IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, June 2026
Impact Factor: 8.2

Development of In Vitro Characterization of the Carrageenan Mediated Sustained Release Tablet of the Repaglinide

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Abstract: *Objective: The present study focuses on the formulation and evaluation of sustained release matrix tablets of repaglinide to prolong drug release and improve therapeutic efficacy.*
Methods: Tablets were prepared using hydrophilic polymers by the direct compression method and evaluated for pre-compression and post-compression parameters, including flow properties, hardness, friability, drug content, and in vitro dissolution behavior.
Result and Discussion: Preformulation studies confirmed that repaglinide complied with pharmacopoeial standards, showing expected organoleptic properties and a melting point within the reference range, indicating drug purity. The drug exhibited maximum solubility in methanol and a partition coefficient of 3.33, confirming its lipophilic nature. UV analysis showed maximum absorbance at 288 nm, and the calibration curve demonstrated excellent linearity. Pre-compression parameters indicated good flow and compressibility of the powder blend. Optimization using factorial design revealed that carrageenan and potassium chloride significantly influenced drug release, with the optimized formulation showing desirable characteristics. The optimized tablet exhibited sustained drug release up to 12 hours, following Higuchi kinetics, indicating diffusion-controlled release and improved performance over the pure drug.
Conclusion:Sustained release matrix tablets of repaglinide were successfully formulated using hydrophilic polymers. The optimized formulation demonstrated controlled drug release over an extended period and satisfactory physicochemical properties. The study indicates that matrix tablets are an effective approach for improving the therapeutic performance and patient compliance of repaglinide..

Keywords: Repaglinide, Sustained release, Matrix tablet, In vitro dissolution, Drug release kinetics, Oral delivery

I. INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (American Diabetes Association, 2020). It represents a major global health challenge, with the International Diabetes Federation projecting that the number of affected individuals will exceed 700 million by 2045 (IDF, 2021). Type 2 diabetes mellitus accounts for the majority of cases and is associated with complications such as neuropathy, nephropathy, and cardiovascular diseases. Effective glycaemic control is essential to prevent these long-term complications. Repaglinide is a short-acting oral hypoglycaemic agent belonging to the meglitinide class, widely used in the management of type 2 diabetes mellitus (Reddy et al., 2018). It lowers blood glucose levels by stimulating insulin secretion through inhibition of ATP-sensitive potassium channels in pancreatic β-

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cells. However, repaglinide has a short biological half-life of approximately 1 hour and undergoes rapid metabolism, requiring frequent dosing. This frequent administration may lead to poor patient compliance and fluctuations in plasma drug concentration. Sustained release (SR) drug delivery systems offer a promising approach to overcome these limitations by maintaining constant drug levels over an extended period (Nayak et al., 2019). Among various SR approaches, matrix tablets are widely preferred due to their simplicity, cost-effectiveness, and reproducibility (Bodmeier & Paeratakul, 1998). These systems utilize polymers such as hydroxypropyl methylcellulose (HPMC), Carbopol, and ethyl cellulose to control drug release through diffusion and erosion mechanisms (Patel et al., 2020). The present study focuses on the formulation of sustained release matrix tablets of repaglinide using suitable polymers by direct compression method. The prepared formulations are evaluated for pre-compression parameters such as flow properties and post-compression characteristics including hardness, friability, and drug content. In vitro dissolution studies are performed to assess the drug release profile over time. The optimized formulation is expected to provide controlled drug release up to 12 hours, following zero-order and Higuchi kinetics. Thus, the development of sustained release matrix tablets of repaglinide aims to improve therapeutic efficacy, minimize dosing frequency, and enhance patient compliance (Costa & Sousa Lobo, 2001).

II. MATERIALS AND METHODS

2.1 Materials

- Repaglinide (Active Pharmaceutical Ingredient)
- Hydroxypropyl Methylcellulose (HPMC K100M)
- Carbopol 934
- Ethyl Cellulose
- Lactose (diluent)
- Magnesium stearate (lubricant)
- Talc (glidant)(Patel et al., 2020).

