International Research Journal of Plant Science (ISSN: 2141-5447)
Vol. 13(5) pp. 01-13, November, 2022
DOI: http:/dx.doi.org/10.14303/irjps.2022.031
Available online @ https://www.interesjournals.org/plant-science.html


*Research Article*

# Formulation and development of pediatric herbal jelly from papaya seeds for anthelmintic infection

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**Abstract**

Papaya seeds are claimed to possess anthelmintic property in traditional system of medicines. Papaya seeds extract was incorporated in the jelly which is administered orally without water. The oral jelly was prepared by heating method by using various polymer with different concentration. As the extract was bitter in taste so taste masking is important parameter while designing the dosage forms, it is mainly done by adding sweeteners and flavors.

**Keywords:** Medicated jelly, Taste masking, Anthelmintic property, Gelling agents.

## INTRODUCTION

Tropical plant Carica papaya Linn. A member of the Brassicales family and a member of the Caricaceae, is widely cultivated in tropical and subtropical regions. It is one of the most fertile fruits, the whole papaya includes the leaves, roots, barks, peels and seeds have the biological processes that include antioxidants, anti- inflammatory, anti-cancer, anti-bacterial and anti- fungal activity.( Gathuma et al., 2004), (Mhaskar et al., 2000), (Gill 1992), (Manivannan et al., 2009), (Adebiyi & Adaikan 2005), (Verma et al., 2006), (Cuña et al., 19997). The papaya fruits are tasty and healthy. Numerous amino acids and trace elements are present, Benzyl isothiocyanate (BITC), an active compound of papaya fruit, is an isothiocyanate (ITC). ITC are widely distributed naturally in cruciferous plant, including broccoli, watercress, and Brussels sprouts, cabbage, cauliflower, and sprouts. There are report of them, to possess qualities that benefit human health. These days BITC has also developed into a hub for its actions that are antibacterial, anticancer, and other. In 2017, in papaya, or study discovered that BITC had antifungal properties against Candida spp. In the course of ripening, papaya seeds and pulp undergo transformation. The nutritional value and the action components of BITC are both significant. The amount of BITC present in papaya fruits must be closely monitored, Chromatography is the primary method used at the moment of analysis BITC in papaya fruits. In order to accomplish the goal of this approach, sample are often pretreated before examination technique such concurrent distillation and steam. There have been application of distillation and solvent extraction to papaya, extract BITC .(Arora et al., 2018), (Huang et al., 2019), (Azaiez et al., 2013), (Yang et al., 2020), (Nakamura et al., 2007), (He et al., 2017), (Almora et al., 2004), (Li et al., 2014), (da Rocha et al., 2017), (Soria et al., 2015), (Xie, Yu & Gong 2019). These techniques call for a lot of hazardous and hostile organic solvents and are typically time- consuming, labor-intensive, and poorly sensitive sensitive. To examine BITC in papaya pulp, headspace solid- phase microextraction (HS-SPME) has been used as an alternative. However, the material utilized in HS-SPME are pricy, transient, and frequently leave residuals behind. Therefore, creating a sample pretreatment procedure that is quick, precise, highly selective, and environmentally friendly is crucial for the determination of BITC in papaya fruits (Gimeno et al., 2018), (Khandelwal 1994).

**Received:** 29-Sep-2022, Manuscript No. IRJPS-22-77297; **Editor assigned:** 01-Oct-2022, PreQC No. IRJPS-22- 77297(PQ); **Reviewed:** 15-Oct-2022, QC No. IRJPS-22- 77297; **Revised:** 20-Oct-2022, Manuscript No. IRJPS-22- 77297(R); **Published:** 27-Oct-2022

**Citation:** Mrynal Chamoli (2022). Formulation and development of pediatric herbal jelly from papaya seeds for anthelmintic infection. IRJPS. 13: 031.

# METHODOLOGY

The papaya seeds were obtained from nearby market in premnagar, Uttarakhand. The gelatin, citric acid, methyl paraben, propyl paraben, dextrose was issued from the central store of our collage (SGRRU). All chemicals and reagents were used of analytical grade and were procured from authorized dealers

### Extraction procedure

- The papaya seed was removed from the papaya fruit and rish it twice and dried in shade for 2 weeks.
- The dried seeds were grinded and then sieve through sieve no 40 and stored in air tight container separately for the further procedure.
- The powered seeds were filled in the thimble in the soxlet apparatus for the extraction process through hot percolation method.
- In this process methanol used as a solvent and reflux it for 3 hours.
- After 3 hours the obtained yellow color liquid extract was complete dried and stored in the air tight container for the further process and evaluation parameters testing (Nayak et al., 2016).

### Preparation method of herbal jelly

i. The jellies were prepared by heating method using different polymers of different quantities.

ii. The sugar syrup will be prepared.

iii. To the sugar syrup the gelling agent is added with continuous stirring and heated.

iv. As the gelling agent dissolves completely, stabilizers and solubilizes are added to it and boiled for few min, thoroughly mixed.

v. When the mixture was completely dissolved with continuous stirring.

vi. Then, drug (herbal extract) was added to it with continuous stirring, colour and flavour was added, jellies could have settled down and thoroughly mixed.

vii. The final weight was adjusted with purified water

viii. Then, transferred into moulds and the mixture could cool to room temperature to form jelly (Dubey & Sheth 2015), (Ambedkar & Karthik 2015).

### Evaluation parameter

The oral jelly was evaluated for clarity, odor, and color.

Weight Variation: This variable is based on the average weight of 10 jellies after they have been removed from their moulds, weighed, and mixed separately in a beaker.

To Determine Stickiness And Grittiness, Rub The Jelly Between Two: Fingers It is visually determined how sticky and gritty it is (Anand et al., 2015).

Pourability of The Mixture: The major characteristic of jelly is that it can be readily poured into the moulds by adding buffer salts that function as retardants, such as trisodium citrate. These retardants often elevate the pH of the formulation before the addition of acid, halting pre-gelation. As the retarder concentration is high, the lower the setting temperature and longer the setting time, which aids in setting and pouring the jelly.

pH Determination: The pH is determined by digital pH meters as jelly is dispersed in distilled water (50%) and 1%solution is prepared, the pH was noted.( Kumar et al., 2018), (Jadhav et al., 2017).

Content Uniformity: This assessment is carried out for each dosage form to guarantee the consistency of the drug substance's content. The jelly is crushed and then mixed, the extraction of this combination is carried out using appropriate media, and the amount of drug was calculated using an analytical approach (Ahire et al., 2016), (Prakash 2014).

Viscosity: A Brookfield viscometer is used to test viscosity, and a new sample is used each time (Nayak 2016).

