RESEARCH ARTICLE

Formulation and Characterization of Niosomal Gel for Topical Treatment of Psoriasis

Mansi Gupta*, Sarika Shrivastava, Jitendra Banweer

Sanjeev Agrawal Global Educational University, Bhopal, MP-462022, India

Received: 9th Jun, 2025; Revised: 16th Jul, 2025; Accepted: 29th Aug, 2025; Available Online: 25th Sep, 2025

ABSTRACT

The aim of the research work was to formulate and characterize the Calcipotriol loaded niosomal gel for the topical treatment of psoriasis through application of different polymers. Psoriasis is a chronic skin condition in which the skin develops areas that become thick and covered with silvery scales. For psoriasis treatment, topical application is preferred in spite of other dosage form. Use of Fourier transform infrared Spectroscopy (FT-IR) showed that Calcipotriol was compatible with other excipients in terms of its physical and chemical nature. The gels formulated were analysed for their viscosity, extruding potential, drug content, test of skin irritation, pH of final formulation, along with its stability and *in-vitro* diffusion profile. The process includes the release of Calcipotriol from all prepared formulations by using dialysis membrane in the pH 6.8 phosphate buffer at 37°C temperature. This characterization study allowed to select the optimized batch from among the formulations prepared. From the data gathered it was ascertained that Calcipotriol has the potential in being used in gel formulation for the therapeutic management of psoriasis.

Keywords: Psoriasis, Calcipotriol, niosomal gel, topical therapy, carbopol, HPMC

How to cite this article: Mansi Gupta, Sarika Shrivastava, Jitendra Banweer. Formulation and Characterization of Niosomal Gel for Topical Treatment of Psoriasis. International Journal of Drug Delivery Technology. 2025;15(3):1077-81. doi: 10.25258/ijddt.15.3.23

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Psoriasis is a disease of the skin that is auto immune in nature. It takes place when the body immune system detects the own skin cells as an invader and sends wrong signals that encourage the growth of skin cells at a faster rate than is actually required. It is a long-standing inflammation and proliferation of skin whereby genetic and environmental factors play a significant role[1]. Psoriasis is chronic in nature and is likely to relapse again and again. Skin continues to develop flakes called psoriatic plaques because of proliferation of epidermis cells, which resemble fish like skin and eventually exfoliates[2].

Though not contagious, the probability of developing psoriasis increases in one having chances of getting stroke. The types of psoriasis includes guttate, plaque, pustular, inverse and erythro-dermic types. The most frequent type of the skin disorder is called plaque psoriasis and is distinguished as red and whitish scaly formation on the outermost layer of the skin, known as the epidermis. Some patient however will present with no skin manifestations at all. In plaque psoriasis the skin is characterized by rapid accumulation of cells.

They mainly develop on the bit harder skins of the elbow and knee. However, these may also be present anywhere on other body skins including that of scalp, palm and sole, genital areas as well. Unlike in the case of eczema, psoriasis is mostly likely to appear at the extensor surface of the joint[2].

Calcipotriol, a synthetic Vitamin D3 derivative, is immunomodulatory drug. Calcipotriol causes the change in a Th2/T-reg cellular response. These T-reg cells are involved in actively suppressing inflammation by suppression of effector T-cells. Additionally, this drug also inhibits the local factors responsible for inflammation such as ketamine etc.

Calcipotriol is useful in the management of psoriasis since it interferes with the excessive growth of keratinocytes. It also enhances the normal maturation of the keratinocyte and as stated earlier, it has immunomodulatory actions which assist in reducing local inflammation mediators. Hence, Calcipotriol is among the drugs that have been studied in the treatment of psoriasis most extensively[3].

MATERIALS AND METHODS

Materials

Calcipotriol was received from Krishna Pharma Ltd., India, as sample gift. The Gelling agents hydroxypropyl methyl cellulose (HPMC) and Carbopol 940 were received as gift sample from TKM Pharmaceuticals, India. Remaining solvents and the excipients employed in the study were purchased of Analytical Reagent Quality Standards.

