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Research Article

FORMULATION AND EVALUATION OF DOMPERIDONE MICROPARTICLES USING NATURAL POLYMERS BY IONIC GELATION TECHNIQUE

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ABSTRACT

The present study aimed to formulate and evaluate domperidone microparticles using natural polymers through an ionic gelation technique to achieve controlled drug release. Domperidone is an anti-dopaminergic drug widely used as a prokinetic and antiemetic agent. However, its short biological half-life necessitates frequent dosing, which may reduce patient compliance. In this work, microparticles were prepared using natural polymers such as pectin, guar gum, and xanthan gum with calcium chloride as a cross-linking agent. Preformulation studies including identification, solubility analysis, melting point determination, and compatibility studies were performed. The microparticles were evaluated for morphology, percentage yield, entrapment efficiency, particle size, and in-vitro drug release. The prepared microparticles were spherical and smooth in morphology. Entrapment efficiency ranged from 23.1% to 80.24%. Among the prepared formulations, F5 exhibited the highest entrapment efficiency while F7 showed prolonged drug release behavior. In-vitro dissolution studies indicated sustained drug release for up to 24 hours. The results demonstrate that domperidone microparticles prepared using natural polymers through ionic gelation can serve as an effective controlled drug delivery system.

Keywords: Domperidone, Microparticles, Ionic gelation, Natural polymers, Controlled release.

INTRODUCTION

Microparticles are solid spherical particles ranging from 1–1000 µm in diameter that consist of a drug dispersed within a polymeric matrix. These systems have gained significant attention in pharmaceutical research because they can improve drug stability, control drug release, and enhance therapeutic efficacy (Singh, 2010). Controlled drug delivery systems are designed to deliver drugs at a predetermined rate for a specified period, thereby reducing dosing frequency and improving patient compliance (Chien, 1992). Conventional drug delivery systems often result in fluctuations in plasma drug concentrations, which may lead to reduced therapeutic efficacy or increased adverse effects. Microparticulate drug delivery systems have been developed to overcome these limitations by providing sustained drug release and protecting unstable drugs from degradation (Langer, 1998).

Domperidone is a dopamine receptor antagonist widely used as an antiemetic and prokinetic agent. It enhances gastrointestinal motility and facilitates gastric emptying by blocking dopamine receptors in the gastrointestinal tract (Jain, 2000). However, domperidone exhibits relatively low oral bioavailability and a short half-life of about 4–6 hours, which necessitates repeated dosing (Kumar, 2014). Natural polymers such as pectin, guar gum, and xanthan gum have gained importance in pharmaceutical formulations because of their biodegradability, biocompatibility, and non-toxic nature (Jain, 2007). These polymers can form cross-linked gel structures in the presence of multivalent ions, making them suitable for controlled drug delivery systems (Lee, 2001). Among the various preparation techniques, ionic gelation is considered a simple and efficient method for preparing polymeric microparticles. In this technique, polymer chains interact with cross-linking ions to form a gel matrix that encapsulates the drug (Park, 2002, Garud, 2012). Therefore, the present study was undertaken to formulate domperidone microparticles using natural polymers through ionic gelation technique and evaluate their physicochemical properties and drug release behavior.

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MATERIALS AND METHODS

Materials

Domperidone was obtained from Yarrow Chemical Products (Mumbai). Xanthan gum and guar gum were procured from S.D. Fine Chemicals Ltd., while pectin was obtained from Nice Chemicals Pvt. Ltd. Calcium chloride used as a cross-linking agent was purchased from Finar Chemicals Ltd.

Instruments

The instruments used in this study included a magnetic stirrer, UV–visible spectrophotometer, dissolution apparatus, hot air oven, and scanning electron microscope.

Preformulation Studies

Identification of Drug

The identity of domperidone was confirmed using Fourier Transform Infrared (FTIR) spectroscopy by comparing the obtained spectrum with the standard reference spectrum. Determination of Melting Point. The melting point of domperidone was determined by the open capillary method.

