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Research Article

Formulation and Evaluation of the Sustained Release Tablet of Ketorolac Tromethamine Using Natural Polymer as an Extended Releasing Agent

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ABSTRACT

Sustained release tablets of Ketorolac Tromethamine were formulated using Aloe vera Gel Powder as extended drug releasing agent. The tablets were evaluated for preformulation studies like angle of repose, bulk density, compressibility index and physical characteristics like hardness, weight variation, friability and drug content. *In-vitro* release of drug was carried out in phosphate buffer solution pH 6.8 for twelve hours. All the physical characters of the formulated tablet were found within the acceptable limit. The tablet with Aloe Vera gel powder in Batch-F3 exhibited greater drug release than other batches. It is proved from the dissolution profile of Ketorolac Tromethamine, that Aloe Vera gel powder possess the drug release retarding ability.

keywords: Ketorolac Tromethamine, *Aloe Vera Gel Powder, Sustained release tablets, release retarding ability.*

INTRODUCTION

Drug products designed to reduce the frequency of dosing by altering the rate of drug absorption. Regular research aroundis, that the use of natural biocompatible polymer while formulating the dosage form for oral sustained release administration. The advantages of natural plant based excipients include low cost, natural origin, free from side effects,biocompatible, bioacceptable, renewable source; environmental friendly processing,local availability, better patient tolerance as well as patient acceptance. The Ketorolac Tromethamine is the NSAID belongs to BCS-I that exhibit the analgesic activity, used in treatment of rheumatoid arthritis. Itgives upto the approximately 100% absorption upon oral administration. But the half life of the drug is 2.5hrs which requires frequent administration of drug to maintain the required therapeutic level in body.Hence it is required to be formulated in sustained release dosage form. This study mainly aimed for oral controlled delivery system of highly water soluble drug i.e. Ketorolac Tromethamine using *Aloe Vera gel* powder as extended drug releasing agent. The genus Aloe belongs to the family, Liliaceae and includes the species *Aloevera barbadensis miller*, commercially known as *Aloe vera*. Chemical analysis has shown that the Aloe vera gel powder contains amino acids, minerals, vitamins,enzymes, proteins, polysaccharides and biological stimulators.

MATERIAL AND METHOD

Material

The Ketorolac Tromethamine was obtained as gift sample from Divis Pharmaceuticals Pvt.Ltd. India. And the Aloevera Gel powder was gifted from Maple Biotechpvt.ltd Bhosari, Pune. All other excipients and chemicals used were of analytical reagent grade.

Method

Preparation of sustained release tablet of ketorolac tromethamine using natural polymer(aloe vera gel powder)

The direct compression method was used for the formulating the sustained release tablet of the ketorolac tromethamine using the natural polymer aloevera gel powder.

The Ketorolac Tromethamine, Aloevera gel powder,lactose were mixed and passed through the 40# sieve. Afterward magnesium stearate and talc was added and mixed to it. Final mixture was compressed on the multistation rotary tablet compression machine.

Evaluation parameters

Phytochemical studies

A*loe vera* gel powder was subjected to preliminary tests to confirm the nature of the obtained powder. The tests

Table 1: Formula for the formulation of the suatained release tablet using aloevera gel powder.

Ingridient (mg)	F1	F2	F3
Ketorolac Tromethamine	20	20	20
Aloevera Gel Powder	40	60	80
Magnessium stearate	2	2	2
Talc	4	4	4
Lactose	84	64	44
Total	150	150	150

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Drug polymer compatibility studies.