2.2 Method of Preparation

Sustained release matrix tablets were prepared using the direct compression method:

- All ingredients were accurately weighed.
- Drug and excipients were passed through sieve (60).
- Mixed uniformly using geometric dilution.
- Lubricants were added and blended.
- The mixture was compressed using a tablet compression machine. (Shanmugam et al., 2015; Kumar et al., 2020).

2.3 Pre-compression Parameters

Drug Content Uniformity are performed to assess powder characteristics and drug–excipient compatibility.

- **Fourier Transform Infrared Spectroscopy (FTIR)**
- **Ultraviolet (UV) scanning of the**
- **Determine flow properties and compressibility of the powder was evaluated for:**

1. Organoleptic properties (API)
2. Melting point
3. Partition coefficient
4. Solubility Studies
5. Angle of repose
6. Bulk density

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7. Tapped density
8. Carr's index
9. Hausner's ratio (Martin et al., 2011).

2.4 Post-compression Evaluation

2.4.1 Physical Parameters

- Weight variation
- Hardness
- Thickness
- Friability (United States Pharmacopeia, 2020).

2.5 In Vitro Dissolution Study

Apparatus: USP Type II (Paddle)
Medium: 0.1N HCl (first 2 hours), followed by phosphate buffer pH 6.8
Temperature: 37 ± 0.5°C
Speed: 50 rpm
Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically. (Aulton & Taylor, 2018).

2.6 Drug Release Kinetics

Release data were fitted into various kinetic models:

- Zero-order kinetics
- First-order kinetics
- Higuchi model (Costa & Sousa Lobo, 2001).

III. RESULTS AND DISCUSSION

Organoleptic Properties

The organoleptic characteristics of the drug (API) were evaluated and found to comply with the specifications of the Indian Pharmacopoeia (IP). The observations are presented in Table 1.

Table 1: Organoleptic Characteristics of Repaglinide

S. No.	Test	Specification	Observation
1.	Colour	White crystalline powder	White crystalline powder
2.	Odour	Odor less	Odor less
3.	Appearance	Tasteless	Tasteless

Melting Point Determination

Melting Point Determination

The melting point of repaglinide was determined using the capillary method. The observed melting point was found to be in close agreement with the reported standard value, indicating the purity of the drug.

Table 2 : Melting Point of Repaglinide

Drug	Specification (°C)	Observation (°C)
Repaglinide	126–130	128 ± 1.52 – 130 ± 1.0

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Determination of λmax of Repaglinide in Methanol

The maximum absorption wavelength (λmax) of repaglinide was determined by scanning a 5 µg/mL solution in methanol over a wavelength range of 200–400 nm using a UV spectrophotometer. The λmax was found to be 288 nm, indicating the wavelength of maximum absorbance for further analytical studies.

Standard Calibration Curve of Repaglinide in Methanol

A standard calibration curve was constructed by plotting absorbance against concentration in the range of 1.5–25 µg/mL. The absorbance values for different concentrations are shown in Table 8. The calibration curve exhibited excellent linearity with a regression equation:

$$Y = 0.0326x + 0.012$$

$$R^2 = 0.999$$

Table 3: Calibration Data of Repaglinide in Methanol

Concentration (µg/mL	Absorbance (Mean ± SD)
1.5	0.055 ± 0.002
3	0.105 ± 0.005
4.5	0.155 ± 0.003
6	0.155 ± 0.003
7.5	0.256 ± 0.002
9	0.301 ± 0.003
10.5	0.358 ± 0.001
12	0.402 ± 0.001
13.5	0.451 ± 0.001
15	0.501 ± 0.002
16.5	0.555 ± 0.002
18	0.608 ± 0.003
19.5	0.658 ± 0.004
21	0.704 ± 0.003
23.5	0.760 ± 0.002
25	0.815 ± 0.004

The solubility of repaglinide was determined in various solvents, and the results are summarized in Table 4. The drug exhibited maximum solubility in methanol, followed by glycerin, while it showed very low solubility in aqueous media.