Solubility Studies

Solubility of domperidone was evaluated in water, phosphate buffer (pH 6.8), methanol, and dimethyl sulfoxide.

Drug–Polymer Compatibility Studies

Drug–excipient compatibility was evaluated using FTIR spectroscopy to detect possible interactions between domperidone and selected polymers. Compatibility studies are essential to ensure stability and performance of the final formulation (Singh, 2010).

Preparation of Domperidone Microparticles

Domperidone microparticles were prepared by ionic gelation technique. The drug was dissolved in distilled water and mixed with polymer solution containing pectin, guar gum, and xanthan gum. The mixture was added dropwise through a syringe into a calcium chloride solution under continuous stirring to form microparticles. The formed microparticles were filtered, washed with distilled water, and dried at room temperature (Park, 2002, Garud, 2012).

Evaluation of Microparticles

The prepared microparticles were evaluated for: Morphology using scanning electron microscopy, Percentage yield, Entrapment efficiency, Particle size, In-vitro drug release. Microparticle characterization is essential for understanding the influence of formulation variables on drug release behavior (Kumar, 2012).

RESULTS AND DISCUSSION

Microparticles were successfully prepared using ionic gelation technique with natural polymers such as pectin, guar gum, and xanthan gum. The formation of cross-linked polymer networks in the presence of calcium ions resulted in stable (Table 1-5) microparticles capable of encapsulating the drug effectively. Similar findings have been reported in previous studies involving ionic gelation methods for polymeric microparticles (Park, 2002, Garud, 2012). Entrapment efficiency increased with increasing polymer concentration due to the formation of a denser polymer matrix that restricted drug diffusion (Kumar, 2012). Natural polymers also contributed to sustained drug release because of their gel-forming and swelling properties (Jain, 2007). The sustained drug release profile observed in the present study can be attributed to diffusion of the drug through the polymer matrix and gradual erosion of the polymer network (Figure 1-8). Controlled drug delivery systems such as microparticles have been widely investigated for improving therapeutic outcomes and reducing dosing frequency (Hoffman, 2008, Zhang, 2013). Overall, the results indicate that natural polymer-based microparticles are promising carriers for controlled release of domperidone.

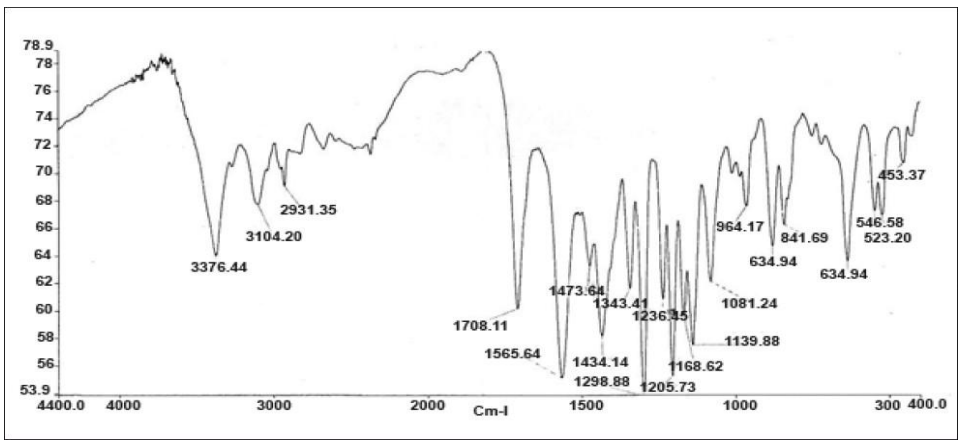

Figure 1. FTIR Spectrum of Pure Drug.