It is computed as follows: Dial reading factor+viscosity in centipoise 2

Spreadability: Spreadability is assessed by sandwiching jelly between two glass slides, which is then uniformly flattened with a weight of 1000gm. The Spreadability of the two slides' separation time was calculated. it is determined by

a. $S=m \times L/T$

b. Where m=weight tide to upper slide

c. T=time taken

d. L=length moved on glass slide (Prakash 2014)

Stability studies: Stability studies are carried out in accordance with ICH criteria and may be evaluated by storing the produced jelly for 90 days at room temperature and analyzing the physical changes that occur (Mathew 2015).

Syneresis: This process involves the separation of liquid by the contraction of a gel, and the jelly preparation was assessed after 24 hours at room temperature

Microbial investigations: These studies are critical in establishing the microbial composition of jellies. since

jellies' high-water content makes them more susceptible to microbial development. E. coli, S. aureus, and P. aeruginosa were examined in the jellies' ability to cultivate infections on a particular medium.

The consistency of the gel was created by compressing 20 jellies. A predetermined amount of gel equal to 50mg of the medicine is added, and this is well mixed with the necessary amount of water. The solution was sonicated for 45 minutes, followed by the preparation of a 50ml volume, a filter, and a dilution. UV spectroscopy is used to verify the absorption as a result.

Invitro Taste Analysis: Prepared jelly's taste competence was evaluated using a 5-cc simulated salivary pH. One jelly from each batch is added to 5 ml of solution in a 50 ml beaker and stirred for 60 to 120 seconds before the solution is filtered. The presence of drugs was checked in filtrates using UV.

Dissolution Studies: Using a USP paddle device type 2 and 900 ml of phosphate buffer 6.8 as the dissolution medium at 50 rpm, jelly was successfully drug-dissolved in vitro. The temperature was maintained at 37 C plus or minus 0.5 C. At predetermined intervals of 5, 10, 15, 20, 25, 30, 35, and 40 minutes, 5 ml of sample was removed from the dissolving equipment and replaced with new dissolution medium. A U.V spectrometer was used to identify the release method, and the release study was computed using kinetic models.

# RESULT AND DISCUSSION

Organoleptic properties of Herbal powder was observed by physical and visual method. The observed properties were matched with the given standard observed data. (Table 1)

As per the observation Herbal powder is sparingly soluble in water, soluble in ethanol and soluble in phosphate buffer 6.8. (Table 2).

The standard calibration of Herbal powder was prepared in phosphate buffer 6.8: (Table 3-14).

The standard curve plot between concentration and absorbance. The value of $R^2$ was found to be 0.9971. So, the

**Table 1.** Qualitative chemical tests for extracts of Anthelmintic drugs.

| Constituents | Aq. Extract |
|---|---|
| Flavonoids | + |
| Tannins | + |
| Alkaloids | + |
| Phlobatannins | - |
| Steroids | + |
| Glycosides | - |

**Table 2.** Organoleptic properties.

| S.No. | Properties | Result |
|---|---|---|
| **1.** | Description | Solid |
| **2.** | Colour | Brownish black |
| **3.** | Odour | Pungent |

**Table 3.** Solubility studies.

| S.No | Solvents | Concentration (µg/ml) | Report |
|---|---|---|---|
| **1** | Water | 12.5033 | Sparingly soluble |
| **2** | Ethanol | 65.4014 | Soluble |
| **3** | Phosphate buffer 6.8 | 44.145 | Soluble |

**Table 4.** Calibration Curve of Herbal Powder.

| S.No | Concentration(µg/ml) | Absorbance(nm) |
|---|---|---|
| **1** | 2 | 0.1181 |
| **2** | 4 | 0.2243 |
| **3** | 6 | 0.3252 |
| **4** | 8 | 0.4520 |
| **5** | 10 | 0.5481 |
| **6** | 12 | 0.6295 |
| **7** | 14 | 0.7875 |
| **8** | 16 | 0.8730 |

**Table 5.** The standard calibration of Herbal powder was prepared in water.

| S.No | Concentration(µg/ml) | Absorbance (nm) |
|---|---|---|
| **1** | 0 | 0 |
| **2** | 5 | 0.2156 |
| **3** | 10 | 0.2864 |
| **4** | 15 | 0.3586 |
| **5** | 20 | 0.5316 |
| **6** | 25 | 0.6350 |
| **7** | 30 | 0.8522 |
| **8** | 35 | 0.9820 |

**Table 6.** The standard calibration of Herbal powder was prepared in ethano.

| S.No | Concentration(µg/ml) | Absorbance(nm) |
|---|---|---|
| **1** | 0 | 0 |
| **2** | 5 | 0.1270 |
| **3** | 10 | 0.2659 |
| **4** | 15 | 0.4287 |
| **5** | 20 | 0.6201 |
| **6** | 25 | 0.6838 |
| **7** | 30 | 0.9169 |
| **8** | 35 | 1.0801 |

**Table 7.** Interpretation data.

| S.No | Herbal powder | Herbal powder + gelatine | Herbal Powder + sodium alginate | Standard frequency range ($cm^1$) | Interpretation |
|---|---|---|---|---|---|
| **1** | 1598.84 | 1595.63 | 1598.98 | 1600-1200 | Alkyl compound C=C |
| **2** | 722.22 | 765.85 | 776.11 | 900-650 | Aromatic bending C=C |
| **3** | 2924.27 | 2925.65 | 2925.67 | 3000-2850 | C-H |

**Table 8.** Formulation composition of Herbal Jelly.

| Ingredients | S1 | S2 | S3 | S4 |
|---|---|---|---|---|
| **Herbal extracts mL** | 10 | 10 | 10 | 10 |
| **Gelatine (%)** | 1.5 | 2 | 2.5 | 3 |
| **Glycerine (ml)** | 2 | 2 | 2 | 2 |
| **Citric acid (%)** | 1 | 1 | 1 | 1 |
| **Propylene-glycol(ml)** | 3 | 3 | 3 | 3 |
| **Sugar (%)** | 60 | | | |
| **Colouring agent(ml)** | 0.5 | 0.5 | 0.50 | 0.5 |
| **Flavouring agent(ml)** | 1ml | 1ml | 1ml | 1ml |
| **Distilled water** | q.s | q.s | q.s | q.s |

