume using buffersolution which now contain 1 mg/ml solution.

From this primary stock solution pipette out 10 ml of solution in to 100 ml volumetric flaskand make it up to the volume using buffer solution which now contain 0.1 mg/ml solution. From this secondary stock solution pipette out 0.3, 0.6, 0.9, 1.2, 1.5 ml of solutions in to 10ml volumetric flask and make it up to the volume using buffer solution which gives 3,6,9,12,15 µg/ ml respectively. The absorbance of the results solution was then measured at 243 nm using UV spectrophotometer. The calibration curve was obtained by plotting Absorbance vs. Concentrationin µg/ ml.[8]

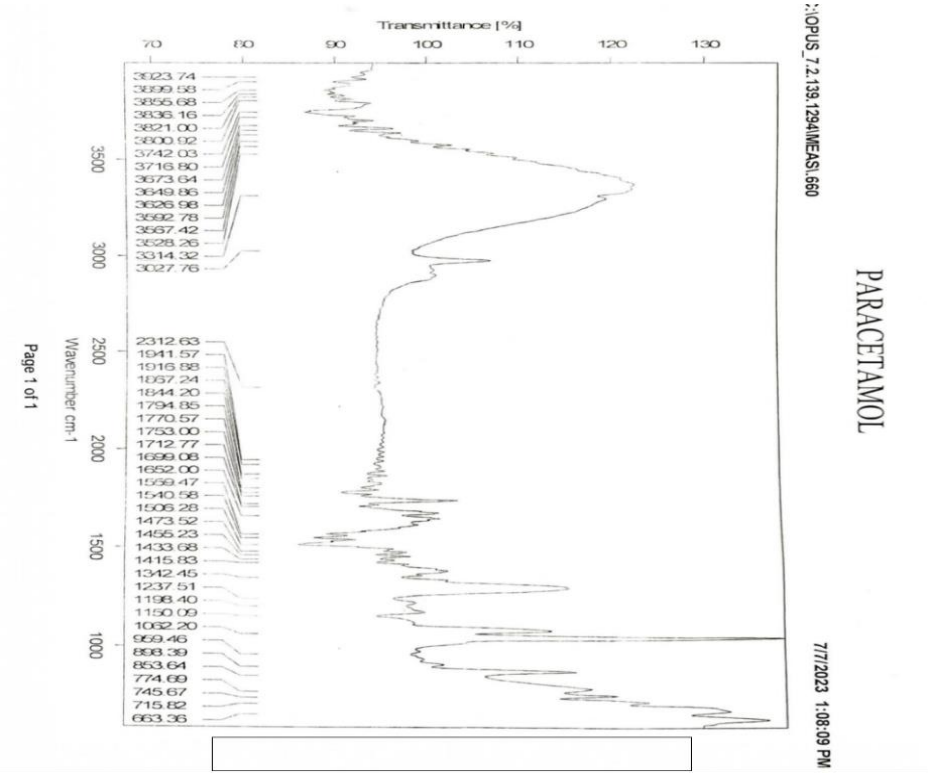

Fig. No: 2 FTIR Spectroscopy of Paracetamol

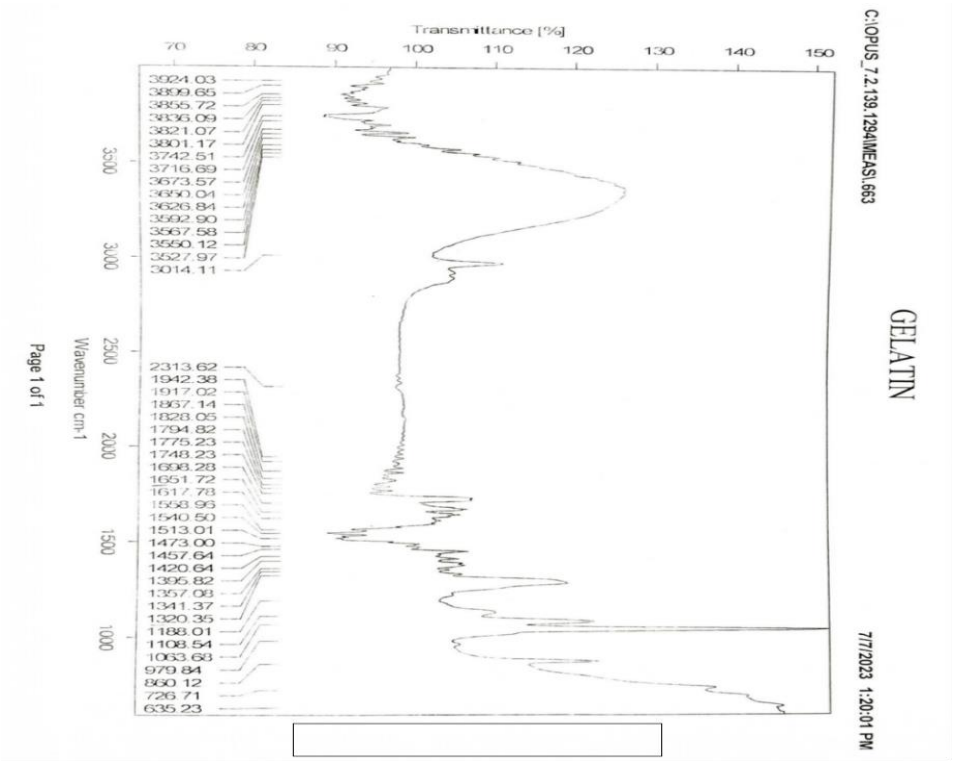

Fig.No: 3 FTIR Spectroscopy of Gelatin

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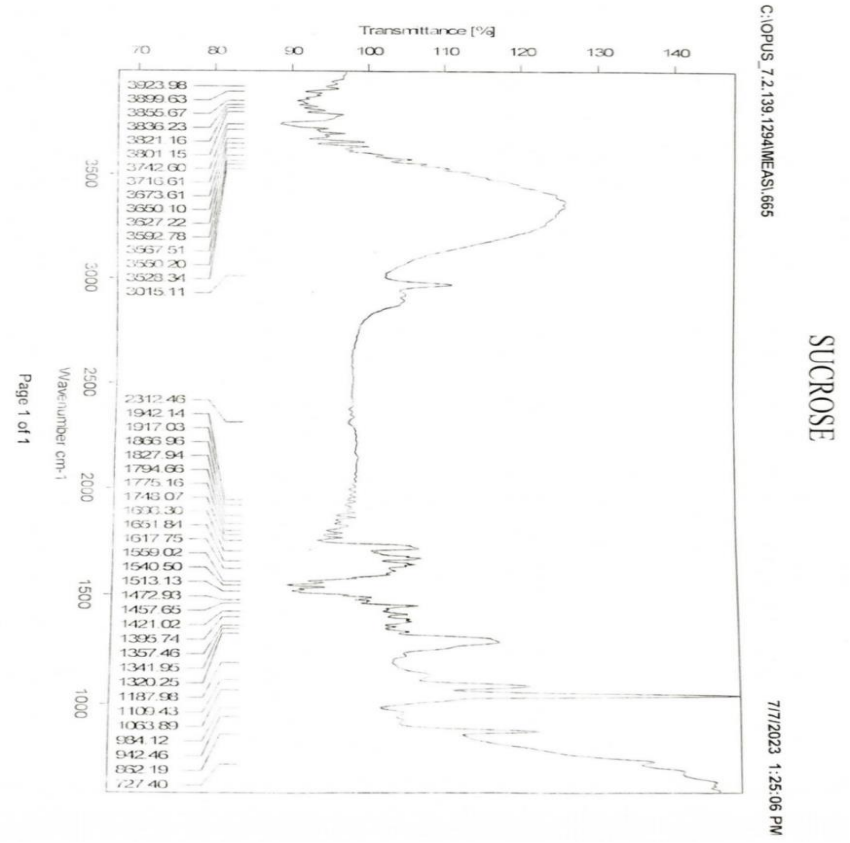