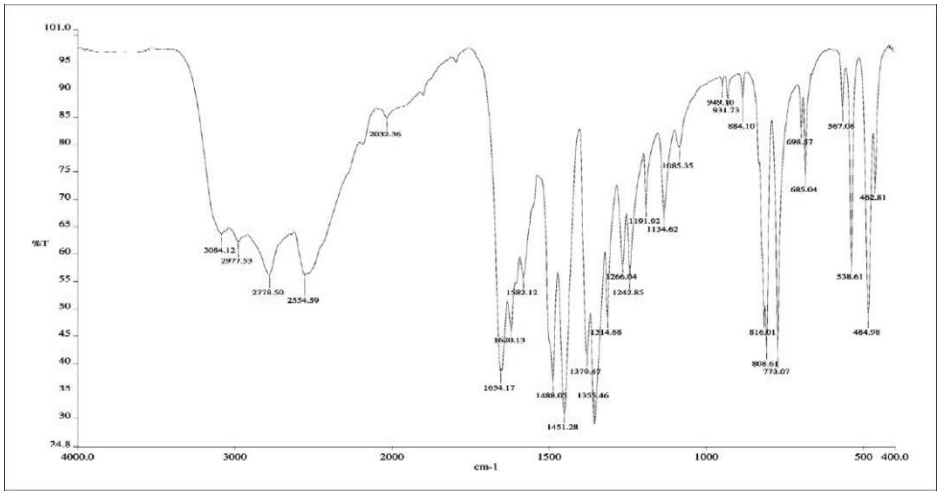

Figure 2. FITR Spectrum of Polymer Pectin

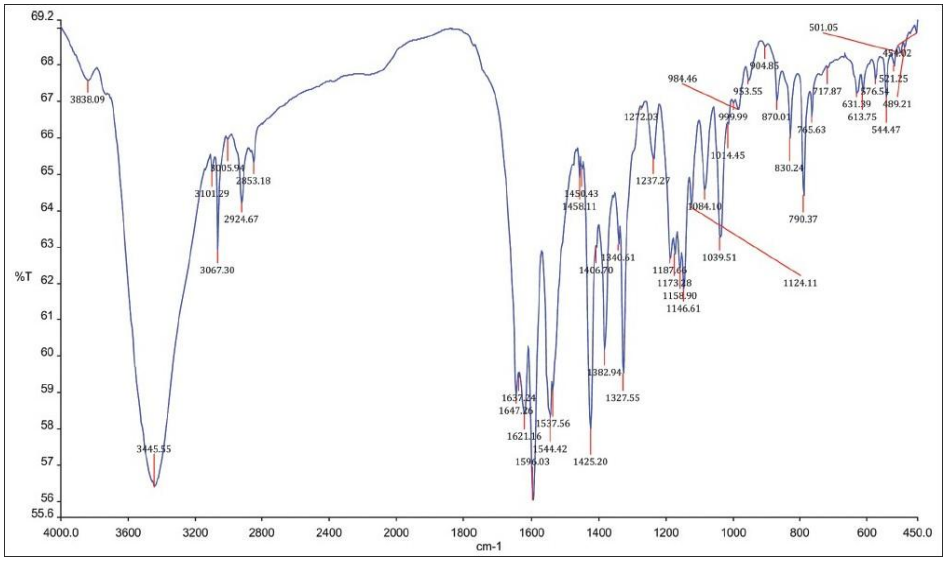

Figure 3. FTIR Spectrum of polymer Xanthun Gum.

Table 1. FTIR Spectrum of Drug and Polymers for the Functional Groups assigned.

Polymer	Groups assigned			
	C ═ O stretch	N ─ H stretch	C ─ H stretch	C ─ N stretch
Domperidone	1708 cm^{-1}	3360cm^{-1}	3104.20cm^{-1}	1675cm^{-1}
Pectin	1620.13cm^{-1}	3084.12cm^{-1}	2977.53cm^{-1}	1654.17Cm^{-1}
Xanthun gum	1637.24cm^{-1}	3445.55cm^{-1}	3067.30cm^{-1}	1647.26cm^{-1}

Table 2. Physiochemical Evaluation of Domperidone Microparticles.