**Table 9.** Various evaluation parameters of Herbal Oral Jelly.

Organoleptic properties:

| Formulation code | Appearance | Texture | Sugar crystallization | Stickiness and grittiness |
|---|---|---|---|---|
| **S1** | Translucent but water bubbles are found | Smooth | No | Slightly sticky & gritty |
| **S2** | Translucent with uniform consistency | Smooth | No | Non-sticky & less gritty |
| **S3** | Translucent with uniform consistency | Smooth | No | Non-sticky & less gritty |
| **S4** | Translucent but slightly thick | Smooth | No | Non-sticky & less gritty |

**Table 10.** Observation.

| Formulation code | pH±S.D (n=3) | Viscosity (cps) | Spreadability ±S.D(n=3) $cm^2$ | Weight variation ± S.D (n=3) | Syneresis | Taste analysis | Drug content ± S.D (n=3) |
|---|---|---|---|---|---|---|---|
| **S1** | 7±0.404 | 35200 | 22.21±0.15 | 22.21±0.15 | No | 1.82% | 98.66±0.428 |
| **S2** | 6.8±0.321 | 28200 | 18.70±0.09 | 18.70±0.09 | No | 0.97% | 99.10±0.502 |
| **S3** | 6.7±0.267 | 44000 | 12.90±0.12 | 12.90±0.12 | No | 0.92% | 96.66±0.297 |
| **S4** | 6.9±0.503 | 44600 | 13.56±0.14 | 13.56±0.14 | No | 0.87% | 97.51±0.492 |

**Table 11.** *In-vitro* drug release studies.

| S.no. | Time (min) | Cumulative percent drug release (%C. R) | | | |
|---|---|---|---|---|---|
| Formulation code-> | | SF1 | SF2 | SF3 | SF4 |
| **1** | 0 | 0 | 0 | 0 | 0 |
| **2** | 5 | 23 | 20.28 | 14.28 | 11.5 |
| **3** | 10 | 28.43 | 28.04 | 19.8 | 18.14 |
| **4** | 15 | 33.65 | 39.81 | 23.95 | 26.94 |
| **5** | 20 | 43.57 | 52.26 | 31.28 | 31.94 |
| **6** | 25 | 59.33 | 64.50 | 40.71 | 34.32 |
| **7** | 30 | 74.85 | 77.69 | 45.71 | 39.54 |
| **8** | 35 | 87.44 | 89.81 | 59.99 | 44.44 |
| **9** | 40 | 96.21 | 97.08 | 69.39 | 58.52 |

**Kinetic studies**

**Table 12.** Formulation SF1.

| S.no. | time | Square root of time | Log time | Cumulative percent drug release | Log cumulative percent drug release | Log cumulative percent drug remaining |
|---|---|---|---|---|---|---|
| **1** | 0 | 0 | 0 | 0 | 0 | 0 |
| **2.** | 5 | 2.23 | 0.698 | 23 | 1.36 | 1.886 |
| **3.** | 10 | 3.16 | 1 | 28.43 | 1.453 | 1.854 |
| **4.** | 15 | 3.87 | 1.17 | 33.65 | 1.526 | 1.821 |
| **5.** | 20 | 4.47 | 1.301 | 43.57 | 1.639 | 1.751 |
| **6.** | 25 | 5 | 1.397 | 59.33 | 1.726 | 1.609 |
| **7.** | 30 | 5.47 | 1.477 | 74.85 | 1.874 | 1.400 |
| **8.** | 35 | 5.91 | 1.544 | 87.44 | 1.941 | 1.098 |
| **9.** | 40 | 6.32 | 1.620 | 96.21 | 1.983 | 0.578 |

**Table 13.** Formulation SF2.

| S.no. | Time | Square root of time | Log time | Cumulative percent drug release | Log cumulative percent drug release | Log cumulative percent drug remaining |
|---|---|---|---|---|---|---|
| **1** | 0 | 0 | 0 | 0 | 0 | 0 |
| **2.** | 5 | 2.23 | 0.698 | 20.28 | 1.3070 | 1.901 |
| **3.** | 10 | 3.16 | 1 | 28.04 | 1.4477 | 1.857 |
| **4.** | 15 | 3.87 | 1.17 | 39.81 | 1.599 | 1.779 |
| **5.** | 20 | 4.47 | 1.301 | 52.26 | 1.718 | 1.678 |
| **6.** | 25 | 5 | 1.397 | 64.50 | 1.809 | 1.550 |
| **7.** | 30 | 5.47 | 1.477 | 77.69 | 1.890 | 1.3484 |
| **8.** | 35 | 5.91 | 1.544 | 89.81 | 1.953 | 1.008 |
| **9.** | 40 | 6.32 | 1.620 | 97.08 | 1.9871 | 0.465 |

**Table 14.** Formulation SF3.

| S.no. | Time | Square root of time | Log time | Cumulative percent drug release | Log cumulative percent drug release | Log cumulative percent drug remaining |
|---|---|---|---|---|---|---|
| **1** | 0 | 0 | 0 | 0 | 0 | 0 |
| **2.** | 5 | 2.23 | 0.698 | 14.28 | 0.1072 | 1.933 |
| **3.** | 10 | 3.16 | 1 | 19.8 | 1.296 | 1.904 |
| **4.** | 15 | 3.87 | 1.17 | 23.95 | 1.379 | 1.881 |
| **5.** | 20 | 4.47 | 1.301 | 31.28 | 1.495 | 1.837 |
| **6.** | 25 | 5 | 1.397 | 40.71 | 1.609 | 1.772 |
| **7.** | 30 | 5.47 | 1.477 | 45.56 | 1.658 | 1.735 |
| **8.** | 35 | 5.91 | 1.544 | 59.99 | 1.7749 | 1.602 |
| **9.** | 40 | 6.32 | 1.620 | 69.39 | 1.8412 | 1.485 |

equation can be used for the further calculation (Figure 1).

The standard curve plot between concentration and absorbance. The value of $R^2$ was found to be 0.9833. So, the equation can be used for the further calculation (Figure 2).

The standard curve plot between concentration and absorbance. The value of $R^2$ was found to be 0.9936. So, the equation can be used for the further calculations (Figure 3).

Drug- excipient compatibility study was performed by using FTIR. By matching the main peak of drug with polymers, there is no significant difference observed in between the peaks of the herbal powder and polymer. So, it may be concluded that there was no possible interaction between drug and selected polymer. (Figure 4-6).

From all formulation we concluded that each batch having smooth texture. Although appearance is translucent in all formulation but the S1 contain little bubble in it, S4 is slightly thick and S2 & S3 formulation having uniform consistency. While formulation S2 to S4 exhibit no such stickiness and grittiness. The formulation S1&S2 show no sugar crystallization means sugar is properly dissolved in mixture i.e. no crunches are present. It was concluded that S2&S3 formulation showed acceptable jelly formulation. (Figure 7).