Fig. No 4 Ftir Spectroscopy Of Suvrose

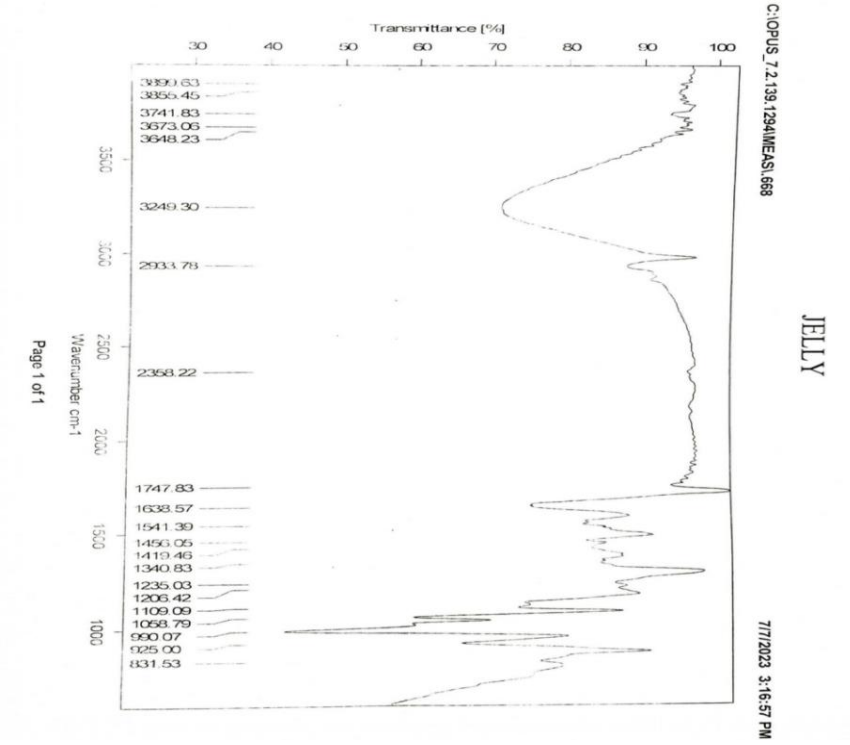

FIG.5 Ftir Spectroscopy Of Jelly

PREPARATION OF JELLY

The main criteria of our project are to prepare stable jelly at room temperature having uniformweight, size, shape and colour even after incorporation of drug. Required amount of water is weighed and taken in a beaker and allowed it to boil. Weighed sugaris added to it and stirred until it gets dissolved. In another beaker we have taken required quantity gelatine and dissolved it in 30 ml of water. Then added this to the prepared sugar syrup. Two dropsof food colour and two drops of food essence is added and mixed well. Transferred the prepared jelly mixture into petri dish. Placed one petri dish in refrigerator and other at room temperature.[9]

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3. EVALUATION

1. Physical appearance

The treated jelly was examined for physical appearance in terms of clarity, texture and thickness. Stickiness and grit Texture of the treated jelly in terms of stickiness and grit hadbeen estimated by visual examination of the product after mildly rubbing the jelly samplebetween two fritters.

Fig.No: 6 Prepared Paracetamol Chewable Paediatric Oral Jelly

Percentage drug content

Jelly is heated until they get liquefied then diluted suitability and absorbents aremeasured. Here blank jelly was also liquefied and used as blank.

After suitable dilutions, absorbance was determined using the UV spectrophotometerkeeping blank jelly as control at wavelength 243 nm.

Dissolution

We are using 6 jelly and 8 litters of 5.8 pH phosphate bufferApparatus – Paddle Medium – pH 5.8 buffer Volume – 900 ml Temperature – 37 +/- 0.5 ℃ Sampling time – 10 min, 20 min, 30 min, 45 min, and 60 min.Rpm – 50 rpm

At each sampling time, 5 ml of sample was removed using pipette and filter the sample and replacewith fresh phosphate buffer pH 5.8. The concentration of drug was determined using a UV spectrophotometer at a wavelength of 243 nm. The percentage drug released was calculated.[10]

4. RESULTS AND DISCUSSION

Spectroscopic studies

Determination of λ_{max}

Diluted samples of concentration 10 ug/ml were prepared from standard solution of Paracetamol in distilled water. The samples were scanned in the range of 200 – 400 nm in 1.0 cm cell against distilled water. Fig. shows the UV absorption spectrum of paracetamol.

