ORIGINAL ARTICLE

Comparative Evaluation of Two Natural Gelling Agents in Valdecoxib Emulgels Formulations

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Abstract

Introduction: In recent years, there has been great interest in the use of novel polymers with complex functions as emulsifiers and thickeners because of the gelling capacity of stable emulsions. Emulgel for dermatological use has several favorable properties, such as being thixotropic, greaseless, non-staining, easily spreadable, easily removable, emollient, having a long shelf life, transparent, and pleasing appearance. **Objectives:** To develop suitable topical gel formulations of valdecoxib using different gelling agents with permeation enhancers to reduce adverse drug reactions associated with oral formulations. **Materials and Methods:** A total of six, i.e., F1–F6, valdecoxib emulgel formulations were prepared using two different gelling agents in different concentrations, and the prepared formulations were further evaluated for various parameters. **Results:** The formulation F3 showed the overall best results. Valdecoxib emulgel formulations were successfully achieved.

Key words: Emulgel, *in vitro* drug release, pectin, tragacanth, valdecoxib

INTRODUCTION

The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentration. One of the drug delivery systems used since ancient times is the topical drug delivery system (TDDS).[1] Skin is one of the most readily accessible organs on the human body for topical administration and is the main route for TDDS. Topical drug delivery is an attractive route for local and systemic treatment.[2]

In recent years, there has been great interest in the use of novel polymers with complex functions as emulsifiers and thickeners.[3] The presence of a gelling agent in the water phase converts a classical emulsion into Emulgel. Emulgel for dermatological use has several favorable properties, such as being thixotropic, greaseless, non-staining, easily spreadable, easily removable, emollient, with a long shelf life, transparent, and pleasing appearance.[4,5]

Emulgel emerges as one of the important and better ways of delivering the drug; it is because of its better control ability over other topical dosage forms. Many widely used topical agents, such as ointments, creams, and lotions, have many disadvantages, i.e., very sticky, causing uneasiness to the patient when applied. They have a lower spreading coefficient and need to be applied with rubbing, and exhibit a stability problem. Due to all these factors within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations.

The aim of this study was to develop suitable topical gel formulations of valdecoxib using different gelling agents with permeation enhancers to reduce adverse drug reactions associated with oral formulations.

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MATERIALS AND METHODS

Materials

Valdecoxib was purchased from Aarti Drugs Pvt. Ltd, Mumbai. Pectin, tragacanth, glycerin, triethanolamine, methyl paraben, and propyl paraben were purchased from SD Fine Chem, Mumbai.

Methods

- Step-I: Preparation of gel bases: The quantities of tragacanth and pectin were weighed and mixed homogeneously with distilled water at 65–70°C using a hot plate and a mechanical stirrer. The mixture was stirred at 1000 ± 200 RPM for 10 min to form a smooth dispersion. The preparations were allowed to stand, permitting entrapped air to separate. Then the pH was adjusted to 6–6.5 using triethanolamine.[6]
- Step-II: Formulation of emulsion, either O/W or W/O, preparation of emulsion. The oil phase of the emulsion was prepared by dissolving isopropyl alcohol, propyl paraben in light liquid paraffin, and glycerine monostearate, and finally, almond oil was mixed in the oil phase. Preparation of the aqueous phase of the emulsion. The aqueous phase was prepared by dissolving methyl paraben, propylene glycol, and glycerine in water. Both the oily and aqueous phases heated separately to 70–80°C. The oily phase was added to the aqueous phase slowly at constant stirring until it cooled to room temperature, resulting in the formulation of an emulsion [Table 1]. Then valdecoxib was dissolved in propylene glycol and added to an emulsion.[7]
- Step-III: The prepared emulsion was mixed with the prepared gel bases in the ratio 1:1 with constant gentle stirring at 600 RPM to obtain emulgel.

Spectrophotometric characterization of valdecoxib

Determination of λ_{max} of valdecoxib: For the determination of the wavelength of the maximum absorption of valdecoxib a solution of suitable dilution in ethanol was prepared and the sample was scanned in the range of 200–400 nm using Labindia ultraviolet (UV) 3000+ and the λ_{max} of valdecoxib was noted, and UV spectrum was recorded as shown in Figure 1 as follows:[8]

The absorption maximum, i.e., λ_{max} value of valdecoxib was found to be 243 nm. This complies with the reported literature value of valdecoxib.