Table 4: Solubility Profile of Repaglinide

S. No.	Solvent	Solubility (mg/mL)	Inference
1	Water	0.185 ± 0.001	Very slightly soluble
2	0.1 N HCl	0.076 ± 0.002	Very slightly soluble
3	Phosphate buffer (pH 7.4)	0.069 ± 0.001	Very slightly soluble
4	Methanol	3.773 ± 0.122	Soluble
5	PEG 400	1.066 ± 0.009	Sparingly soluble
6	Glycerin	1.638 ± 0.061	Slightly soluble
7	Propylene glycol	0.458 ± 0.015	Sparingly soluble

Discussion:

The solubility study indicates that repaglinide is poorly soluble in aqueous media but shows significantly higher solubility in organic solvents, particularly methanol. This behavior suggests the need for formulation strategies (e.g., matrix systems, solubilizers) to enhance its dissolution and bioavailability.

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Preformulation Studies

Partition Coefficient

The partition coefficient of repaglinide was determined using the n-octanol:water system. The observed Log P value was 3.33 ± 0.009, which is close to the reported value (3.97), indicating the lipophilic nature of the drug (Table 5).

Table 5: Value of the Repaglinide Partition Coefficient

S. No.	Drug	Coefficient of reference partitioning	Partition coefficient observed (Log P)	The drug's nature
1.	Repaglinide	3.97	3.33±0.009	Lipophilic

FT-IR Spectroscopy

FT-IR analysis of pure repaglinide showed characteristic peaks at 3308 cm^{-1} (N–H stretching), 2936 cm^{-1} (C–H stretching), and 1688 cm^{-1} (C=O stretching). Additional peaks at 1215 cm^{-1} and 1038 cm^{-1} correspond to C–O stretching, while peaks at 1565 cm^{-1} and 1636 cm^{-1} indicate aromatic C=C and N–H bending, respectively.