The pH determines the taste and stability of jellies formulation are found in the range 0f 6.9 ± 0.503 to 7 ± 0.404 which is near to neutral. So, minimum amount of citric acid is added to maintain pH (Figure 8).

The viscosity was found in the range of 44600-28200 cps. As the viscosity is decrease the drug flow increases (Figure 9)

The Spreadability of formulation was found to decrease with the increase in the concentration of gelling agent. (Figure 10)

The weight variation varies from 0.82 gm to 0.91gm (Figure 11).

There was no syneresis observed in the optimized formulation at the specified temperature The taste determination was found in the range of 0.87% to 1.82%

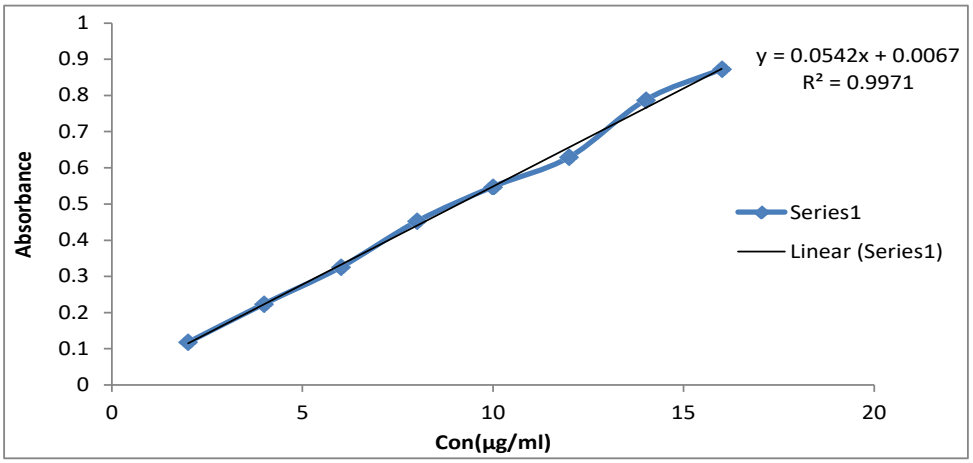


**Figure 1.** Calibration Curve in phosphate buffer.

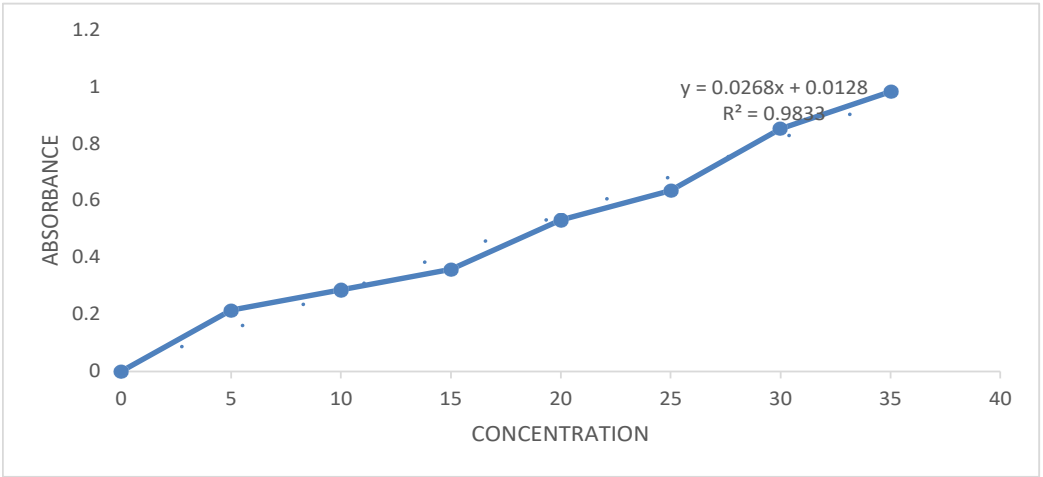