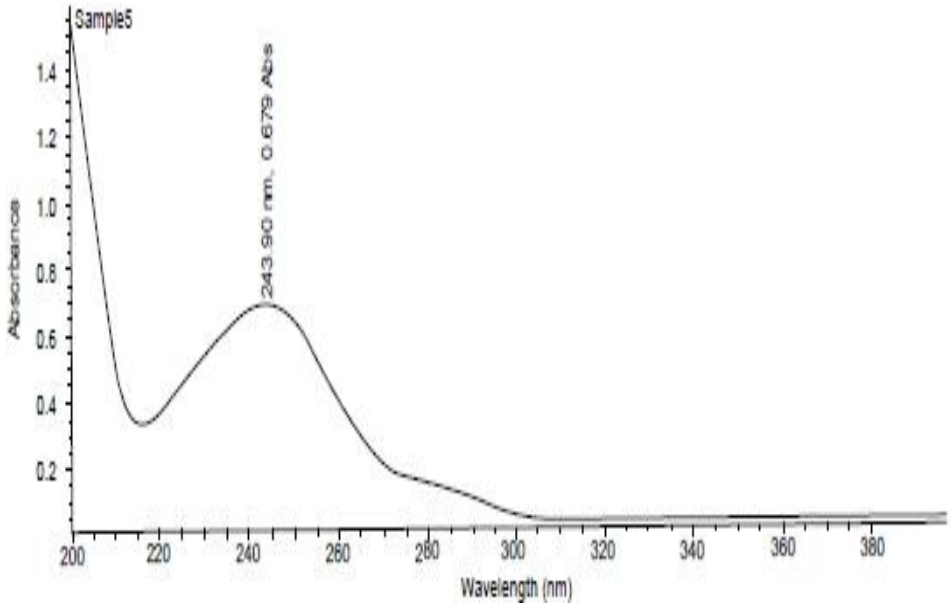

Fig.No: 7 UV absorption spectrum of Paracetamol

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A. Preparation of Standard solutions and Calibration Curve of Paracetamol

Table. 1 : Calibration data of paracetamol

S.No	Concentration (ug/ml)	Absorbance
1.	3	0.134
2.	6	0.251
3.	9	0.365
4.	12	0.472
5.	15	0.596

Diluted samples from standard stock solution of paracetamol were prepared in concentration range of 3 ug/ml to 15 ug/ml. The samples were scanned in the range of 200 – 400 nm in 0.1 cm cell against buffer solution and the spectrum was recorded to determine the linearity of the drug. The UV spectrum for linearity of paracetamol was shown in Fig.18 and data given in Table 10.

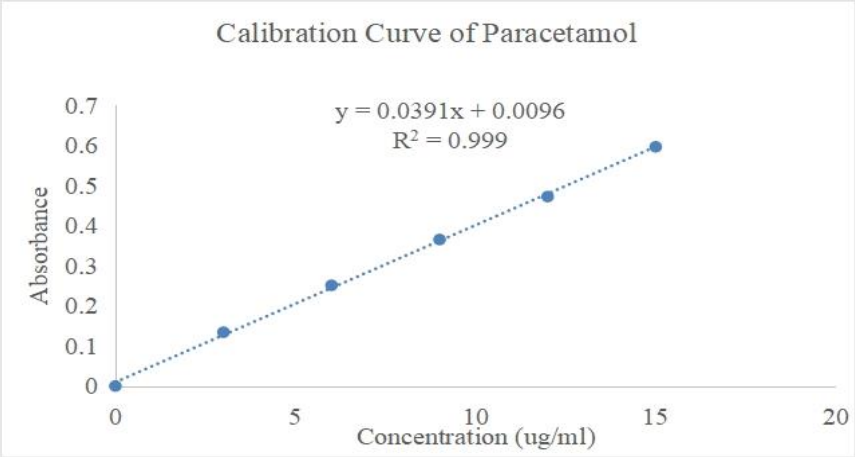

Fig.No: 8 Calibration Curve of Paracetamol

2. Drug – Excipient compatibility studies by FTIR

Fourier Transform infrared spectroscopy (FT-IR) is a simple technique for the detection of changes within excipient-drug mixtures. Disappearance of an absorption peak or reduction ofthe peak intensity combined with the appearance of new peaks give clear evidence for interactions between the excipient and the drug investigated.