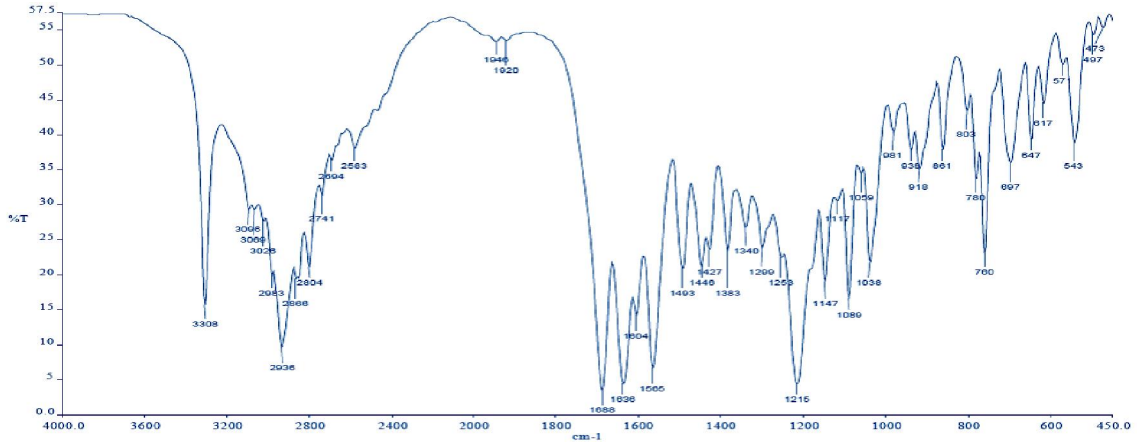

Figure 1: FTIR spectra of repaglinide

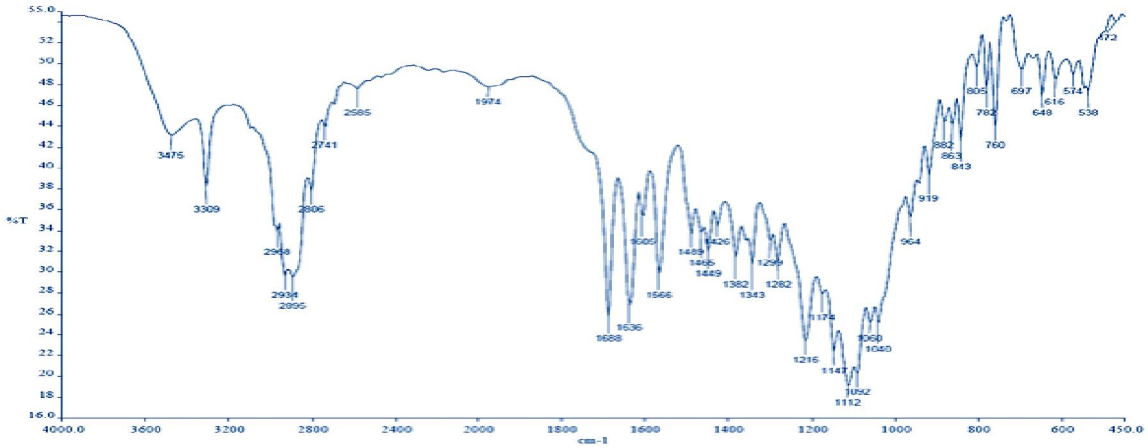

Figure 2: FT-IR spectrum of repaglinide containing sustained release tablet

DOI: 10.48175/568

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The FT-IR spectra of the formulation containing excipients (kappa carrageenan, potassium chloride, MCC, magnesium stearate, and talc) showed no significant shift or disappearance of characteristic peaks, confirming compatibility between the drug and excipients (Figures 1 and 2.)

Precompression Parameters

Precompression studies indicated that all formulations exhibited acceptable flow and compressibility properties. Bulk density ranged from 0.372–0.396 g/cm³, while Carr's index values (<18%) and Hausner's ratio (1.05–1.10) confirmed good flowability and compressibility of the powder blend (Table 6).

Table 6: Pre-compression parameter assessment for each composition

Formulation no.	density of bulk (gm/cm3)	Density of tapping (gm/cm3)	The Carrs index	The Hausner ratio
SRT1	0.365±0.005	0.391±0.002	6.646±1.97	1.071±0.022
SRT2	0.379±0.008	0.410±0.006	7.537±1.80	1.081±0.021
SRT3	0.372±0.020	0.413±0.009	9.752±4.24	1.1097±0.052
SRT4	0.382±0.008	0.419±0.007	8.783±2.80	1.096±0.033
SRT5	0.393±0.011	0.420±0.010	6.463±2.13	1.069±0.024
SRT6	0.391±0.006	0.413±0.12	5.229±2.26	1.055±0.025
SRT7	0.383±0.010	0.406±0.001	5.699±0.166	1.060±0.001
SRT8	0.391±0.011	0.424±0.006	7.719±1.77	1.083±0.020
SRT9	0.389±0.007	0.418±0.007	7.028±2.08	1.075±0.024
SRT 10	0.392±0.009	0.419±0.003	6.401±2.77	1.069±0.031
SRT 11	0.388±0.008	0.412±0.006	5.73±1.21	1.061±0.036
SRT12	0.384±0.005	0.408±0.009	5.733±3.26	1.061±0.037
SRT13	0.396±0.001	0.424±0.005	6.628±1.08	1.071±0.012
SRT14	0.390±0.005	0.414±0.006	5.770±0.11	1.061±0.001

Preparation and Optimization of Sustained Release Tablets

Repaglinide sustained release matrix tablets were prepared using the direct compression method. The tablets showed acceptable physical characteristics without defects such as capping, chipping, or lamination.

A 3^2 full factorial design was employed to study the effect of two independent variables:

X_1: Amount of kappa carrageenan (40–80 mg)

X_2: Amount of potassium chloride (10–20 mg)

The response variable was percentage drug release after 12 hours.

The model was found to be significant (F-value = 687.93, $p < 0.05$), with no significant lack of fit. The polynomial equation obtained was:

$$Y = 95.68 + 4.72X_1 + 1.84X_2 + 0.95X_1X_2 - 2.75X_1^2 - 0.68X_2^2$$

Positive coefficients of X_1 and X_2 indicated that increasing polymer and salt concentration enhanced drug release. ANOVA results showed good agreement between predicted and adjusted R^2 values, confirming model reliability.

3D surface and contour plots demonstrated that both variables independently influenced drug release, with a near-linear increase observed (Figure 3).