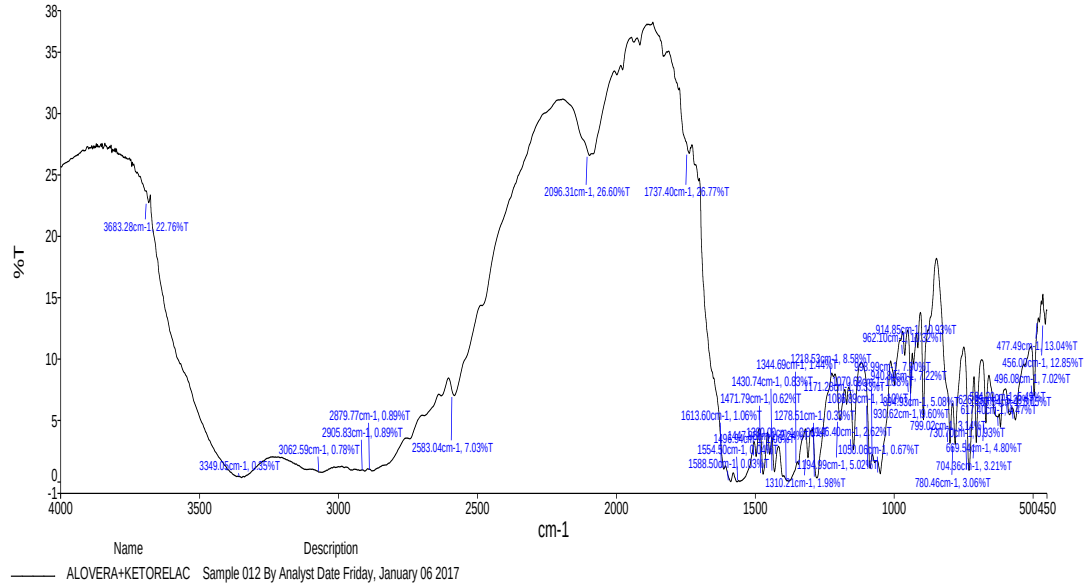

Figure 1: IR spectra of aloevera gel powder plus ketorolac tromethamine.

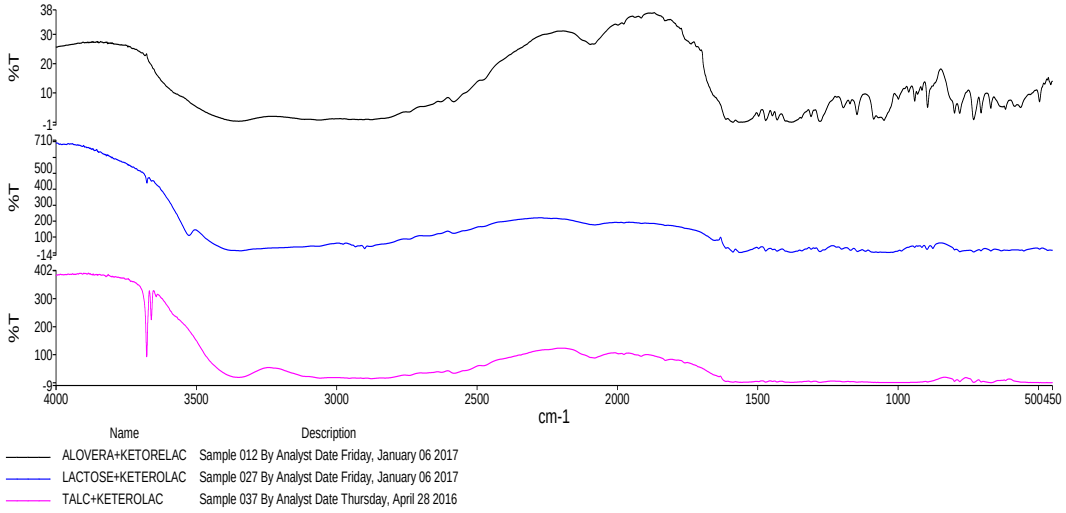

Figure 2: IR spectra of all excipients with ketorolac tromethamine.

Table 2: Tests for Aloevera gel powder.

Sr.No.	Phytochemical tests	Observations	Results
1	Test for Alkalloids		
	Wagner's Test	Reddish brown ppt	Passes
	Mayer's Test	Ppt observed	Passes
	Dragondorff Test	Orange ppt	Passes
2	Test For Carbohydrates(molisch test)	Violet ring formed at junction	Passes
3	Test For Proteins(Biuret test)	Pink colour appears	Passes

performed were to determine the presence of alkaloids, amino acids, minerals, proteins and polysaccharides.

flow properties of aloe veragel powder

The *Aloe vera gel* powder was evaluated for flow properties like Bulk density (BD), Tapped density (TD), Carr's index, Hausner's ratio and Angle of repose.

