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Evaluation of Gels and Films of Triamcinolone for the Treatment of Aphthous Ulcer

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ABSTRACT
The present work was aimed to develop a in-situ gels and films of Triamcinolone for the treatment of aphthous ulcer. The in-situ gels and film were developed by using methylcellulose, based on the concept of temperature dependent gelling system. The sol-to-gel transformation occurred during the reduction of temperature. The in-situ gels were evaluated for gelling capacity, drug content, viscosity & in-vitro release was as in the film it evaluated for tensile strength, folding endurance, thickness etc. The experimental part shows that viscosity of the sol was increased by increasing the concentration of polymer. All the results were found to be satisfactory, when compared between the in-situ gels and films. The has shown the best formulation because of their therapeutic efficacy and provided sustained release of the drug over a period of time. These results demonstrate that the developed system is an alternative to conventional drug delivery system, patient compliance, industrially oriented and economical.

I. INTRODUCTION

Sustained release system includes any drug delivery system that achieves slow release of the drug over an extended period of time. If the system is successful in maintaining control drug level in the blood or target tissue it is considered as controlled release system. If it is unsuccessful at this but nevertheless extends the duration of action over that achieved by conventional delivery, it is considered a prolonged release system[3]. The oral route of administration for sustained release system has received greater attention because of more flexibility in dosage form design.

Greater attention has been focused on development of sustained release[1], sustained action, prolonged action, controlled release, extended release and depot release dosage form are the terms used to identify drug delivery system that are designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose of a drug and become the standard in modern pharmaceutical design[2]

Advantages:
1. The frequency of drug administration is reduced
2. Patient compliance can be improved
3. Drug administration can be made more convenient
4. The blood level oscillation characteristics of multiple dosing of conventional dosage form is reduced, because a more even blood level can be maintained
5. Better control of drug absorption can be attained, since the high blood level peak that may be observed after administration in an extended action form

Disadvantages:
1. Administration of sustained release medication does not permit prompt termination of therapy
2. Flexibility in adjustment in dosage regimen is limit
3. Controlled release forms are designed for normal population i.e., on the basis of average drug biological half-lives.
4. Economy factors may also be assessed, since most costly process and equipment are involved in manufacturing so many controlled release dosage forms.

Oral In situ gel:

In situ gel forming drug delivery is a type of mucoadhesive drug delivery system. The development of in situ gel systems has received considerable attention over the past few years[7]. Capable of releasing drug in a sustained manner maintaining relatively constant plasma profiles. These hydrogels are liquid at room temperature but undergo gelation when in contact with body fluids or change in pH. These have a characteristic property of temperature dependent, pH dependent and cation induced gelation. Compared to conventional controlled release formulations, in

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situ forming drug delivery systems possess potential advantages like simple manufacturing process, ease of administration, reduced frequency of administration, improved patient compliance and comfort[8]. In situ gel can be easily applied in liquid form to the site of drug absorption.

Oral Films:

A Film can be defined as a dosage form that employs a water-dissolving polymer (generally a hydrocolloid, which may be bio adhesive polymer), which allows the dosage form to quickly hydrate, adhere and dissolve when placed on the tongue or in that oral cavity (i.e., buccal, palatal, gingival, lingual or sublingual, etc.) to provide rapid local or systemic drug delivery. Peroral dosage forms can be distinguished as solid or liquid oral dosage form in which the prior fall in category of pills, capsules, granules and powders. While the later includes solution/ suspensions or emulsions offering more advantages over monolithic solid dosage forms.

Formulation design of in situ gel

Batch Code	Triamcinolone (%w/v)	Methyl cellulose (%w/v)	Sodium citrate (%w/v)	Triethan olamine	Distilled Water
F1	1	0.25	0.25	Q.S	Q.S
F2	1	0.50	0.25	Q.S	Q.S
F3	1	0.75	0.25	Q.S	Q.S
F4	1	1.00	0.25	Q.S	Q.S
F5	1	1.25	0.25	Q.S	Q.S
F6	1	1.50	0.25	Q.S	Q.S
F7	1	1.75	0.25	Q.S	Q.S
F8	1	2.00	0.25	Q.S	Q.S

Stability studies:

The stability studies were carried out for prepared in situ gelling systems. All the formulations were analysed for visual appearance, clarity, pH, gelling capacity, drug content and in vitro release studies. 90days of stability studies revealed that there was no change in visual appearance and clarity. All the formulations have shown slight changes in pH which was in acceptable limits (±0.3). Study of drug content and in vitro drug release revealed that there were no definite changes observed to justify for drug degradation.

