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Formulation Development and Evaluation of Triamcinolone Ointment

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Abstract

This Study was carried out with an aim of formulation development and in vitro evaluation of triamcinolone ointment 0.5%. An attempt was made to formulate a bioequivalent ointment dosage form of anti-inflammatory agent and anti-pruritics with in vitro release profile matching the standard specification. Based on literature information, pre-formulation studies and also result of first batch the manufacturing process in point no (7.2.2.1) was decided to adopt. Results of the present study advocate that Experiment for triamcinolone Ointment was selectedbased on 2 month stability studies at 25°C/60%, 30°C/65% and 40°C/75% conditions. The good degree of *in vitro* release study established the triamcinolone drug availability. Although remarkable achievements in topical corticosteroid therapy have been attained since this diseases was first recognized more than a decade ago, enormous challenges remain for the researchers to ultimately curb the progression and find a cure for Topical inflammations.

Keywords: Formulation, Triamcinolone Ointment, Evaluation

Introduction

Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes.Skin is one of the most readily accessible organs on human body for topical administration and is main route of topical drug delivery system.This review is concern with all detail information regarding rational approach to topical formulations, principles of topical permeation and basic components of topical drug delivery systems.Overall, the clinical evidence indicates that topical Formulations is a safe and effective treatment option for use in the management of skin related disease. Topical preparations are applied to the skin for surface, local or systemic effects. In some cases, the base may be used alone for its therapeutic properties, such as emollient, soothing or protective action. Many topical preparations, however, contain therapeutically active ingredients which is dispersed or dissolved in the base.

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Materials and Methods

Formulation Development

As per drug-excipient compatibility study result drug compatible excipients were selected for formulation process development and evaluation of triamcinolone ointment.

Manufacturing process

Preparation of oil phase: White petrolatum was taken in a SS vessel and heated till temperature 65-70°C. Maintain the temperature of oi l phase at 65ºC-70°C.

Preparation of drug dispersion: Light mineral oil was taken in SS vessel and heated to 60°C-65°C. Slowly added Triamcinolone USP under stirring at temperature between 60°C to 65°C and continue stirring for 15-2 0 minute maintaining temperature at 60°C-65°C.Ensured homogeneous dispersion.

Homogenization:

Oil phase was transferred to the main manufacturing vessel maintained at temperature at 65ºC-70°C. Drug dispersion was transferred to the main manufacturing vessel containing oil phase maintained at 65°C -70° C under stirring. Rinse thoroughly the drug vessel with of light mineral oil heated up to temperature 60 to 65°C and transfer to the main manufacturing vessel under stirring. Homogenize the bulk with recirculation for 30 minutes under stirring maintaining temperature at 65°C to 70°C.

Cooling under homogenization

Cool the bulk under homogenization and stirring till temperature 40°C -45°C.

Cooling under stirring

Continue cooling by water circulation under stirring till temperature of the bulk reaches between 29°C and 32°C.

Development Trials

The development trial was carried out with the concentrations of light mineral oil (20%, 14%%, 12% 8%, and 3%) for evaluating effect of emollient to match the consistency and to reduce the oily feeling. The ointment was prepared as per the formulation given in Table using the above mentioned manufacturing process and subjected to evaluation of physical and chemical stability.

Table 1: The formula for process development

S/No	Ingredients	EXP-1	EXP-2	EXP-3	EXP-4	EXP-5
1	Triamcinolone acetonide	0.5	0.5	0.5	0.5	0.5
2	Mineral oil	20	14	12	8	3
3	White petrolatum	79.5	85.5	87.5	91.5	96.5
	Total	100	100	100	100	100

During development it was optimized the ratio of light mineral oil: White petrolatum results were found complies with the specification. Based on the physicochemical properties .3% Light mineral oil was proposed for further trials**.**

Trials with Alternate Grade of White Petrolatum

The further trial is carried out with different grades of white petrolatum to unfold the effect on in vitro release testing. The different grade of white petrolatum (Ultima, Snow white, Wax oil, Sasol and Sonnebern).

Table 2: The formula for process development

S/N	Ingredient	EXP-6 ULTIMA	EXP-7 WAX OIL	EXP-8 SASOL	EXP-9 SONNEBORN	EXP-10 SNOWWHITE
1	Triamcinolone	0.5	0.5	0.5	0.5	0.5
2	Mineral oil	3	3	3	3	3
3	White petrolatum	96.5	96.5	96.5	96.5	96.5
	Total	100	100	100	100	100

Formulation optimization batch

The development trial was carried out with (snow white) white petrolatum complied with IVRT. The ointment was prepared as per the formulation given in Table using the manufacturing process as discussed above and subjected to stability for evaluation of physical characteristic.

Table 3: Formula Optimization

S/N	Ingredient	% w/w (gram)	Formula for 15 kg (gram)
1	Triamcinolone	0.5	7.5
2	Mineral oil	3	45
3	White petrolatum(Snow White)	96.5	1447.5
	Total	100	1500

Evaluation was done asper standard procedure

Results and Discussion

Primary batches (Exp-1 and Exp-2) of triamcinolone ointment were formulated but result of physical parameter show poor rheological properties and desired consistency could not be achieved. In the Exp-1 and Exp-2 the ointment found to be was not good in consistency and oily after touch when compared to reference product. The batches discarded and reduced concentration of mineral oil tried in further trials. Next Exp-3 were taken by decreasing the concentration of mineral oil to overcome the problem viscosity and grittiness. The problem of viscosity solved in Exp-4 but could not matched specification of IVRT. In the further (Experiment) to minimize the problem in vitro release different grades of excipients were used.

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Table 4: Physicochemical parameter of development batches

Experiment No	Viscosity In poise	Assay	Homogeneity	IVRT
1	EEE	94.7	Clear	Not comply
2	EEE	95.6	Clear	Not comply
3	EEE	93.7	Clear	Not comply
4	3.45	97.1	Clear	Not comply
5	2.51	97.7	Clear	Not comply

Table 5: Relative substances development batches

Exp. No	Relative substances				
	Imp-H (1.0%)	Imp-D (1.0%)	Imp-I (1.0%)	Unsp imp(0.5%)	Total Imp (4.0%)
1	Nil	Nil	Nil	Nil	Nil
2	Nil	Nil	Nil	Nil	Nil
3	Nil	Nil	Nil	Nil	Nil
4	Nil	Nil	Nil	Nil	Nil
5	Nil	Nil	Nil	Nil	Nil

Table 6: Tube uniformity of batch

Tube uniformity of batch (% Assay)						
Exp. No	Top	Middle	Bottom	Mean	RSD	Particle size (NMT 15µ)
1	94.4	95.4	94.3	94.7	0.6	3.8µ

2	96.3	94.5	95.9	95.6	0.9	3.84µ
3	93.3	95.1	92.8	93.7	1.2	4.28µ
4	97.6	97.1	96.6	97.1	0.5	3.74µ
5	97.5	98.4	97.3	97.7	0.9	3.82µ

Table 7: In vitro evaluation using different grades white petrolatum

Experiment No	**Specification**	**% drug release Results (8th /29th hr)**
6	% drug release (75%-133.3%)	112.3% - 140.0%
7	% drug release (75%-133.3%)	90.96% - 103.35%
8	% drug release (75%-133.3%)	93.46% - 108.97%
9	% drug release (75%-133.3%)	94.16%to126%
10	% drug release (75%-133.3%)	78.08% - 132.79%