FTIR Based Compatibility Studies of Drug and Excipients

The FTIR studies for the individual drug and for drug-polymer physical mixtures were done. For this KBr disc method was used, IR graded. In this the proportion of 100 mg / 1mg of the drug and corresponding disks made with the help of applying 5.5 metric ton pressure in hydraulic press, with the aid of FTIR spectrophotometer (Brooker Alpha T). These disks were scanned through a wavelength of 4000cm-1 to 400 cm-1.

**Author for Correspondence: mansigupta.sagebhopal@gmail.com*

Table 1: Calcipotriol Gel Formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Carbopol	0.5	1	1.5	2	-	-	-	-
HPMC	-	-	-	-	0.5	1	1.5	2
Purifiedwater (upto 100ml q.s.)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

HPMC: Hydroxy propyl methyl cellulose

Table 2: Physical Properties of Calcipotriol Gels

Formulation code	Color	Homogeneity	Grittiness
F1	Glossy clear	++	decent
F2	Glossy clear	++	decent
F3	Glossy clear	+++	decent
F4	Glossy clear	+++	usual
F5	Transparent	++	decent
F6	Transparent	++	usual
F7	Transparent	+++	decent
F8	Transparent	+++	usual

++ = Decent; +++ = Usual/Outstanding

Preparation of Calcipotriol Gel

Calcipotriol gel formulae is dealt in table 1, that exemplifies the composition of the Calcipotriol gel formulae. Calcipotriol for the formulation studies was found to be 0.1% w/w; it was dissolved in hot propylene glycol (25% w/w), also glycerin (10% w/w), later used as a humidifying agent[4]. Preparation of gel formulations involved the use of weighed amount of polymers such as Carbopol 940 and HPMC in water that was stirred at speed kept moderate, using a magnetic stirrer. After that, the Carbopol gel was neutralised with tri-ethanol amine. Then, preservatives methyl parabens (0.03% w/w) and propylparabens (0.01% w/w) were added gradually while stirring continually. The prepared gels were filled and packed in wide mouth glass containers and the containers were covered with screw-capped plastic lid and labelled. The containers in which reagents were kept were also covered with aluminium foil and were stored in dark and cool area[5-10].

Evaluation of Calcipotriol Gel Formulations[4,11-17]

Visual Examination

The color, syneresis, and the presence of lumps were checked on all the prepared gel formulations, after gels were stored in selected containers for a certain period of time.

Homogeneity

In this case all the gels that were prepared were subjected to homogeneity analysis after formulations of gels were allowed to set in given containers. Then these were analysed for appearance, and also to determine if there were any formation of aggregates in gel.

Grittiness

The prepared formulations were also analysed microscopically for the presence particles or grittiness, if any. There was formation of no significant granularity which can be observed under light microscope. The result is tabulated in table 2.

Spreading Ability

From each formulation, sample of 0.5 gm was weighed. It was placed between two glass slide plates in form of squares of 5 mm sides. This was allowed to stand for about 5 min, at which no more spreading was observable. Two comparative measures of spreading ability were obtained through press: diameters of spreaded circles, in centimetres.

Table 3: Evaluation of Calcipotriol Gels

Formulation code	pH values	Spreading ability	Extrude ability
F1	6.21	4.3	++
F2	5.89	4.1	++
F3	5.50	4.1	++ +
F4	5.72	3.5	++ +
F5	6.21	4.6	++
F6	6.23	4.6	++ +
F7	6.32	3.7	++ +
F8	6.75	3.9	++

++ = Good; ++ + = Excellent

Table 4: Rheological, Percente Drug Content and Skin Irritation Studies

Formulation code	Viscosity (cps)	% Drug content	Skin irritation
F1	7880	92.24	A
F2	6985	95.34	A
F3	5116	98.81	A
F4	5158	97.42	A
F5	8013	87.65	A
F6	8176	88.10	A
F7	6592	91.32	A
F8	5931	90.37	A

A- Absence of any reaction, B- Minor redness, C- Reasonable redness

pH Determination

To measure the pH of the formulated Calcipotriol gels, the reading was taken with the help of Systonic digital pH meter, available in SAG approved labs. The readings are highlighted in table 3.