Calibration curve of valdecoxib

Preparation of calibration curve in ethanol

A standard calibration curve of valdecoxib was prepared by preparing the various concentrations of working solutions from the valdecoxib's standard stock solution in ethanol, and absorbance was taken at 243 nm by UV Spectroscopy using Labindia UV 3000+. The obtained readings of the absorption with respect to various concentrations of valdecoxib calibration curve[9] are shown in the following Figure 2.

Infrared spectroscopy

The Fourier transform infrared spectroscopy (FT-IR) spectrum of valdecoxib was recorded by the potassium bromide dispersion technique using FT-IR with diffuse reflectance attachment on IR Affinity-1 (FT-IR-8001, Shimadzu, Japan).[10] The obtained FTIR spectrum of valdecoxib is shown in Figure 3.

Differential scanning calorimetry (DSC)

The differential scanning calorimetric analysis of valdecoxib was performed using DSC, Mettler-Toledo for the DSC study. The obtained differential scanning calorimetric graph is shown in Figure 4 as follows:

DSC thermogram of valdecoxib showed an endothermic peak at 158°C–162°C, which complies with the reported transition temperature value of valdecoxib in the literature, and had good thermal stability.[11]

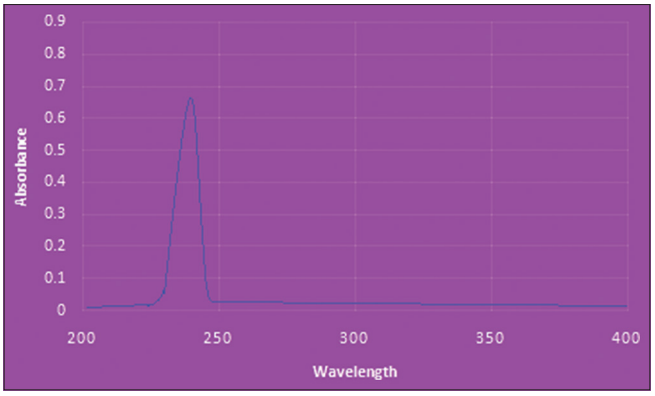

Figure 1: Determination of λ max of Valdecoxib

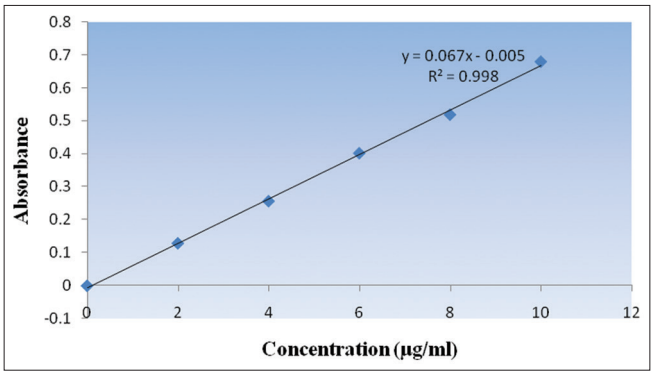

Figure 2: Standard calibration curve of valdecoxib in ethanol

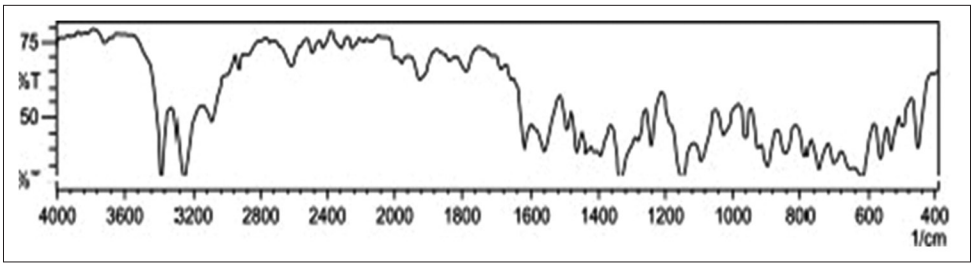

Figure 3: Fourier transform infrared spectroscopy spectrum of valdecoxib