Stability studies of formulations stored at 40 ±1°C/ ambient humidity

No. of days	Drug content%							
	F1	F 2	F 3	F 4	F 5	F6	F7	F8
15	80.3	76.4	81.10	84.70	97.61	85.15	96.40	94.80
30	80.29	76.39	81.09	84.69	97.59	85.12	96.38	94.79
45	80.27	76.37	81.08	84.67	97.58	85.11	96.37	94.77
60	80.26	76.35	81.06	84.66	97.56	85.10	96.36	94.75
75	80.25	76.34	81.04	84.65	97.55	85.08	96.35	94.74
90	80.24	76.32	81.05	84.63	97.52	85.06	96.32	94.73

Preparation of in situ gelling system:

For the preparation of methyl cellulose containing in situ gel formulations, sodium citrate was added to distilled water with continuous stirring until clear solution was obtained. Methyl cellulose was added to above solution with continuous stirring and allowed to hydrate overnight. Calculated amount of Triamcinolone (1% w/v) drops triethanolamine was added separately and then added to polymer solution under constant stirring. The formulation design Of Triamcinolone in situ gel was tabulated. The

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optimization concentration of methyl cellulose was selected on the basis of gelation temperature and gelation time. Further, the prepared formulations were evaluated for various characterization studies.

Formulation design of oral films

Batch Code	Triamcinolone (%w/v)	Methyl cellulose (%w/v)	Sodium citrate (%w/v)	Propylin glycol	Distilled Water
F1	1	0.25	0.25	0.25	Q.S
F2	1	0.50	0.25	0.50	Q.S
F3	1	0.75	0.25	0.75	Q.S
F4	1	1.00	0.25	1.00	Q.S
F5	1	1.25	0.25	1.25	Q.S
F6	1	1.50	0.25	1.50	Q.S
F7	1	1.75	0.25	1.75	Q.S
F8	1	2.00	0.25	2.00	Q.S

Comparison between release behaviour of in-situ gel and oral film

In-vitro release behaviour of both in-situ gel and oral film were preformed in same medium. The data obtained from the experiment reviled that the film based formulation released all most all percentage of drug within 8 minutes, but it took almost 8 hours for same amount of drug release from the in-situ gel formulation. Longer time period for the drug release from the gel might be the diffusion controlled mechanism. When we see the release pattern it was higher and faster for oral film i.e. within 8 minutes, but the formulation was designed for aphthous ulcer, so we consider in-situ gel formulation was suitable formulation for the treatment of aphthous ulcer, as it sustain the drug release up to 8 hours. The frequency of the drug application also reduced significantly and also improves patient compliance.

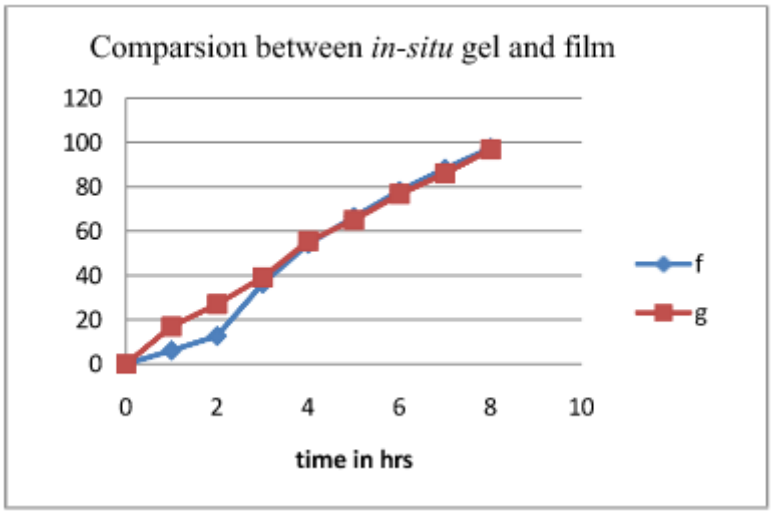

Figure: Comparsion between in-situ gel and film

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