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Development and Evaluation of Ophthalmic Drug Delivery System

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ABSTRACT: This research paper is about development and evaluation of ophthalmic drug delivery system. In the current work an endeavour was made up to set up to create a sustained release in-situ solution to gel polymeric delivery system utilizing polymer (Pluronic F-127, Methyl cellulose, hydroxyl propyl methylcellulose, and polyethylene glycol 6000) as copolymers. Permeability, bioavailability & Solubility of drug was enhanced. We use cold method for preparation of polymer solution. The ultimate goal of formulating in situ solution to gel with enhanced pharmacokinetic with ideal discharge of drug was prepared.

I. INTRODUCTION

In this paper i.e., polymeric solution was prepared by cold method. It has normal features and benefits over conventional dosage in better form. Drug rapidly get discharge after giving it subcutaneously or via eyes.

Controlled drug delivery refers to the administration of a medication at a preset rate and/or location based on the requirements of the body and illness over a certain length of time. Controlling the drug's release has been done in a variety of ways. Drug alteration and dosage form modification are two typical approaches. One of the most frequent methods for delaying the release of the medication from the dosage form and therefore prolonging the effective time period is to change the dose form.

The lower critical solution temperature is the name for this transition temperature (LCST). The polymers are water soluble below this temperature. These polymers become hydrophobic and water insoluble above the LCST, resulting in solidification. To validate the sol–gel transition of such thermo-reversible polymeric solutions, several methods such as spectroscopy [10], differential scanning calorimetry (DSC), and rheology may be used

The increase in hydrophobicity causes physical reversible connection between the polymer chains, allowing gels to return to solution when the temperature stimulus that caused gelation is removed.

Because of their high compatibility, degradability within the biological system, and temperature sensitivity, biodegradable thermo-reversible polymers have been widely investigated

These polymer solutions are liquid at ambient temperature, but when injected into the body, they change into gels, a process known as the sol-gel transition. When opposed to gel/semisolid dosage forms, liquid dosage forms are easier to produce, package, and give quantitatively.

II. METHODOLOGY

Preparation of Diclofenac Sodium In-situ Gel Formulations

5mg diclofenac sodium+ 180mg PLF127 The solution is continuously stirred till clear solution is obtained The final solutions were sterilized by autoclaved Afterward it was evaluated for their physicochemical properties

Composition of Diclofenac Sodium thermoreversible gel

S. No	Formulation	Diclofenac Sodium (mg)	PL (mg)	F127	MC (mg)	PEG (mg)	Distilled Water
1.	DP18	5.0	180		-----	-----	qs to 1 ml
2.	DP20	5.0	200		-----	-----	qs to 1 ml

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3.	DPM 15/3	5.0	150	30.0	-----	qs to 1 ml
4.	DMPG 1.5/10	5.0	-----	15.0	100.0	qs to 1 ml
5.	DMPG 3/2	5.0	-----	30	20.0	qs to 1 ml

Preparation of Timolol Maleate In-situ Gel Formulations

5mg Timolol Maleate + 180mg PLF127 The solution is continuously stirred till clear solution is obtained

The final solutions were sterilized by autoclaved Afterward it was evaluated for their physicochemical properties

Composition of Timolol maleate thermoreversible gel

S. No	Formulation	Timolol maleate (mg)	PL (mg)	F127	MC (mg)	PEG (mg)	Distilled Water
1.	TP18	5.0	180		-----	-----	qs to 1 ml
2.	TP20	5.0	200		-----	-----	qs to 1 ml
3.	TPM 15/3	5.0	150		30.0	-----	qs to 1 ml
4.	TMPG 1.5/10	5.0	-----		15.0	100.0	qs to 1 ml
5.	TMPG 3/2	5.0	-----		30	20.0	qs to 1 ml

Evaluation

- The **elimination half-life** obtained was in average 15.17
- **Mean residence time** 60.83
- The **plasma drug concentration** 2.2025
- **pH** the pH of gel formulation was determined by digital pH meter. Each formulation was done by triplet. At last, the value was calculated.
- **Viscosity study**

Viscosity of this prepared formulation was determined by the using of rotational viscometer (fungi lab) with the spindle no. PA, PC, PB, PD, PE, PF

- **Spread ability**

The evaluation of Spread ability of formulation was detected by measured using
calculated that by using of bellowing formula.

S=M×L/T

S= Spread ability (gcm^{-1}/sec)

M=weight of tied gel on the upper plate

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L=length of glass slide
T= Time

- **Extrudability study**

The Extrudability was determine by the extruded the gel from tube.

- **Melting Point** Melting point of the drug was determined by Theil's melting point apparatus and temperature at which the drug melt was noted.

III. RESULT AND DISCUSSION

Pharmacokinetic parameters of diclofenac sodium commercial formulation and in-situ gel after subcutaneous administration

Formulation		DPL 20		DPM15/3		Reference
Pk Parameter	**Unit**	**Mean ± SD**	**P Value**	**Mean ± SD**	**P Value**	**Mean ± SD**
E Half-life	**hr.**	23.109±9.70	0.008	6.785±0.07	0.013	4.038±0.19
Cmax (obs)	**µg/ml**	2.4017±0.109	0.004	2.724±0.06	0.001	0.671±0.061
Tmax (obs)	**hr.**	48±0.0	----	48±0.0	----	2±0.0
AUC(0-t) (obs area)	**µg-hr./ml**	156.61±11.71	0.002	85.757±0.21	0.001	4.608±0.15
AUC (0-∞)	**µg-hr./ml**	202.22±44.68	0.017	88.058±0.12	0.001	5.493±0.09
AUMC (0-∞)	**µg-hr.*hr./ml**	14731 ±6097.78	0.005	3370.8±19.18	0.001	38.19±12.43
MRT (area)	**hr.**	70.901±13.19	0.015	38.279±0.27	0.001	6.953±0.31
Vd (area) / kg	**ml/kg**	802.39±152.59	0.002	555.94±6.42	0.001	5304.60±4.56
CL (area) / kg	**ml/hr./kg**	25.486±5.19	0.001	56.780±0.08	0.001	910.190±0.10
Half-life from Vd and CL	**hr.**	23.109±9.70	0.008	6.7851±0.07	0.013	4.038±0.19

IV. CONCLUSION

The goal of this research was to create a sustained release in-situ solution to gel polymeric delivery system for medicines that would be given subcutaneously or via the eyes. Four polymers (Pluronic F-127, Methyl cellulose, hydroxyl propyl methylcellulose, and polyethylene glycol 6000) were utilized in various quantities and ratios alone and in combination. For Tso-gel, a total of thirty-four formulations were created and tested.

The in-vivo dissolution profile matches the in-vitro dissolution profile. When compared to reference conventional formulations of these medicines, the thermoreversible in-situ gel formulations of all three medicines exhibited higher and longer bioavailability. All of the

medicines examined had formulations that were able to sustain plasma and AH steady state concentrations for extended periods of time.

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