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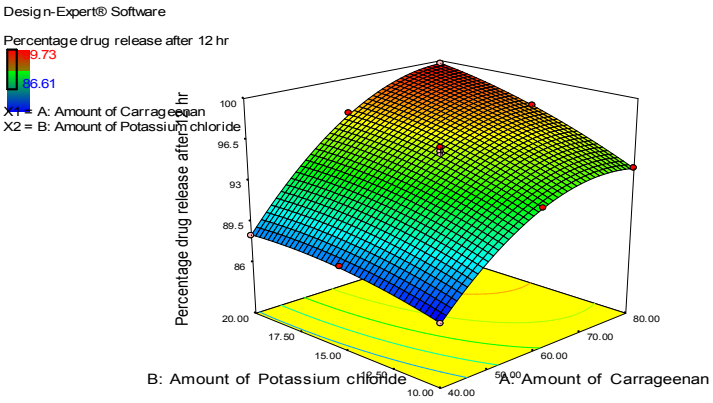
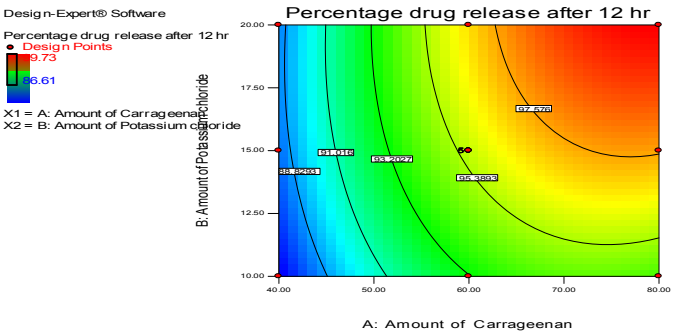


a)



b)

Figure 3 shows a) a 3D surface graph and b) a counterplot showing the impact of combining

Optimized Formulation

The optimized formulation was obtained with 79.90 mg of kappa carrageenan and 19.93 mg of potassium chloride, showing a predicted drug release of 99.74% and an observed value of 99.73 ± 1.46% after 12 hours (Table 7).

Table 7: Optimised formulation composition and medication release % after 12 hours

Formulations	Kappa Carrageenan Amount (mg)	Con. of Potassium chloride (mg)	Predicated Percentage medication release (%) after 12 hours	ObservedPercentage medication release (%) after 12 hours
SRT14	79.90	19.93	99.74	99.73±1.46

In Vitro Characterization

The prepared sustained release tablets were further evaluated for in vitro parameters such as drug release, hardness, friability, weight variation, and drug content, confirming their suitability for sustained release delivery.

Uniformity of Weight

All formulations complied with pharmacopeial limits for weight variation. The average tablet weight ranged from 119.67 ± 1.50 mg to 121 ± 1.67 mg, while the optimized formulation (SRT14) showed a weight of 120.30 ± 1.03 mg, indicating uniformity in tablet weight (Table 8, Figure 4).

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Table 8: Weight of all formulation

Formulation code	Weight (mg)
SRT1	120.16±1.16
SRT2	119.83±1.32
SRT3	120.84±0.75
SRT4	120.67±1.50
SRT5	121±1.67
SRT6	120.85±1.60
SRT7	120.5±0.54
SRT8	120±0.63
SRT9	120.66±1.03
SRT10	120.67±0.75
SRT11	120.38±0.51
SRT12	119.67±1.50
SRT13	120.17±1.72
SRT14	120.30±1.03