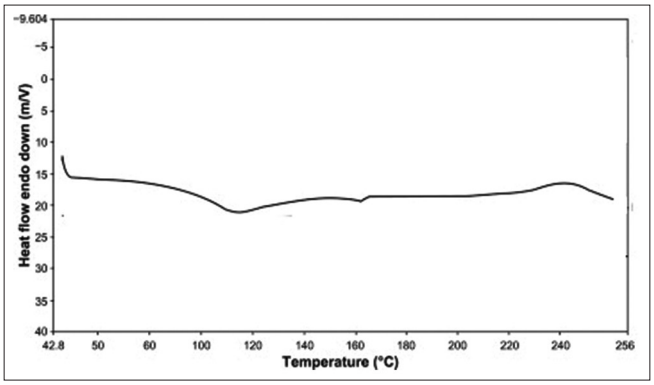

Figure 4: Differential scanning colorimetric graph of valdecoxib

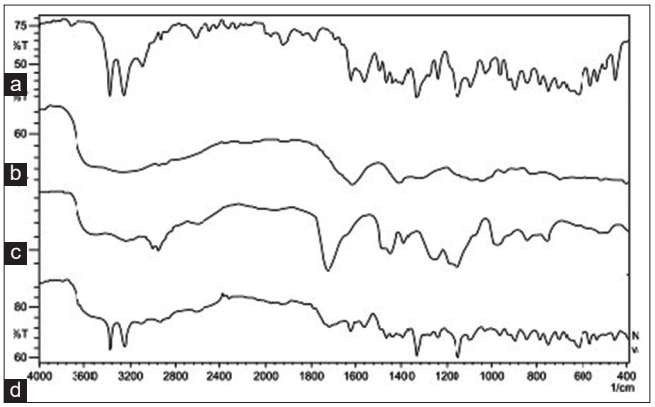

Figure 5: Drug-excipients compatibility studies performed by plotting the Fourier transform infrared spectroscopy spectra of (a) valdecoxib, (b) tragacanth, (c) pectin, and (d) optimized formulation (F3)

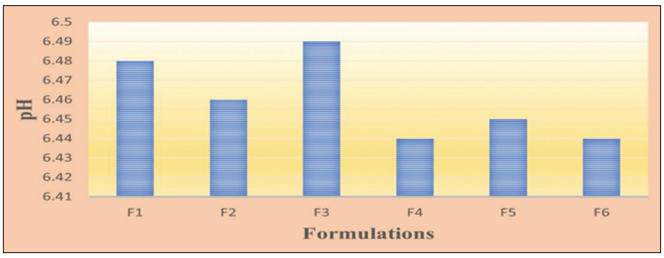

Figure 6: Graphical representation of pH of valdecoxib emulgel formulations (F1–F6)

Drug excipients compatibility study

Drug excipient compatibility testing was performed using FT-IR spectroscopy. The individual spectrum of valdecoxib, tragacanth, and pectin, as well as the physical mixture of optimized formulation F3, was prepared by mixing valdecoxib with a natural gelling agent used in the preparation of emulgels. Their infrared spectra were recorded by the potassium bromide dispersion technique using FT-IR on IR Affinity-1 (FTIR-8001, Shimadzu, Japan), and the IR spectra are recorded as shown in Figure 5.

When comparing the individual IR spectrum of valdecoxib with the physical mixture of emulgel optimized formulation F3, we found that the various characteristic peaks obtained in the FTIR spectrum of valdecoxib remained nearly unaffected, and there was no shift in the frequencies of the above-mentioned functional groups, and there were no additional peaks observed in the physical mixtures of optimized formulation F3. Hence, the above results concluded that valdecoxib was found to be compatible with gelling agents and other excipients, which were used in the preparation of emulgel.