**Figure 2.** Calibration curve in water.

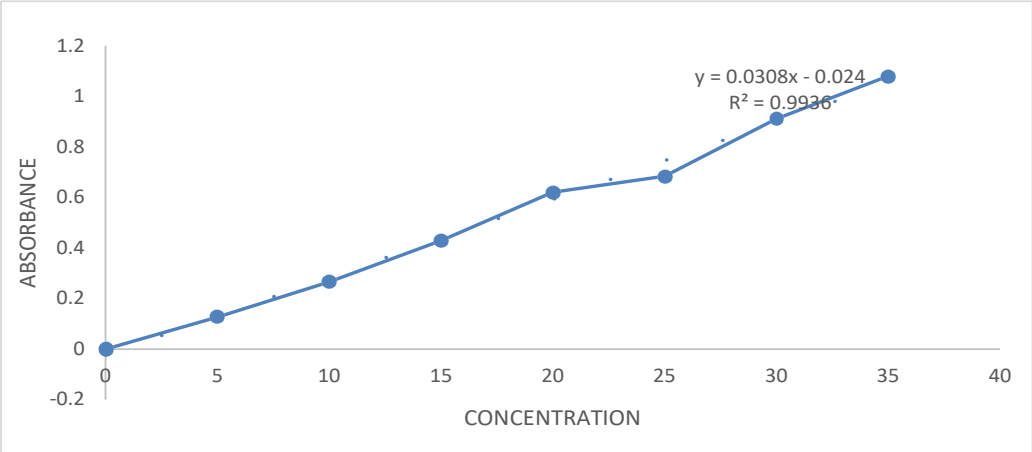


**Figure 3.** Calibration curve in ethanol.

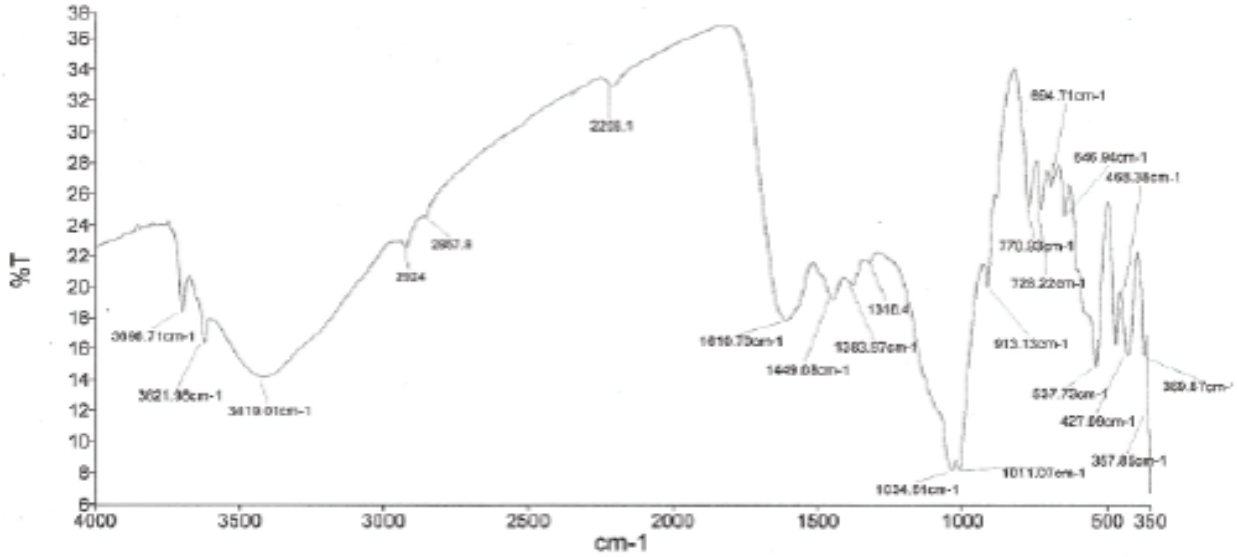


**Figure 4.** Standard FTIR of papaya seed extract.

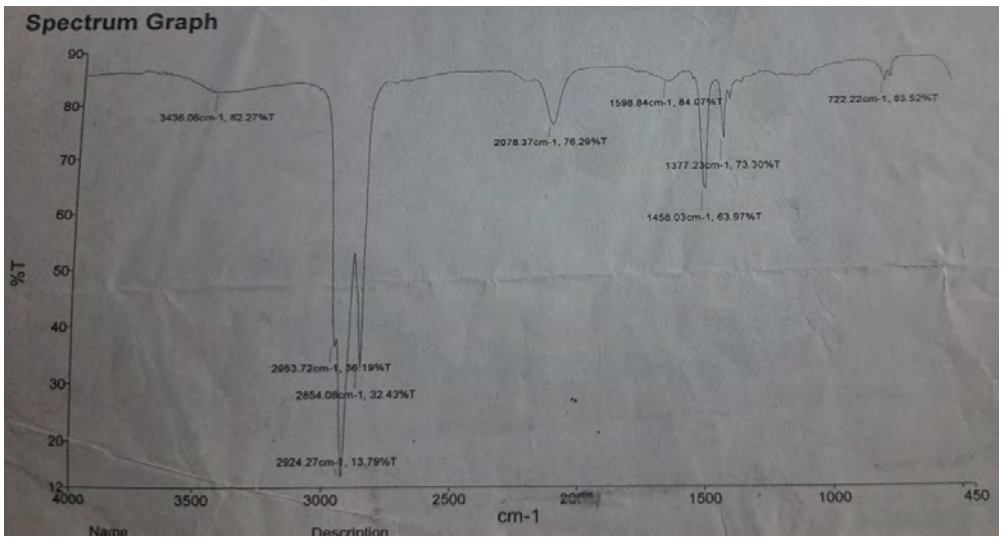


**Figure 5.** FTIR of herbal extract.

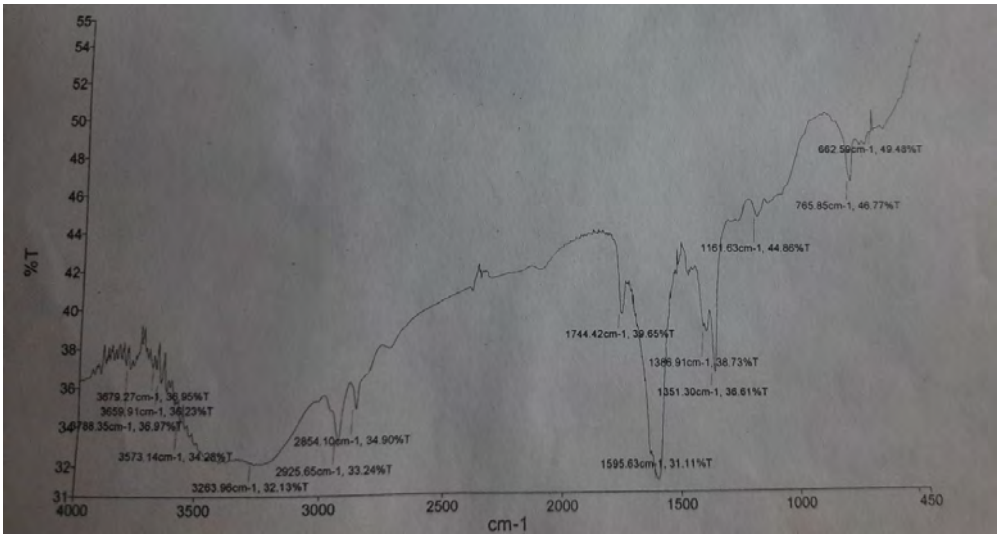


**Figure 6.** FTIR of Herbal powder and gelatin.

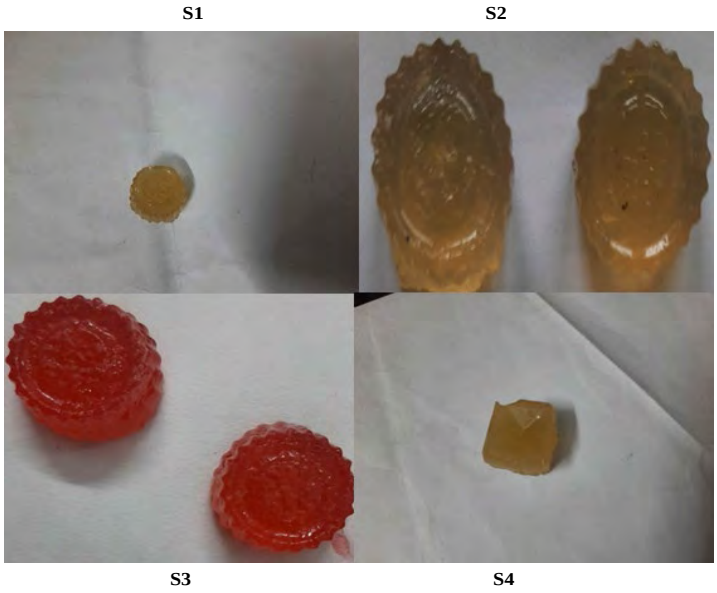


**Figure 7.** Picture of jelly formulation from S1 to S2.

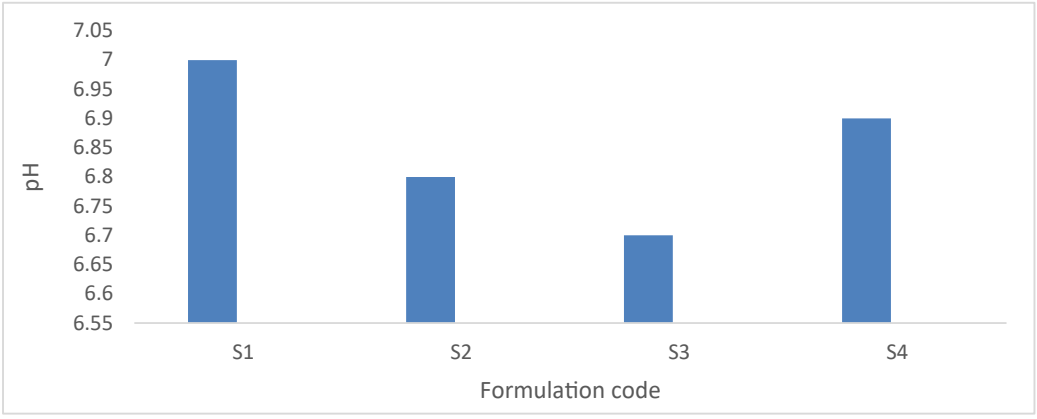


**Figure 8.** pH determination of different formulation.

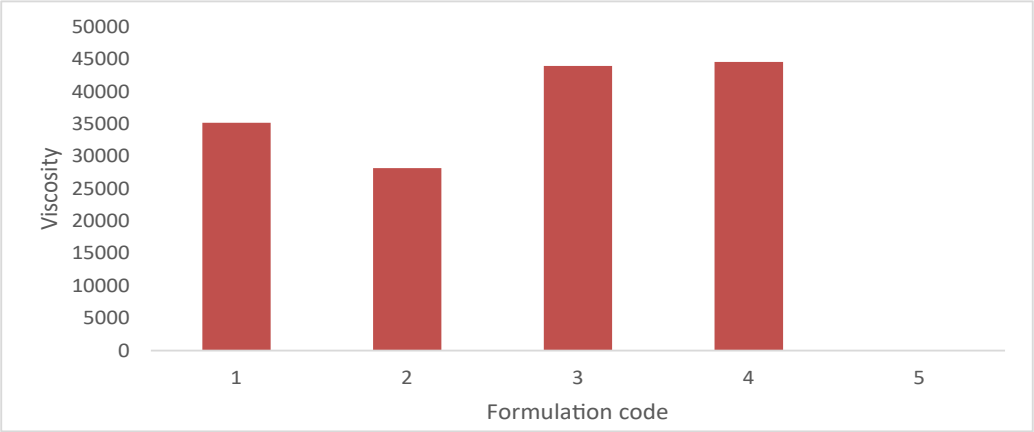


**Figure 9.** Shows the viscosity determination of different formulation.

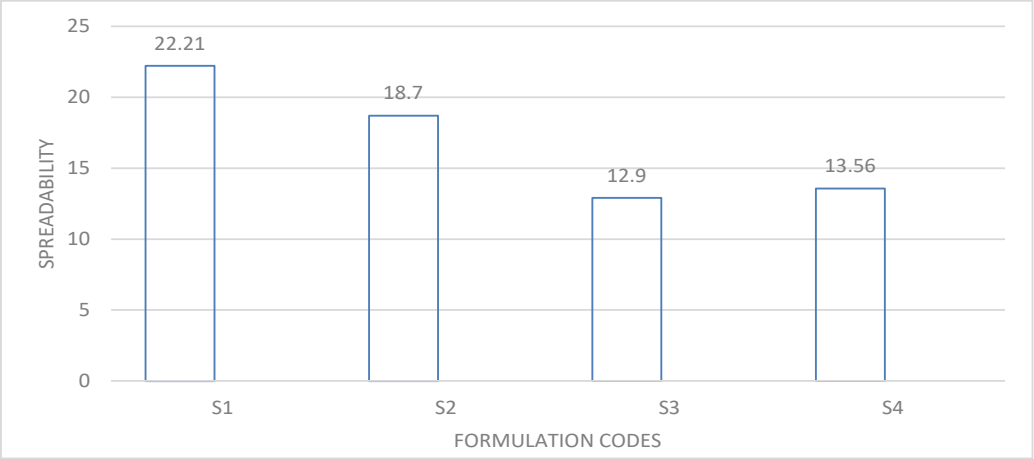