Drug polymer compatibility studies

The compatibility studies of drug, polymer and the physical mixture (1:100) of drug and polymer were carried out using Fourier Transform Infrared Spectrophotometer (Perkin Elmer) by KBr disc method.

Pre-compression and Post-compression studies

The powdered blend was evaluated for micromeritic flow properties like Bulk density (BD), Tapped density (TD), Carr'sindex, Hausner's ratio, Angle of repose and the formulated tablets were evaluated for various parameters like weight variation, hardness and friability studies.

In vitro dissolution studies

Phytochemical study
In-vitro dissolution study

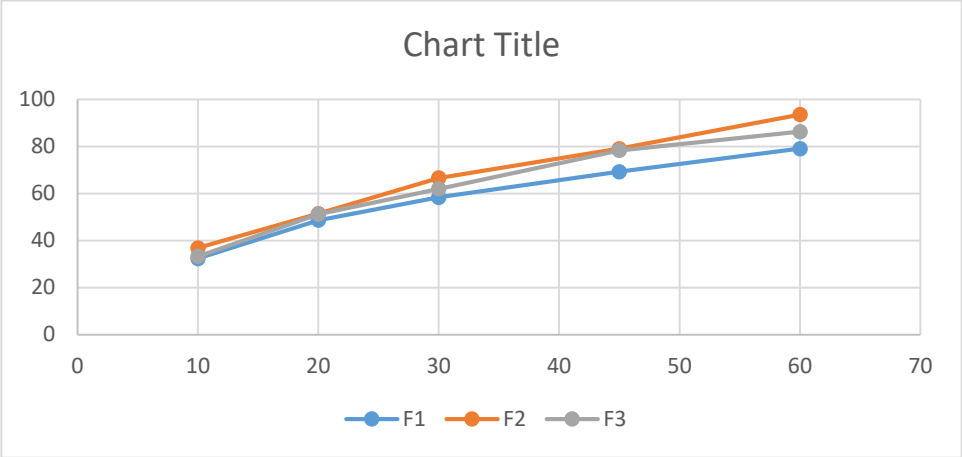

Figure 3: In-vitro dissolution profile for the formulated ketorolac tromethamine tablets.

Flow Properties of aloevera gel powder
Table 3: Flow properties of Aloevera gel powder.

Sr.No	Parametres	Value
1	Bulk density(gm/ml)	0.35
2	Tapped density(gm/ml)	0.40
3	Carr's Index(%)	14.28
4	Hausner'sRatio	1.14
5	Angle of Repose(º)	21º75'

Post compression study
Table 4: Post compression tests.

Sr.No.	Batch	Hardness (kg/cm^2)	Friability (%)	Weight variation(mg)
1	F1	3.8	0.32	153±2.4
2	F2	4.1	0.27	158±2
3	F3	4.4	0.24	155±2.4

The dissolution studies were performed in a USP apparatus II dissolution rate test apparatus (Type II). The release studies were performed at 50 rpm in 900 ml of 0.1N HCl for the 1st 2hrs and replaced with phosphate buffer of pH 6.8 for further studies. Aliquots were withdrawn at predefined intervals, and the volume of the dissolution medium was maintained by adding the same volume of fresh pre-warmed dissolution medium. The absorbance of the withdrawn samples was measured spectrophotometrically at 322nm and the drug release calculated.

RESULT AND DISCUSSION

The Aloevera gel powder gifted is yellowish green in color. The gel powder obtained was subjected to phytochemical tests and it showed the presence on alkaloids, proteins and polysaccharides. The results of the micromeritic flow properties are shown in Table 3, which indicated good flow properties. Drug – excipient compatibility studies were done to evaluate interactions between the drug and polymer.

CONCLUSION

The present study shown that the plant based *aloe vera* gel powder has the potential of sustained release retarding agent in the development of extended release solid dosage forms.

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