Evaluation of prepared valdecoxib emulgels

Physical appearance

All the prepared valdecoxib emulgel formulations with Tragacanth, i.e., F1–F3, and prepared valdecoxib emulgel formulations with pectin, i.e., F4–F6, were examined visually for their color, homogeneity, consistency, phase separation, and texture[12,13], and the obtained results of the same evaluations are summarized in Table 3.

pH determination

The pH of 1% solutions prepared using distilled water of all the valdecoxib emulgel formulations was determined using a digital pH meter. The obtained results of the valdecoxib emulgel pH determination studies are shown in Figure 6.

Rheological study

The Brookfield viscometer model – Brookfield Viscometer (Brookfield DV III Ultra) with spindle was used to find out the rheological behavior of valdecoxib emulgel F1–F6 formulations, and the recorded viscosity readings are shown in Figure 7.

Table 1: Formulation composition of valdecoxib emulgel (%W/W)

Ingredients	F1	F2	F3	F4	F5	F6
Valdecoxib (g)	01	01	01	01	01	01
Tragacanth (g)	2.0	3.0	4.0	-	-	-
Pectin (g)	-	-	-	2.0	3.0	4.0
Isopropyl alcohol (mL)	5	5	5	5	5	5
Liquid paraffin (mL)	2.5	2.5	2.5	2.5	2.5	2.5
Ethyl paraben	0.05	0.05	0.05	0.05	0.05	0.05
Glycerine monostearate (mL)	0.2	0.2	0.2	0.2	0.2	0.2
Glycerine (mL)	6	6	6	6	6	6
Propylene glycol	4	4	4	4	4	4
Methyl paraben (g)	0.05	0.05	0.05	0.05	0.05	0.05
Triethanolamine (mL)	0.5	0.5	0.5	0.5	0.5	0.5
Almond oil (mL)	2	2	2	2	2	2
Rose oil (mL)	0.3	0.3	0.3	0.3	0.3	0.3
Purified water (mL)	Up to 100 mL	Up to 100 mL	Up to 100 mL	Up to 100 mL	Up to 100 mL	Up to 100 mL

Table 2: Micromeritic properties of valdecoxib

S. No.	Name of parameters	Obtained results
1	Angle of repose (0)	27.75
2	Bulk density (g/mL)	0.57
3	Tapped density (g/mL)	0.65
4	Carr's index (%)	15.6
5	Hausner's ratio	1.14

From all the obtained viscosities data of the different valdecoxib emulgel formulations (F1–F6) showed that emulgels prepared with tragacanth F1–F3 had showed more viscosities as compared to Emulgel prepared with pectin F4–F6 and the rheological behaviors of all the valdecoxib emulgel formulations (F1–F6) were at satisfactory level and leading for sufficient gelling efficiency of all valdecoxib emulgel prepared formulations.

Spreadability

Spreadability of the valdecoxib emulgels was determined 48 h after preparation of the emulgel using the wooden block and the glass slide apparatus. The spreadability indicates that the emulgel is easily spreadable by a small amount of shear. The spreadability of valdecoxib emulgels F1-F6 formulations was recorded, and the readings of the same are summarized in Table 4.

Extrudability study

The method adopted for evaluating valdecoxib emulgel formulations for extrudability was based upon the quantity in percentage of emulgel extruded from a lacquered aluminum collapsible tube on application of the weight in grams required to extrude the gel in specific time limit.

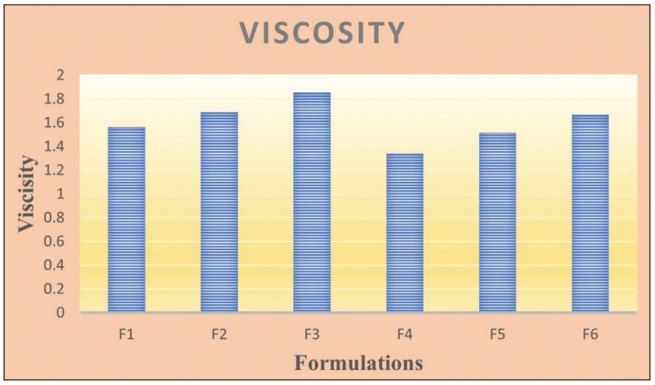

Figure 7: Graphical representation of viscosities of valdecoxib emulgel formulations (F1–F6)

Drug content

The percentage drug content estimation from various valdecoxib emulgel formulations was measured using a UV spectrophotometer (Labindia UV 3000+) after appropriate dilution at 243 nm using a UV spectrophotometer against the corresponding emulgel as blank.