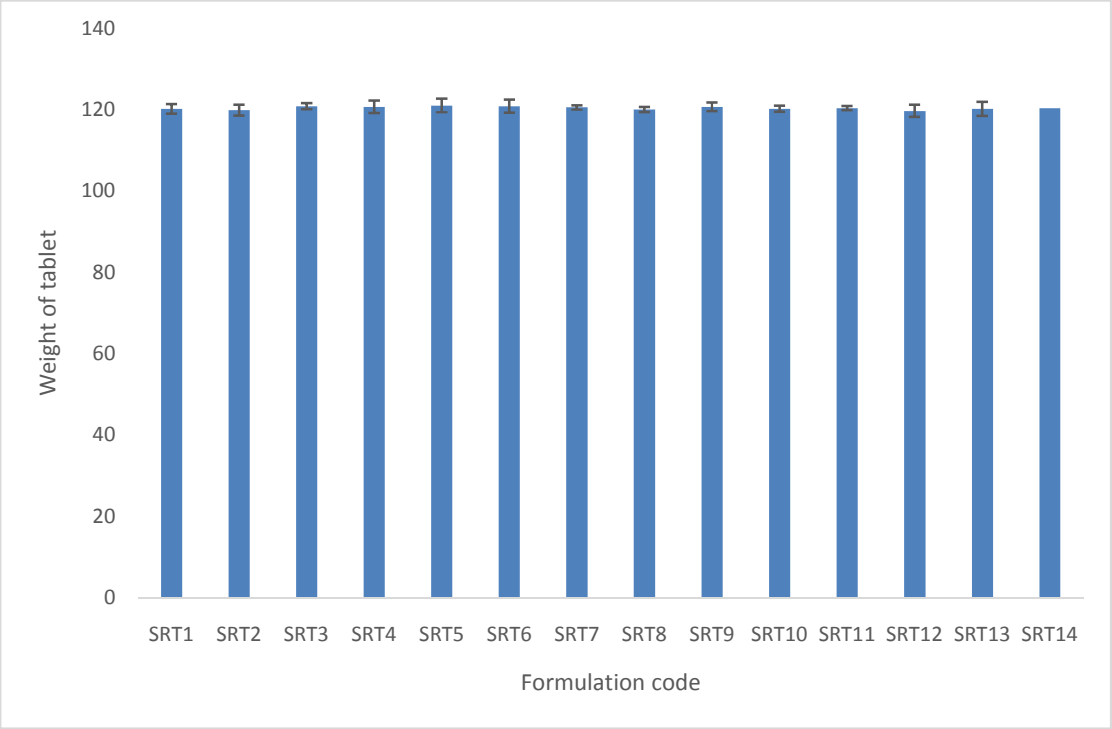

Figure 4: Weight of all formulation and optimized formulation

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Thickness

The thickness of all prepared formulations was found to be in the range of 2.08 ± 0.14 mm to 2.22 ± 0.30 mm. The optimized formulation (SRT14) exhibited a thickness of 2.25 ± 0.14 mm, confirming uniform die fill and compression (Table 9, Figure 5).

Table No. 9 displayed all of the prepared formulasThickness.

Formulation code	Thickness (mm)
SRT1	2.11±0.25
SRT2	2.10±0.36
SRT3	2.18±0.48
SRT4	2.16±0.15
SRT5	2.19±0.37
SRT6	2.08±0.14
SRT7	2.12±0.56
SRT8	2.22±0.30
SRT9	2.17±0.62
SRT10	2.19±0.55
SRT11	2.14±0.48
SRT12	2.15±0.79
SRT13	2.10±0.33
SRT14	2.25±0.14