Extruding Ability

The prepared formulations were packed in standard capped collapsible aluminium tubes. These tubes were then sealed by applying crimping at the end of the collapsible tubes. The weights of the tubes, which had been produced, were noted. The tubes were positioned between a pair of glass slides; after which it was clamped. The preparations of 500 g of each sample were placed on the slide and the cap was lifted there after. The measurements of the amount of extruded gel were recorded and the weights were taken. The amount of gel extruded was calculated based on a grading system, self-designed. This is as: when the extrusion was >90% = it was considered as High extrudability; with 80% = almost Excellent; between 60-80% extrude ability = Decent; while with extrude ability less than 70% = Reasonable. These graded results are indicated in the Table 3.

Determination of Viscosity

To measure the viscosity of the prepared gel formulations, Brookfield viscometer was used. Spindle no. 64 was used in order to assess the properties of formulated gels. As indicated in Table 4 containing the compiled outcomes.

Determination of Drug Content

Certain volume of prepared gel was measured out. It was then solubilised into 5.5pH phosphate buffer taken 100 ml in quantity. The flask that contained gel solution was placed

on mechanical shaker for 2 hrs, to ensure better drug's sufficient solubilisation. After that the resulting solution was passed through filter paper of Millipore brand, having 0. 45µm size of pore, and filtered. As a result, a suitable drug dilution was obtained. Its absorbance was then determined at the wavelength of 294nm by means of a UV-visible spectrophotometer with 5.5pH phosphate buffer, taken as a blank reference.

Evaluation of Irritation to Skin

Skin irritation study was conducted using female and male BALB/c mice weighing 25- 35 gm. The animals were fed with their normal feeding items and had direct access to water. These experimental creatures were maintained under standard environmental changes. From the trunk of BALB/c mice, hair was removed and an area of 4cm 2 was drawn on two sides, one of which was the test side and the other a control side. The formulated gel (50 mg/ BALB/c mice) was applied on the site twice a day and looked for sensitivity and any reaction in the next seven days.

Evaluation of Drug Diffusion, In-vitro

For evaluating the drug's diffusion profile, the study was executed through a dialysis membrane using 1gm of Calcipotriol niosomal gel, plated evenly on membrane of dialysis chamber. Mounting of the preparation was carried out by placing the membrane between the compartments of the Franz diffusion cell. The compartment that served as reservoir, was made full by phosphate buffer, taken in quantity of 15 ml, having pH 6.8. Keeping the apparatus temperature at 37± 2°C, the evaluation was performed. The process was carried out for 24 hrs duration. After which, 1ml sample quantity was taken from the compartment labelled as reservoir, keeping a fixed gap of defined intervals. Each time the amount was withdrawn, refilling of reservoir compartment was done with same 1ml quantity of