Table. 3 : Compatibility studies

Gelatine		Paracetamol drug		Jelly	
C=O	1651.72	OH	3314.32	NH	3648.23
NH	3527.97	NH	3567.42	OH	3249.30
C-N	1320.35	CH	3027.76	C-O-C	2358.22
OH	1420.64			C-N	1340.83
CH	3014.11			C=O	1638.57

The percentage drug content of optimized jelly formulations (C) was tabulated in Table 12. Theresults indicated the suitability of the system for high entrapment in the internal phase.

Table. 2 : Percentage drug content

Formulation code	% Drug content
1	97
2	98
3	98
4	99
5	96

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3. pH determination

The pH of optimized jelly formulation (C) was tabulated in Table.13 The pH of jelly C was nearto the limit.

Table. 3 : pH of Prepared jelly

Formulation code	pH
1	6.8
2	6.9
3	7.0
4	6.5
5	6.8

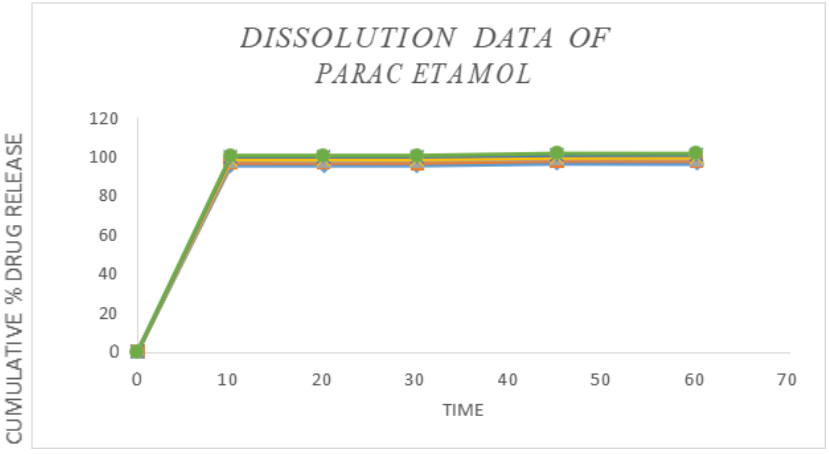
4. Dissolution Studies

After performing dissolution studies on six jelly, the samples of paracetamol were collectedin between the range of 10 min to 60 min. The samples were scanned at the wavelength of 243nm in 0.1 cm cell against buffer solution and the absorbance are been collected and recorded.The % of drug release shown in Table. 14. The graph is plotted between time and cumulative

% drug release shown in Fig. No. 16.

Table. 4: Dissolution data of paracetamol jelly

Time (min)	Cumulative % Drug Release					
	1	2	3	4	5	6
10	95.0191	96.4596	97.6986	98.2345	99.6578	100.2588
20	95.0289	96.4659	97.6245	98.2455	99.6789	100.2789
30	95.0256	96.4245	97.6785	98.2254	99.6236	100.2145
45	96.0785	97.4258	98.6861	99.2168	100.6248	101.2268
60	96.0486	97.4426	98.6153	99.2759	100.6426	101.2486



We observed that more than 95% of paracetamol is released within 10 min.Fig. No: 19 Dissolution studies of Paracetamol jelly

5. Physical Evaluation

Texture, clarity of soft gel is been visually seen with our eyes and analyzed.

5. CONCLUSION

Paracetamol jelly was prepared by using sucrose, gelatine, food colour and essence. The compatibility studies of drug and excipients was by FT-IR and confirmed that there is no physicochemical interaction. The organoleptic properties and physicochemical parameters like stickiness, texture, grittiness, drug content and pH were found to be ideal and within the acceptable range. The average pH was found to be within the range of 6.8. The average of percentage drug content was found to be 97.6 %. The average percentage of drug release is 98.426 %. The texture, clarity of the jelly was also found to be good. This type of jelly can be used not only for synthetic drug but can also be made using herbal and nutritional agents which can be used in children.

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