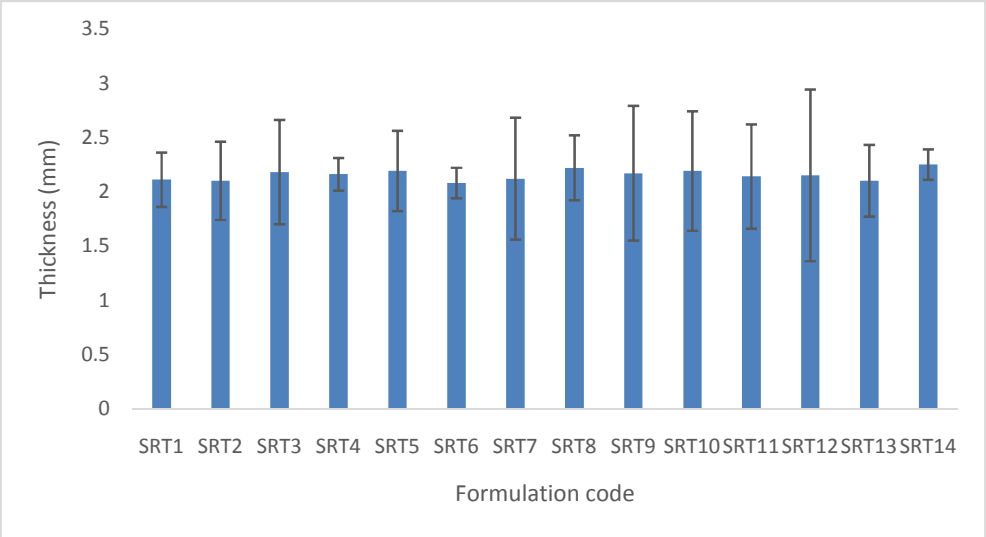

Figure 5: All formulations' thickness as well as the optimal formulation

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Hardness

Tablet hardness ranged from 3.55 ± 0.08 to 4.29 ± 0.01 kg/cm², indicating adequate mechanical strength. The optimized formulation (SRT14) showed a hardness of 4.32 ± 0.19 kg/cm², suggesting good resistance to handling and transportation (Table 10, Figure 6).

Table 10: Hardness of every composition that has been produced and optimized

Formulation code	Hardness (kg/cm2)
SRT1	4.12±0.16
SRT2	3.93±0.11
SRT3	4.02±0.04
SRT4	4.27±0.05
SRT5	4.23±0.04
SRT6	4.07±0.06
SRT7	4.01±0.08
SRT8	4.29±0.01
SRT9	4.11±0.02
SRT10	4.14±0.03
SRT11	4.15±0.04
SRT12	3.78±0.10
SRT13	3.55±0.08
SRT14	4.32±0.19

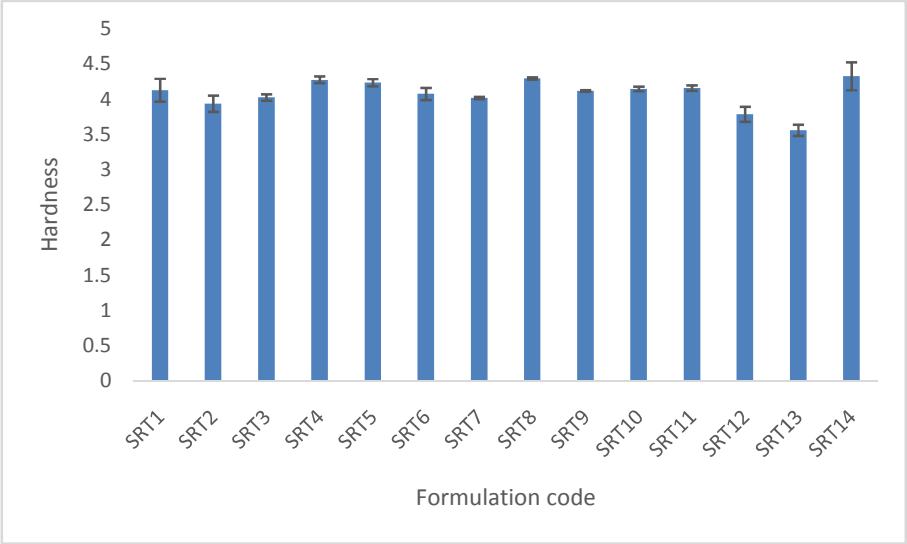

Figure 6: All formulations' hardness as well as the optimum formulations

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Percentage Friability

The percentage friability of all formulations was found to be below 1%, indicating acceptable mechanical integrity. Values ranged from 0.25 ± 0.088% to 0.67 ± 0.012%, while the optimized formulation (SRT14) exhibited 0.58 ± 0.029% (Table 11, Figure 7).

Table 11: The percentage of friability in both the optimum formulation and all manufactured formulations

Formulation code	Percentage friability
SRT1	0.083±0.089
SRT2	0.168±0.015
SRT3	0.088±0.038
SRT4	0.168±0.069
SRT5	0.336±0.048
SRT6	0.334±0.027
SRT7	0.146±0.078
SRT8	0.084±0.015
SRT9	0.5±0.02
SRT10	0.082±0.041
SRT11	0.085±0.055
SRT12	0.67±0.012
SRT13	0.25±0.088
SRT14	0.58±0.029