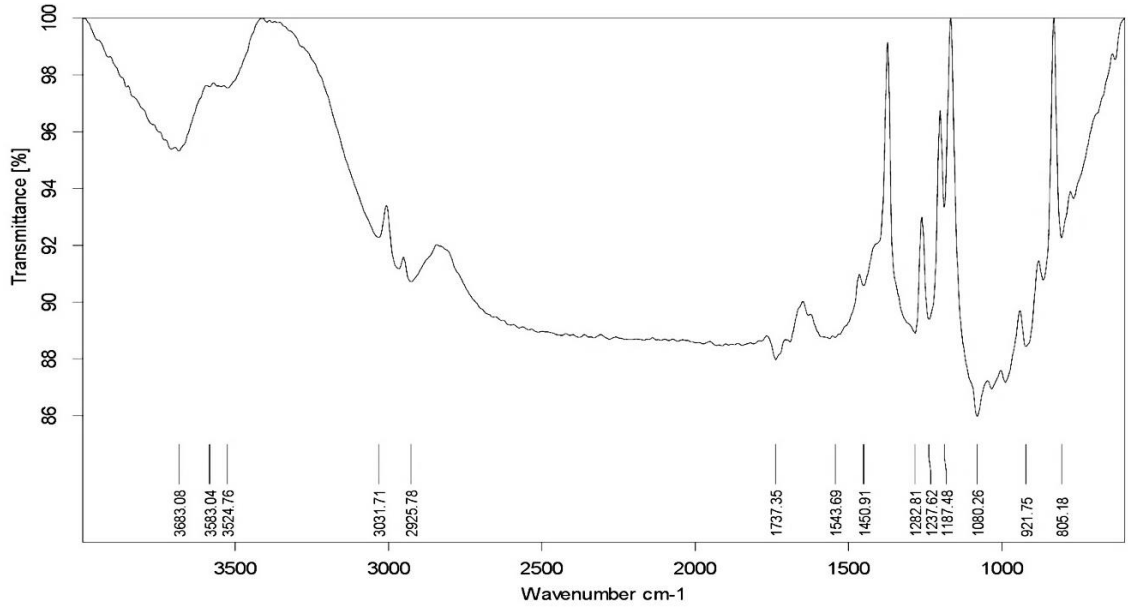

Figure 1: FTIR Spectra of Calcipotriol Drug

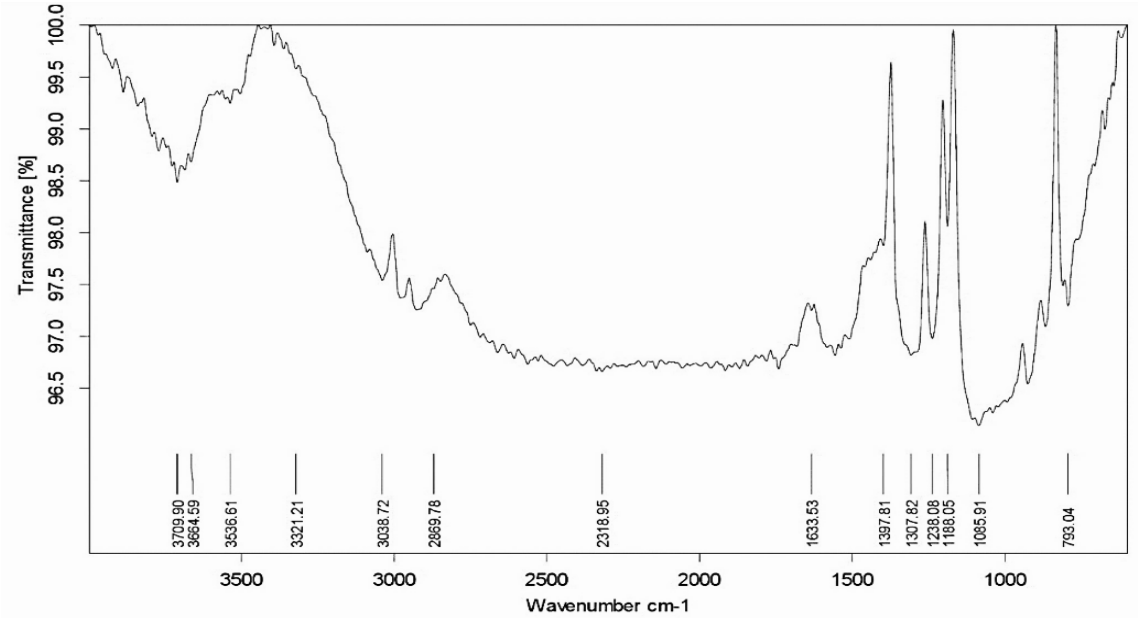

Figure 2: IR Spectrum of Calcipotriol and Carbopol

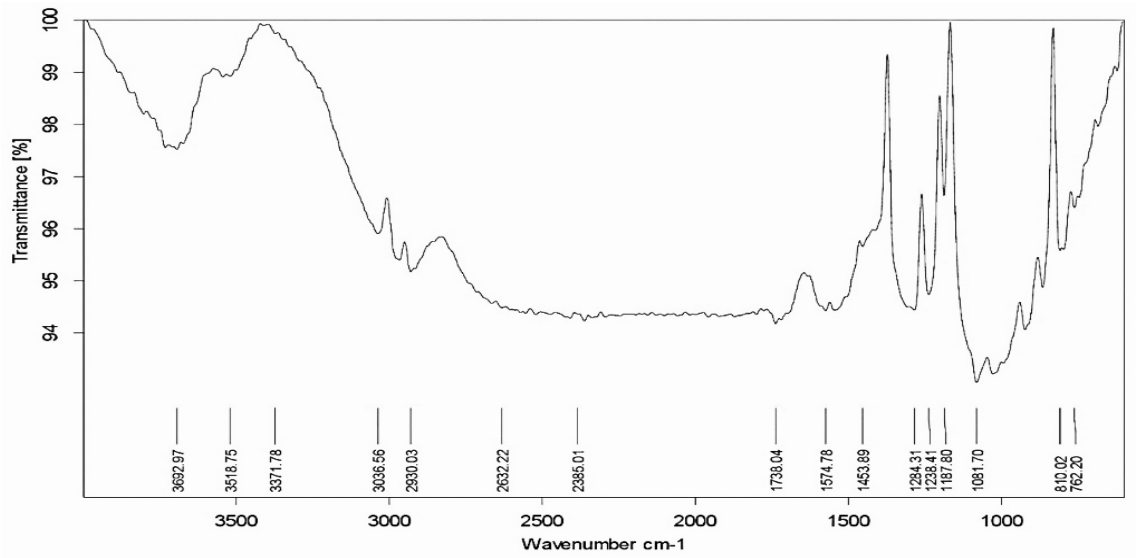

Figure 3: IR Spectrum of Calcipotriol and HPMC

solution of phosphate buffer, having pH 6.8. This was done in order to sustain the sink condition. The same is illustrated in Figure 4.

Formulation Stability Evaluations

Once the niosome gel formulations were prepared, the final one was also tested for their stability performance. Two temperatures were selected, i.e. 37±2°C and 60±2°, at which all the formulations were kept for a duration of one month. After a month, these were characterized based on different physical parameters. Analysis for drug content as well *in vitro* diffusion profile was also done after a month's time. Percentage drug release of the formulations after the stability study is depicted in Figure 5.

RESULTS AND DISCUSSION

Evaluation of Compatibility of Drug and Polymers

The most standard method for evaluation of the compatibility of drug with different excipients used in the gel formulation, is to perform their Fourier transform infrared (FT-IR) spectroscopy. FT-IR spectra in present research was also generated of all the ingredients including of API. The analysis ensured that there is no shift in functional peaks as well as the non-interference of functional groups. Analysing the obtained spectra, one can conclude that there is no interaction between the selected polymers, drug and their mixtures. The spectral graphs are shown in Figure 1 to 3 for the pure API and in combination with the excipients used.

Outcomes from Evaluation of Physical Properties

The result of physical properties shows that the appearance of gel formulations were 'shiny, clear to transparent', for both Carbopol and HPMC. Therefore, it was concluded that the prepared gel formulation is free from particular matter and grittiness, as required in topical preparations. The results are compiled in table 2 under.

The values obtained for spreading ability depict that the Calcipotriol gel formulations belong to the category of easily spreadable gels. Investigations revealed that spreading ability of all prepared formulations were descent, as co-related with the reported literatures. The pH of prepared gel formulations as measured and enlisted in the table 3, which is found in between 5.50 and 6.75, which indicated its usability without harm. Fundamentally, all the gel formulations presented acceptable extrude ability and therefore graded satisfactory, as presented in Table 3, for the same are recorded as good to excellent.