**Figure 10.** Show the viscosity determination of different formulation.

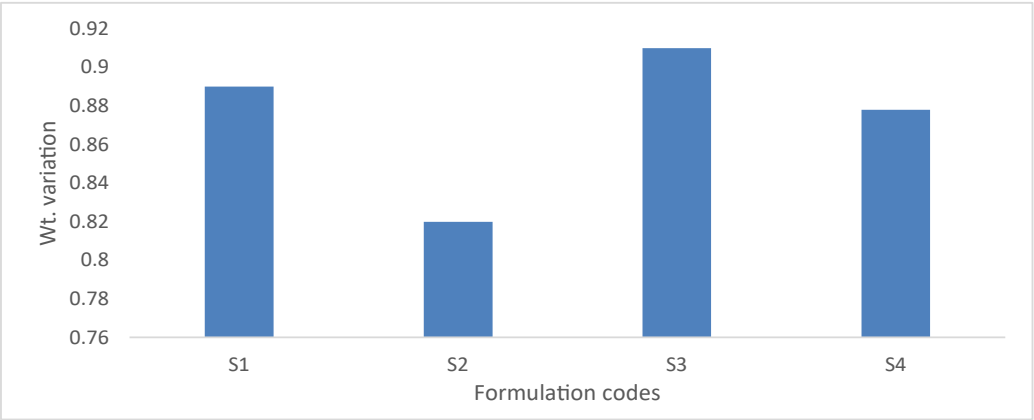


**Figure 11.** Show the weight variation of different formulate.

which lies in scale range of no bitterness and threshold bitter. Hence, it can be co-related to taste feel.(Figure 12).

The drug content of formulation S2 was found to be 99.1(Figure 13).

The invitro drug release of formulation SF1 to S4 were studied. All formulation shows different level of drug release ranging from 58.52 to 97.08%. it has been evaluated that as the low concentration of gelling agent shows the significant drug release SF1 & SF2 (96.21 % & 97.08 %). The formulation SF1 and SF2 containing lowest concentration of gelling agent. (Figure 14).