Formulation Code	Morphology	Percentage yield (%)	Entrapment efficiency (%)	Particle size (µm)
F1	Spherical & smooth	40.0	23.1	23.68
F2	Spherical & smooth	46.0	36.2	23.76

F3	Spherical & smooth	60.1	53.0	23.71
F4	Spherical & smooth	80.0	72.8	24.02
F5	Spherical & smooth	88.83	80.24	24.14
F6	Spherical & smooth	85.0	73.12	24.30
F7	Spherical & smooth	88.5	78.3	25.39
F8	Spherical & smooth	83.23	76.22	23.26
F9	Spherical & smooth	81.22	74.62	22.23
F10	Spherical & smooth.	80.42	72.29	21.39

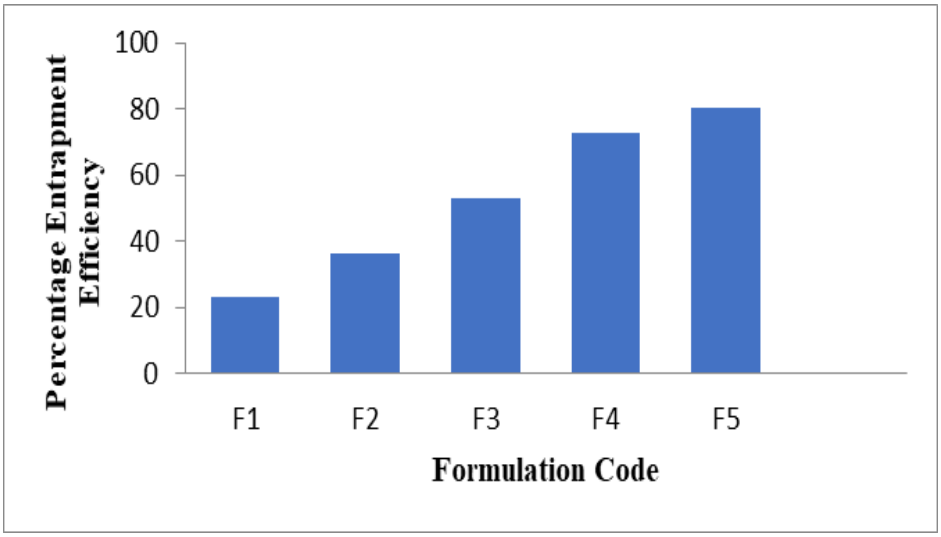

Figure 4. Entrapment Efficiency for F1 to F5 Formulations.

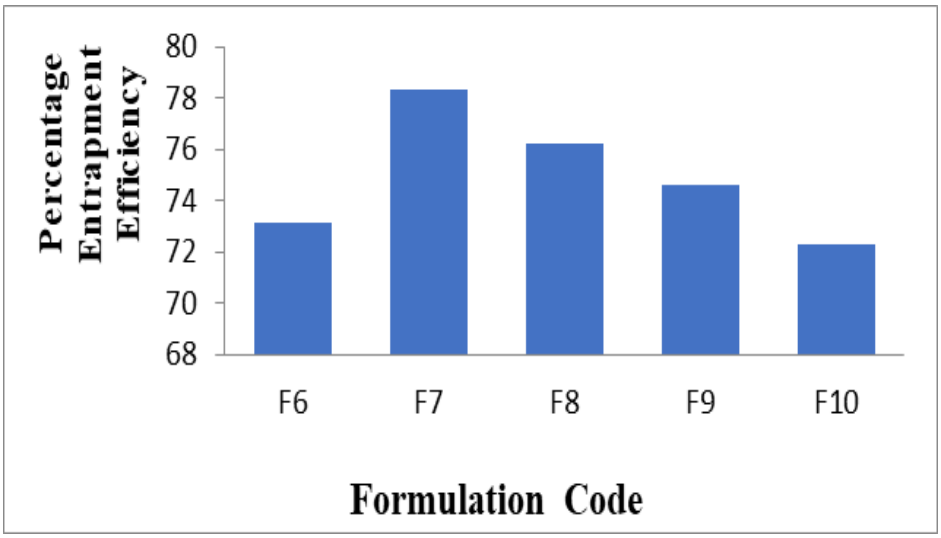

Figure 5. Entrapment Efficiency for F1 to F5 Formulations.