In-vitro drug release study

The *in-vitro* drug release studies of the valdecoxib emulgels were carried out in a modified diffusion cell using a dialysis membrane. The emulgel was spread uniformly on the dialysis membrane, and the phosphate buffer solution pH 6.8 was added to the compartment. This cell was maintained at 37 ± 0.5°C. The sample was withdrawn at suitable time intervals and replaced with equal amounts of fresh dissolution media. Samples were analyzed spectrophotometrically at 243 nm, and the cumulative percentage drug release was calculated. The percent

Table 3: Physical appearances of emulgel formulations (F1–F6)

S. No.	Formulation	Color	Homogeneity	Consistency	Phase separation	Texture
1	F1	Yellowish white creamy	Average	Average	None	Smooth
2	F2	Yellowish white thick	Good	Uniform	None	Smooth
3	F3	Yellowish white thick	Good	Uniform	None	Smooth
4	F4	Whitish	Average	Average	None	Smooth
5	F5	Whitish creamy	Good	Uniform	None	Smooth
6	F6	Whitish thick	Good	Uniform	None	Smooth

Table 4: Spreadability of valdecoxib emulgel formulations (F1–F6)

S. No.	Formulation	Spreadability (g.cm/sec)	Extrudability (g/cm2)	Swelling index (%)	Drug content (%)
1	F1	38.32±0.20	39.85±0.44	26.40±0.20	91.40±0.35
2	F2	38.04±0.05	39.06±0.35	28.55±0.32	94.68±0.44
3	F3	37.86±0.44	38.75±0.80	32.70±0.25	99.70±0.88
4	F4	38.46±0.30	40.38±0.21	23.32±0.40	88.66±0.55
5	F5	38.12±0.10	39.96±0.05	25.98±0.78	91.61±0.78
6	F6	37.92±0.55	38.48±0.55	28.80±0.45	95.42±0.80

Table 5: Accelerated stability study of optimized F3 formulation

Parameters	Days			
	7	14	21	28
Color	Yellowish white thick	Yellowish white thick	Yellowish white thick	Yellowish white thick
Phase separation	None	None	None	None
Texture	Smooth	Smooth	Smooth	Smooth
pH	6.49±0.22	6.48±0.35	6.48±0.10	6.47±0.07
Spreadability	37.86±0.44	37.85±0.35	37.84±0.27	37.84±0.14
Swelling index (%)	32.70±0.25	32.69±0.18	32.69±0.05	32.68±0.02
Drug content (%)	99.70±0.88	99.70±0.75	99.69±0.62	99.69±0.58
In vitro drug release (%)	99.70±0.41	99.70±0.34	99.69±0.55	99.68±0.28

drug release of valdecoxib from emulgel formulations is summarized in Figure 8.

The *in-vitro* drug release from valdecoxib emulgel formulations F1–F3 prepared using tragacanth was found to be in the range 91.4 ± 0.40%–99.07 ± 0.41%, and from formulations F4–F6 prepared using pectin was found to be in the range 88.66 ± 0.42%–95.42 ± 0.88%. Valdecoxib emulgel formulation F3 showed the highest *in vitro* drug release. The drug release from emulgels was attributed to the presence of permeation enhancers in the valdecoxib emulgel formulations.