For the purpose of determining the viscosity of the formulated topical gel, Brookfield viscometer was used. The level of viscosity was higher in formulations F5 and F6 with values being 8176 and 8013 cps. This might be attributed to concentration of gelling polymers. The formulation F3 displayed the lowest viscosity among the

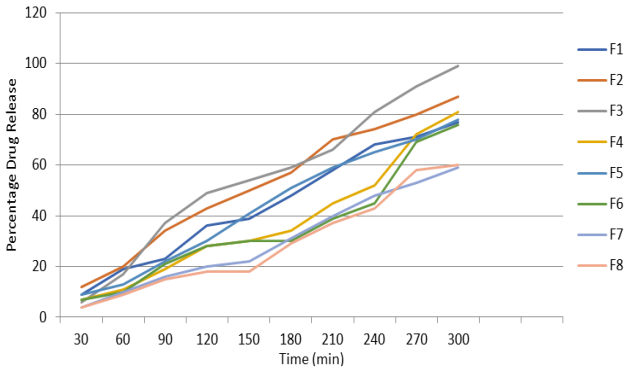

Figure 4: Percentage Drug Release versus Time (min) Graph

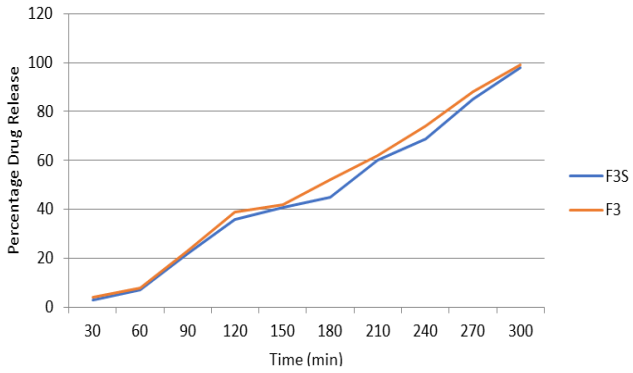

Figure 5: Percentage Drug Release versus Time (min) Graph of Formulation F3 and F3S (after stability studies)

Table 5: Stability Studies F3 Formulation

Parameters	Study Period	
	When kept	After 3 months
Drug content	98.81	98.31
pH values	5.70	5.80
Homogeneity	Homogeneous	Homogeneous
Physical appearance	Shiny clear/ transparent	Shiny clear/ transparent

developed formulations with value being 5116 cps. The yield of the drug content in Calcipotriol gel were determined in range of 88.10 to 98. 81%. The highest levels of the drug content noted in the batch F3. After test of 7 days, no erythema was noted on the skin of the balb/c mice. The outcomes as compiled in table 4 here.

In-vitro Drug Release Profile

The changes in the ratio of the drug and polymer lead to the variation in the *in-vitro* drug release from the gel formulations. From the results obtained, it was therefore determined that the drug diffused from the formulation F3 shows the highest among all the formulations.

The *in-vitro* drug release analysis were conducted for all formulations and it shows the result from 55% to 98%. It can be noted from the results obtained in the release profile of the prepared formulations that F3 has maximum release of drug in all formulations.

Accelerated Stability Study

Optimization of batch formulation F3 was preceded numerous stability tests in accordance with the ICH regulations. As a value of assessment, it was noted that there were insignificant variation in the results of pH, drug content and *in-vitro* drug release study of F3 formulation. The formulation indicates the stability for a period of 3 months, the results are indicated in the table 5.