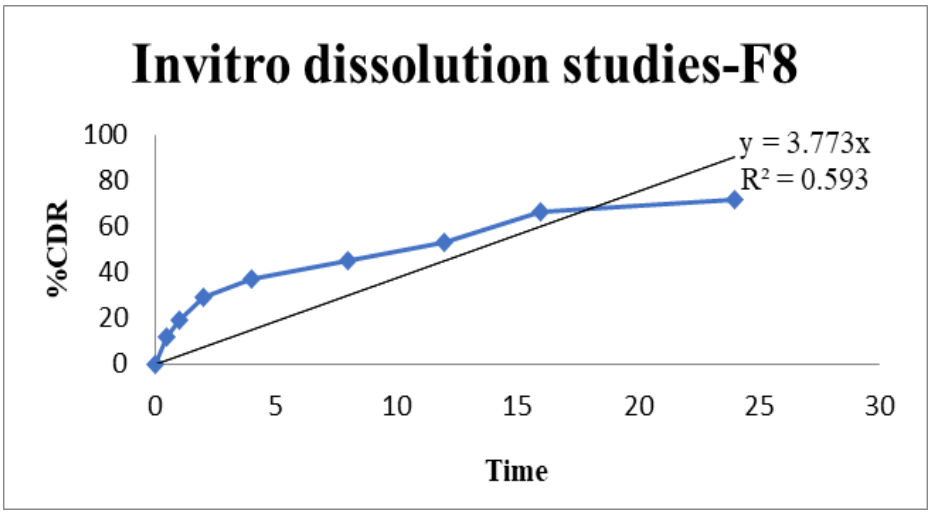

Figure 6. *Invitro* dissolution studies-F8.

Table 3. Invitro Dissolution Studies of Domperidone Microparticles.

S.No.	Time (h)	Abs (nm)	Con. µg/ml	Conc. Mg/ml	Conc.200 ml	Loss	CLS	CDR	% CDR
1	1	0.039	0.43	0.04	8.666667	0.00	0.00	8.67	14.52
2	1	0.051	0.57	0.06	11.33333	0.04	0.05	11.38	19.07
3	2	0.072	0.80	0.08	16	0.06	0.11	16.11	26.99
4	4	0.089	0.99	0.10	19.77778	0.08	0.19	19.96	33.45
5	8	0.111	1.23	0.12	24.66667	0.10	0.29	24.95	41.81
6	12	0.131	1.42	0.14	28.4	0.12	0.41	28.81	49.63
7	18	0.149	1.66	0.17	33.11111	0.14	0.55	33.66	56.40
8	24	0.177	1.97	0.20	39.33333	0.17	0.72	40.05	67.11

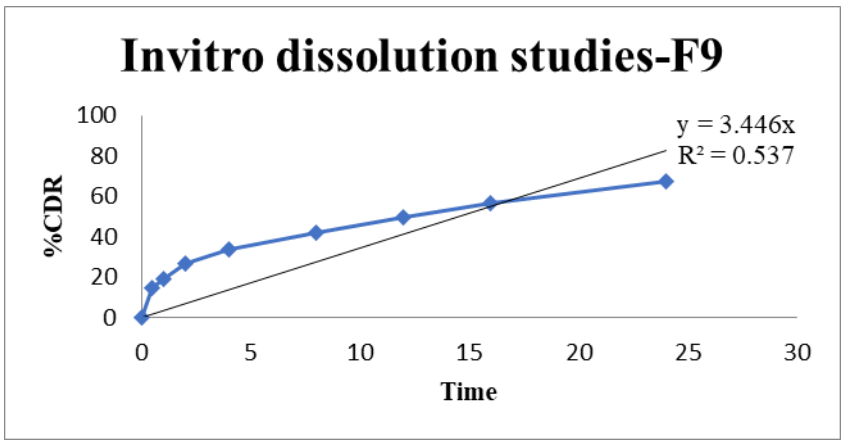

Figure 7. Invitro dissolution studies-F9.