On the basis of data obtained from the evaluation of valdecoxib emulgels prepared using two different gelling agents. The various official as well as parameters such as physical appearance, pH determination, spreadability,

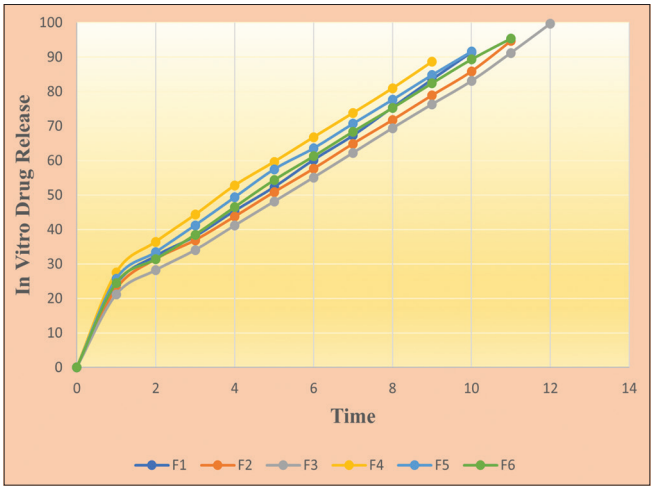

Figure 8: Graphical representation of *in vitro* drug release of valdecoxib emulgel formulations (F1–F6)

extrudability, swelling index, drug content, in vitro drug release study reveals that the formulation F3 had showed the overall best results. Hence the formulation F3 was selected as best emulgel formulation and further subjected to the accelerated stability studies according to ICH guidelines.

Accelerated stability testing of valdecoxib optimized emulgel formulation (F3)

Accelerated stability testing is a validated method by which the product stability may be predicted by storage of the product under conditions that accelerate the change in a defined and predictable manner.

Stability testing of valdecoxib optimized emulgel formulation F3 was carried out to determine the stability of the drug and carrier, and also to determine the physical stability of formulations as per ICH guidelines for stability testing under accelerated storage conditions at various temperatures using Remi Programmable Environmental Test Chamber CHM 06, Vasai, India. The best emulgel formulation, F3, was stored at 40°C ± 2°C with humidity 75% ± 5% RH for the period of 1 month. Samples were withdrawn after 0, 7, 14, 21, and 28 days and evaluated for color, phase separation, texture, pH, spreadability, swelling index, drug content, and % drug release. The obtained results of the accelerated stability study of valdecoxib optimized F3 formulation are summarized in Table 5.

The accelerated stability studies of the optimized valdecoxib emulgel formulation F3 at the intervals of 7, 14, 21, and 28 days did not show any change in color, phase separation, and texture. The pH of the emulgel formulation was found between 6.47 ± 0.07 and 6.49 ± 0.22, spreadability was found between 37.84 ± 0.14 and 37.86 ± 0.44, swelling index was found between 32.68 ± 0.02 and 32.70 ± 0.25, drug contents were found between 99.69 ± 0.58 and 99.70 ± 0.88, and *in vitro* release was found between 99.68 ± 0.28 and 99.70 ± 0.41. Thus, overall accelerated stability studies of the optimized valdecoxib emulgel formulation F3 revealed that there was no significant change in the color, phase separation, and texture when stored at temperature and humidity conditions of 40 ± 2°C/75 ± 5% RH. No significant changes were observed in the pH, spreadability, swelling index, and drug content, and % drug release was observed over a period of 28 days. This indicated that the valdecoxib emulgel formulation F3 was stable at 40°C/75% RH.

RESULTS AND DISCUSSION

The *in-vitro* drug release from valdecoxib emulgel formulations F1–F3 prepared using tragacanth was found to be in the range 91.4 ± 0.40%–99.07 ± 0.41%, and from formulations F4–F6 prepared using pectin was found to be in the range 88.66 ± 0.42%–95.42 ± 0.88%. Valdecoxib emulgel formulation F3 showed the highest *in vitro* drug release. The drug release from emulgels was attributed to the presence of permeation enhancers in the valdecoxib emulgel formulations.

CONCLUSION

The physicochemical, micromeritic, and spectroscopic characterization of valdecoxib confirms the identity and purity of the valdecoxib [Table 2]. A total of six valdecoxib emulgel formulations (F1–F6) were prepared using the two different gelling agents in different concentrations, and the prepared formulations were further evaluated for various parameters. All the obtained results of all the emulgels evaluation parameters were good and analogous. The valdecoxib emulgel formulation F3 was selected as the best emulgel formulation. According to ICH guidelines, it showed that the formulation F3 was stable at 40°C/75% RH.

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