CONCLUSION

In the research, an attempt was made to develop a topical gel loaded with Calcipotriol for the management of psoriasis, as effectiveness depends on the topical delivery of the drug. The novel formulations of the topical gels were developed from gelling agents, Carbopol 940 and Hydroxy propyl methyl cellulose (HPMC) with varying concentrations. The physical parameters like appearance, pH, drug content, viscosity, extrudability, stability studies and skin irritation study were also assessed for all formulations. From the *in-vitro* studies, formulation F3 provided the maximum release of 97%, 350mg / 300 mins equal to 23 %, F3 formulation was found stable for parameters like pH, physical appearance, drug content and *in-vitro* drug release study over a period of three months. In the coming years, there will be a higher usage of topical drug delivery system in order to make the patient more compliant.

REFERENCES

1. Mehta V, Balachandran C. Biologicals in psoriasis. J Paki AssocDermatol 2008;18:100-9.
2. Kuchekar AB, Pujari RR, Kuchekar SB, Dhole SN, Mule PM. Psoriasis: A comprehensive review. Int J Pharm Life Sci 2012; 2:81-87.
3. Thomson AW, Mode of action of Calcipotriol (FK506). Molecular and cellular mechanisms. Ther Drug Monit. 1995;17:584-91.
4. Wikipedia, the Free Encyclopedia. Available from: http://wwwen. wikipedia. org/wiki.
5. Ahmad N, Lonardo EC, Patel KJ, Lin SY, Wearley LL, Matheson JN, *et al.* Novel methods of treating local and bacterial infections US patent. Int J Pharm PharmSci. 2003;1:77-83.
6. Chaudhari P, Ajab A, Malpure P, Kolsure P, Sanap D. Development and *in vitro* evaluation of thermo reversible nasal gel formulations of rizatriptan benzoate. Indian J. Pharm. 2009;43:55-62.
7. Escobar-Chávez JJ, López-Cervantes M, Naïk A, Kalia YN, Quintanar-Guerrero D, Ganem-Quintana A. Applications of thermo reversible pluronic F-127 gels in pharmaceutical formulations. J Pharm Pharma Sci. 2006;9:339-58.
8. El-Kamel AH. *In-vitro* and *in vivo* evaluation of pluronic F127-based ocular delivery system for timolol maleate. Int J Pharm. 2002;241-7.
9. Yanga Y, Shaoning W, Xu H, Sun C, Lic X, Junmin Z. Properties of topically applied organogels: Rheology and *in vitro* drug release. Asian J Pharma Sci.2008;3:175-83.
10. Chang JY, Oh YK, Choi HG, Kim YB, Kim CK. Rheological evaluation of thermo sensitive and mucoadhesive vaginal gels in physiological conditions. Int J Pharm. 2002;2:141-55.
11. Lalit K, Verma R. *In vitro* evaluation of topical gel prepared using natural polymer. Int J Drug Deliv. 2010;2:58-63.
12. Wood JH, Catacalos G, Liberman SV. Adaptation of commercial viscometers for special applications in pharmaceutical rheology-severs extrusion rheometer. J Pharm Sci. 1963;52:375-8.
13. Helal D, el-rhman DA, abdel-halim SA, el-nabarawi MA.Formulation and evaluation of fluconazole topical gel. Int J Pharm Pharma Sci. 2012;4:45-54.
14. Garg A, Aggarwal D, Garg S, Singla AK. Spreading of semisolid formulations; an update. Pharm Tech. 2002;2002:84-104.
15. Amaguchi Y, Sugibayashi K, Morimoto Y. Drug release test to asses quality of topical formulations in Japenese market. Drug Dev Ind Pharm . 996;22:569-77.
16. Laxmi R, Karthikeyan R, Srinivasa P, Babu RV, Babu NV. Formulation and evaluation of antipsoriatic gel using natural excipients. J Acute Dis. 2013;7:115-21.
17. Krishnaiah YS, Satyanarayana V, Karthikeyan RS. Penetration enhancing effect of methanol on the percutaneous absorption of nicardipine hydrochloride from HPC gel through excised rat epidermis. Pharm Dev Technol. 2002;7:305-16.