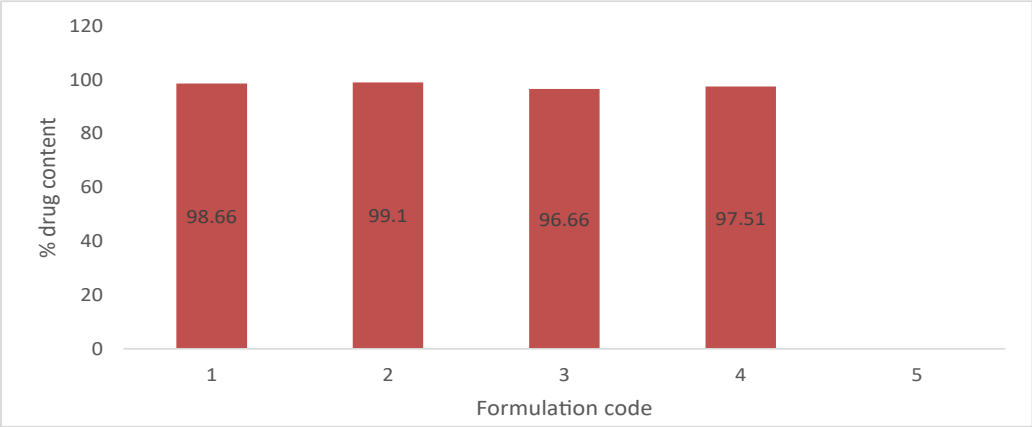


**Figure 12.** Shows the precent drug content.

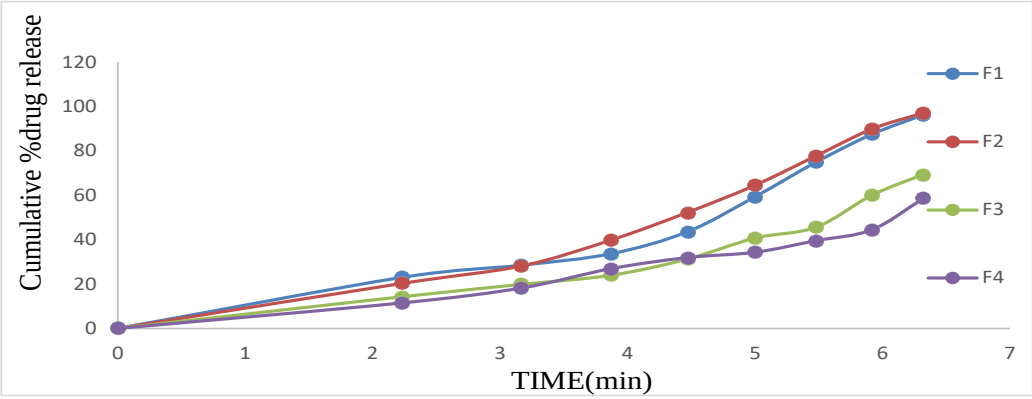


**Figure 13.** Shows the *in vitro* drug release model between %CR and time.

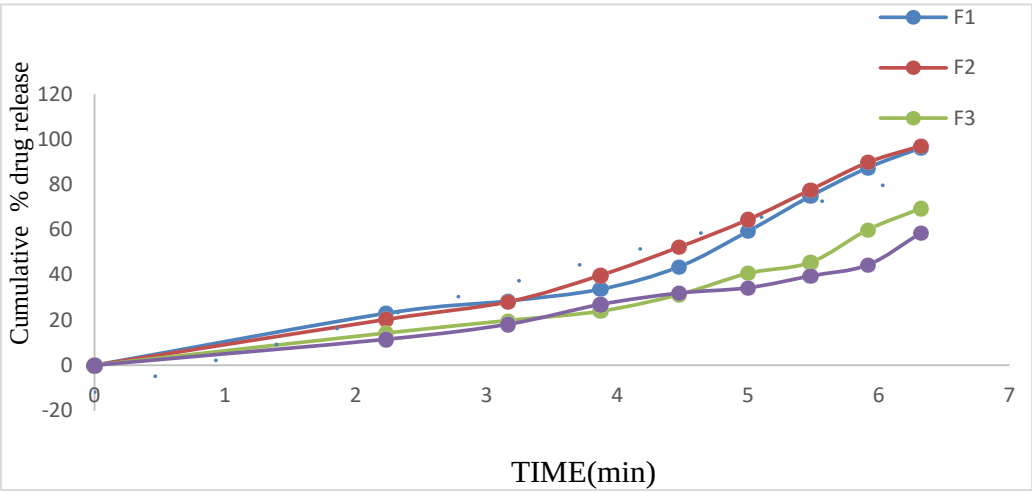


**Figure 14.** Kinetic release model of zero order release between Cumulative %drug release and time.

Drug release kinetic model are used to illustrate the drug release mechanism. For this various model are used like zero order, higuchi, first order, korsmeyer peppas to obtain the value of R2 value and n-value for the determination of best fit model. R2 value was compared for all the formulation which shows the bestfit model and by noticing n-value which is obtained from korsmeyer peppas model (Figure 15-17). Release mechanism was described by an equation:

$Mt/M\infty=ktn$

The observed data of kinetic model shows the best fit model for prepared oral medicated jelly was determined