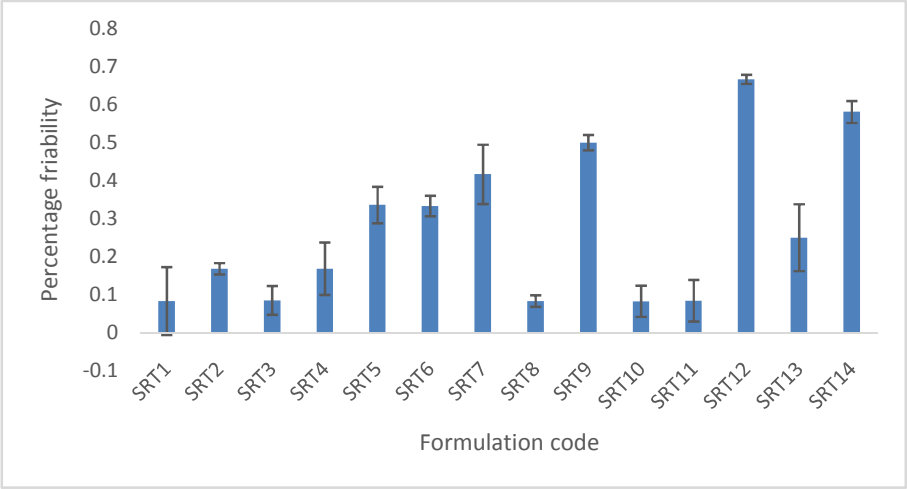

Figure 7: The percentage of friability in both the optimized and total formulations

Percentage Drug Content

The drug content of all formulations ranged between 89.05 ± 0.70% and 100.10 ± 0.88%, demonstrating uniform drug distribution. The optimized formulation (SRT14) showed a drug content of 99.89 ± 0.63%. An increase in kappa carrageenan concentration was observed to enhance drug content uniformity (Table 12, Figure 8).

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Table 12: Drug content as a percentage of Every composition that has been produced and optimised

Formulation NO.	drug content %
SRT1	98.05±0.46
SRT2	98.36±1.16
SRT3	97.95±1.99
SRT4	99.79±0.77
SRT5	97.03±0.93
SRT6	98.15±0.30
SRT7	98.05±0.89
SRT8	100.10±0.88
SRT9	91.92±0.63
SRT10	94.88±0.46
SRT11	98.15±0.81
SRT12	90.18±1.10
SRT13	89.05±0.70
SRT14	99.89±0.63

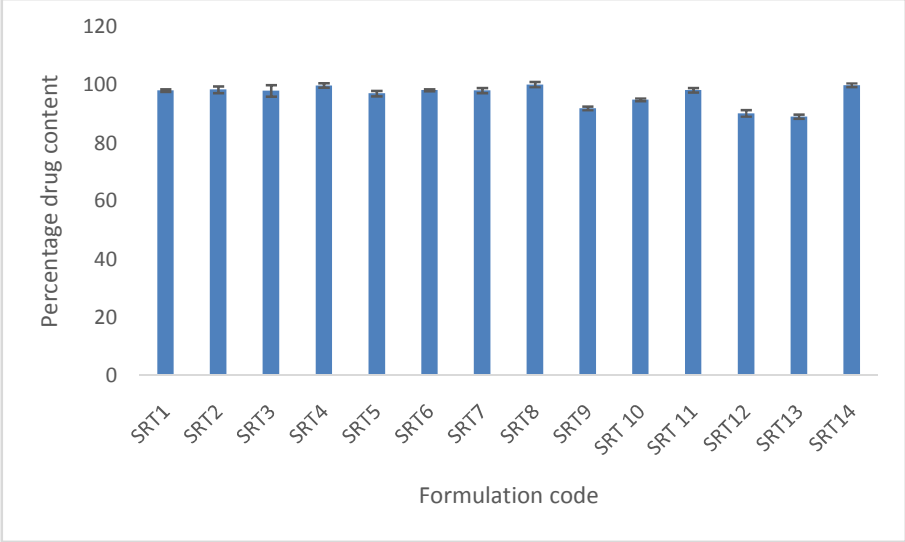

Figure 8: Drug content as a percentage of all formulations and optimized formulations

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