Table 4. Invitro Dissolution Studies of Domperidone Microparticles.

S. No.	Time (h)	Abs (nm)	Con. µg/ml	Conc. Mg/ml	Conc.200 ml	Loss	CLS	CDR	% CDR
1	1	0.031	0.34	0.03	6.888889	0.00	0.00	6.89	11.54
2	1	0.058	0.64	0.06	12.88889	0.03	0.05	12.94	21.68
3	2	0.076	0.84	0.08	16.88889	0.06	0.11	17.00	28.49
4	4	0.091	1.01	0.10	20.22222	0.08	0.20	20.42	34.22
5	8	0.118	1.31	0.13	26.22222	0.10	0.30	26.52	44.44
6	12	0.129	1.42	0.14	28.4	0.13	0.43	28.83	49.63
7	18	0.158	1.76	0.18	35.11111	0.14	0.57	35.68	59.79
8	24	0.169	1.88	0.19	37.55556	0.18	0.75	38.30	64.18

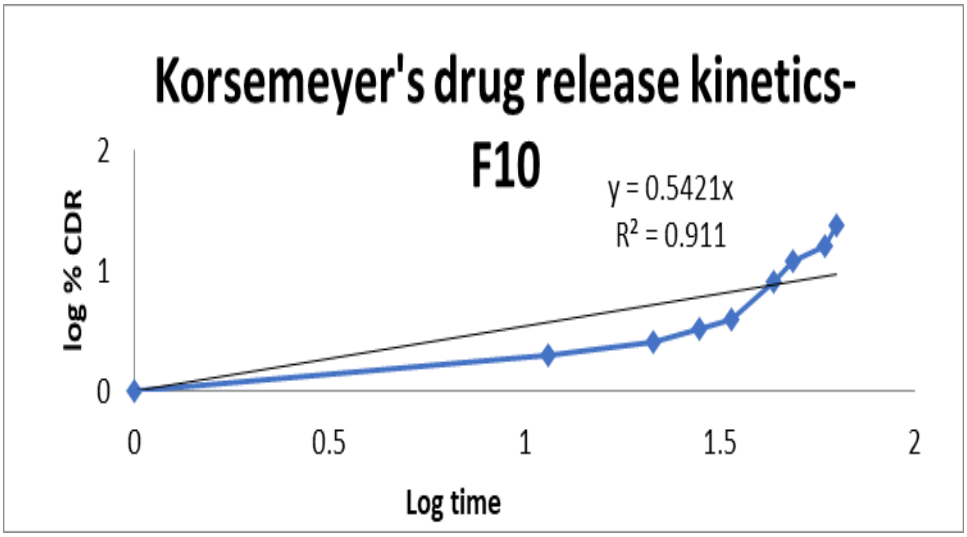

Figure 8. Log time vs log cum % drug release for F10 Formulation.

Table 5. Evaluation parameters of domperidone microparticles.

Formulation code	Zero order	First order	Higuchi's	Korsemeyer's	
	R^2	R^2	R^2	n	R^2
F1	0.639	0.478	0.983	0.732	0.573
F2	0.642	0.388	0.935	0.659	0.491
F3	0.681	0.343	0.902	0.619	0.658
F4	0.611	0.410	0.973	0.672	0.546
F5	0.640	0.466	0.981	0.730	0.638
F6	0.670	0.404	0.959	0.673	0.570
F7	0.653	0.408	0.961	0.608	0.480
F8	0.693	0.434	0.976	0.698	0.583
F9	0.637	0.410	0.973	0.668	0.559
eF10	0.633	0.428	0.953	0.671	

CONCLUSION

Domperidone microparticles were successfully prepared using natural polymers such as pectin, guar gum, and xanthan gum by the ionic gelation method. The formulations exhibited satisfactory morphology, entrapment efficiency, and controlled drug release behavior. Among the prepared formulations, F5 demonstrated the highest entrapment efficiency, while F7 showed sustained drug release over an extended period. These results suggest that natural polymer-based microparticles can serve as an effective controlled release drug delivery system for domperidone.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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