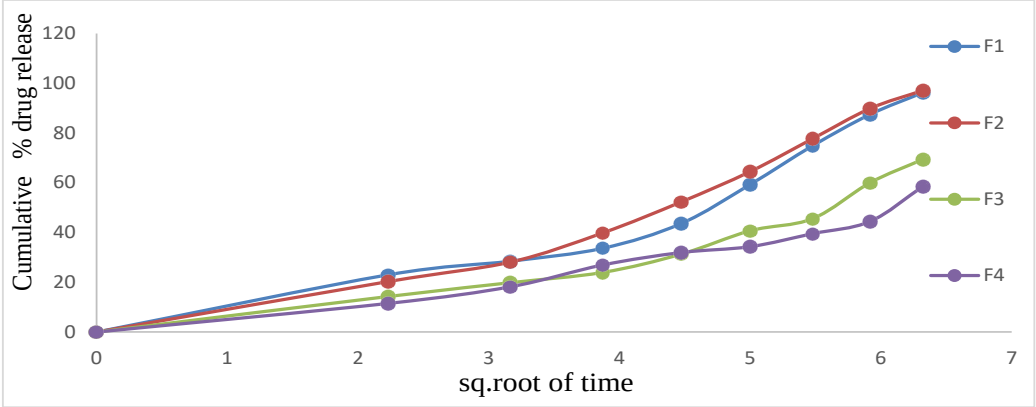


**Figure 15.** Kinetic release model of higuchi release between Cumulative %drug release and square root of time.

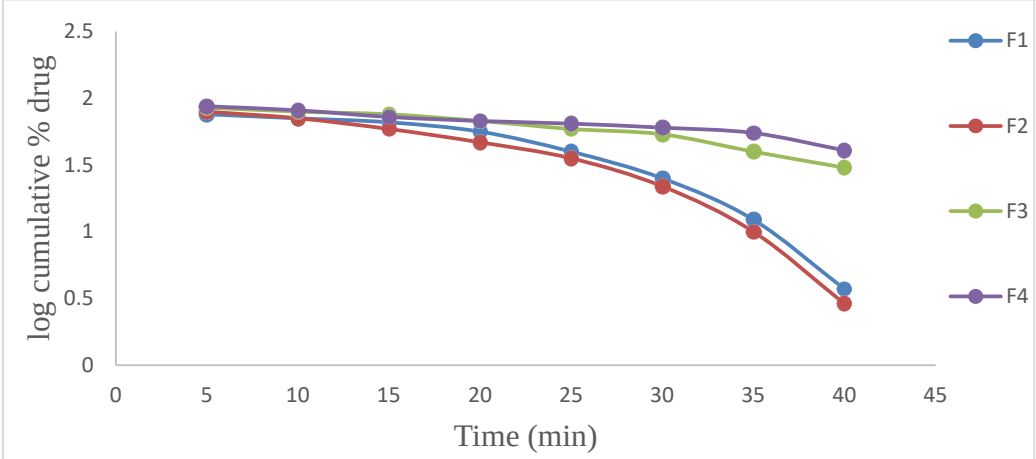


**Figure 16.** Kinetic release model of first order release between log Cumulative %drug release and time.

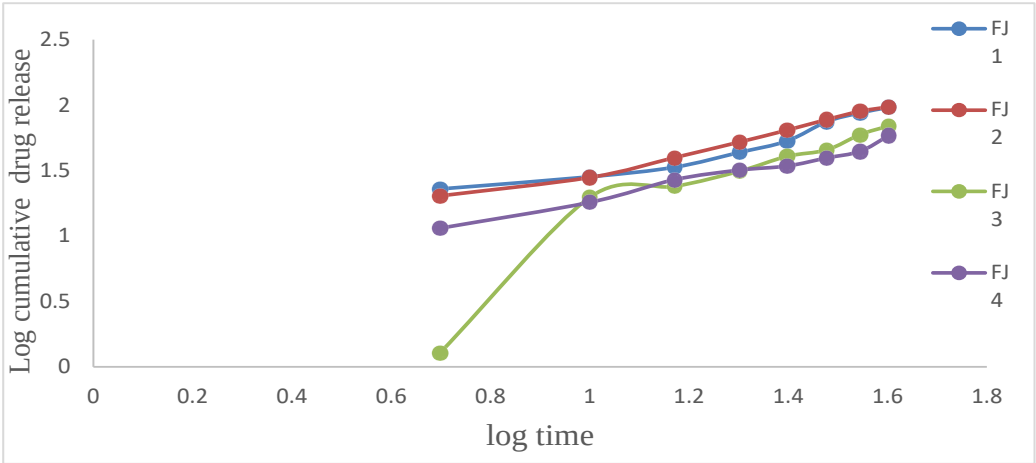


**Figure 17.** Kinetic release model of korsemeyer peppas release between log Cumulative %drug release and log time.

by regression coefficient(r2) in all formulation. The highest r2 value determine the best fit model, the observed data shows the zero- order release in all formulation i.e, the drug release is independent of concentration. Formulation SF1, SF2 & SF4 shows the non-fickian diffusion and SF3 shows the supercase transport which depends upon the loss of polymeric chain and the release of drug takes place (Table 15-17).

**Table 15.** Formulation SF4.

| S.no. | Time | Square root of time | Log time | Cumulative percent drug release | Log cumulative percent drug release | Log cumulative percent drug remaining |
|---|---|---|---|---|---|---|
| **1** | 0 | 0 | 0 | 0 | 0 | 0 |
| **2.** | 5 | 2.23 | 0.698 | 11.5 | 1.060 | 1.946 |
| **3.** | 10 | 3.16 | 1 | 18.14 | 1.258 | 1.913 |
| **4.** | 15 | 3.87 | 1.17 | 26.94 | 1.430 | 1.863 |
| **5.** | 20 | 4.47 | 1.301 | 31.94 | 1.504 | 1.832 |
| **6.** | 25 | 5 | 1.397 | 34.32 | 1.535 | 1.816 |
| **7.** | 30 | 5.47 | 1.477 | 39.54 | 1.597 | 1.781 |
| **8.** | 35 | 5.91 | 1.544 | 44.44 | 1.6477 | 1.744 |
| **9.** | 40 | 6.32 | 1.620 | 58.52 | 1.7673 | 1.617 |

**Table 16.** Drug release kinetic with model fitting.

| Formulation Code | R2 | | | n value | Best fit model | Mechanism of release |
|---|---|---|---|---|---|---|
| | Zero order | First order | Higuchi matrix | | | |
| **SF1** | 0.9813 | 0.8291 | 0.9026 | 0.727 | Zero order | Non- fickian diffusion |
| **SF2** | 0.9944 | 0.8586 | 0.937 | 0.795 | Zero order | Non- fickian diffusion |
| **SF3** | 0.9814 | 0.9182 | 0.8963 | 1.681 | Zero order | Supercase Ⅱ transport |
| **SF4** | 0.9686 | 0.9209 | 0.9376 | 0.73 | Zero order | Non- fickian diffusion |

**Table 17.** Followed by standard release mechanism table.

| n value | Release mechanism |
|---|---|
| 0.5 | Fickian diffusion |
| 0.5<n<1 | Non – fickian diffusion |
| 1 | Supercase Ⅱ transport |

# CONCLUSION

To be concluded that prepared medicated herbal jelly is more organoleptically accepted particularly by patients with disability in ingestion of food and drink, in other words, those having difficulty in mastication and swallowing. The present study concludes that oral medicated jellies can be very promising for effective doses to systemic circulation. These may also provide an added advantage of circumventing the hepatic first pass metabolism. Prepared medicated jelly is cost wise cheap and acceptable and have gained relevance in pharmaceutical industry as a novel, patient friendly, convenient products.

# ACKNOWLEDGEMENTS

We thank Assistant Prof. Shaffi Khurana Tangri, SGRR University, for their support during this work.

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**Citation:** Mrynal Chamoli (2022). Formulation and development of pediatric herbal jelly from papaya seeds for anthelmintic infection. IRJPS. 13: 031.