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Formulation and Evaluation of Clindamycin Peel-Off Gel Face Mask against Acne Vulgaris

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Abstract

The main aim of this project is to formulate and evaluate Clindamycin peel-off gel face mask against Acne vulgaris. Peel off gel mask of Clindamycin phosphate was formulated using different excipients like Triethanolamine, Carbopol, Polyvinyl Alcohol, Glycerine, Xanthan gum, and Benzyl alcohol. Formulation of different composition of polymer was formulated and their pH, extrudability, homogeneity, spreadability, viscosity, washability and other parameters like drug content, permeability and drug release were evaluated. The result showed that the concentration of PVA and Carbopol which are the main polymers used in the formulations had effect on the drug content, drug release, permeability, spreadability and other parameters. The peel off mask prepared by using different concentration of these two polymers showed satisfactory result in all the evaluated parameters.

Keywords: Acne Vulgaris; Clindamycin Phosphate; Gel; Peel-Off Mask

Introduction

Medicated peel off gel mask is a formulation that is applied on the skin which is stripped off after drying, that not only removes debris, but cleans out pores and helps in controlling acne [1]. Acne vulgaris is a source of anxiety, pain, and embarrassment and might lead to depression in adolescence between the ages of 13 and 18 years. The prevalence of acne was 60.7% as per study conducted by Koku et al [2]. It affects adolescents during sexual maturity phase and also adults as some people are sensitive to the comments that are passed on to them regarding their poor skin conditions [3]. Since, acne leads to permanent skin damage (scarring) if not treated on time so effective yet easy, safe peel off mask is expected to show optimistic result in this case.

Clindamycin as a first line treatment for acne helps in treating this skin problem because oral Clindamycin has higher chance of side effects so topical clindamycin is preferred as a treatment for acne (minimal absorption through topical route so is also safe for use during pregnancy) [4].Compared to other medicated gels used topically as anti-acne treatment, they just control acne whereas the medicated form of peel off face mask not only helps in controlling acne but also exfoliates, cleans pores and moisturize the skin [5]. So instead of using systemic medications for acne, gel based peel off face mask provide compliance to patient and are safe during pregnancy as well.

Materials and Methods

Materials

Clindamycin Phosphate was gifted by S.R. laboratories Pvt. Ltd. and other excipients like Carbopol, Glycerin, Triethanolamine (TEA), Benzyl Alcohol, PolyVinyl Alcohol (PVA) and Xanthan gum were obtained from Laboratory of CiST College.

Methods

Design of Peel off Mask

Central Composite Design (CCD) was used to design the formulation which can fit a full quadratic model. A rotatable experimental plan was carried out by a central composite design (CCD) with α=1.414 consisting of 13 experiments. Minitab 17 software was used to design this experment. For two variables (n = 2) and three levels (low (-1), mid (0) and high (+1)), the total number of experiments were 13, determined by 4 cube points, 4 axial points and 5 Centre points.

The concentrations of variables were selected based on the preliminary experiments performed based on the concentration of polymers obtained from Handbook of Pharmaceutical excipients and various literature reviews. The preliminary study had shown that concentration of carbopol below 0.2% and PVA below 2.5% didn't form proper gel for application whereas concentration of carbopol above 2.0% and PVA above 13% formed high viscous gel that had poor spreadability. So, following range of concentrations for carbopol and PVA were selected:

For Carbopol: Low: 0.2% High: 2.0%

For Poly vinyl alcohol (PVA): Low: 2.5%, High: 13%

Formulation of Peel-off gel face mask

For 100 gm formulation,

Table 1: Composition of formulations

S.N.	Drug	Carbopol	PVA	Benzyl Alcohol	TEA	Glycerin	Xanthan gum	Water
1	1	1.25	15.17	1.00	1	5	1.5	74.08
2	1	2	13	1.00	1	5	1.5	75.50
3	1	1.25	0.32	1.00	1	5	1.5	88.92
4	1	1.25	7.75	1.00	1	5	1.5	81.50
5	1	1.25	7.75	1.00	1	5	1.5	81.50
6	1	1.25	7.75	1.00	1	5	1.5	81.50
7	1	0.5	13	1.00	1	5	1.5	77.00
8	1	0.18	7.75	1.00	1	5	1.5	82.56
9	1	2	2.5	1.00	1	5	1.5	86.00
10	1	1.25	7.75	1.00	1	5	1.5	81.50
11	1	2.31	7.75	1.00	1	5	1.5	80.44
12	1	1.25	7.75	1.00	1	5	1.5	81.50
13	1	0.5	2.5	1.00	1	5	1.5	87.50

Formulation of Peel off Mask [6]

Measured quantity of Clindamycin Phosphate powder was dissolved in distilled water. Then, required quantity of PVA was added slowly with continuous stirring using magnetic stirrer. Carbopol was slowly added to the solution and then the Xanthan gum which was mixed with glycerin. The whole mixture was stirred properly and then allowed to soak overnight.

Next day, Triethanolamine was added to the obtained gel to maintain pH and to achieve desired consistency of the formulation. Then, Benzyl Peroxide was added into the gel and mixed thoroughly for few minutes. The final formulation was then filled in a plastic container and stored in a refrigerator.

Evaluation of Clindamycin peel off mask

Determination of Organoleptic Properties

The characteristics like texture, color, phase separation was analyzed by visual inspection of each formulation. The color of the formulation was checked against white background and the grittiness, texture was checked by applying on skin.

Spreadability [6]

Sample gel was applied in between two glass slides and spreaded with uniform thickness. A 50 gm weight was tied around the upper slide and lower slide was fixed to the stand. The time required to separate two slides, i.e. time in which the upper glass slide moves over the lower plate was taken as a measure of Spreadability.

Formula - S = m x l/tWhere,

S - Spreadability

m - Weight tied to upper slide (50gm)

l - Length of glass slide (7.5 cm

t - Time taken (sec)

pH

The pH of the formulation was determined using digital pH meter.1 gm of gel was dissolved in 100ml of distilled water and stored for 2 hours.

Peel Test

The peel-off mask was applied on the skin surface uniformly. The gel was allowed to dry. After 15-30 mins the peel was removed from the skin surface. (Limit 5 to 7)

Washability

The prepared formulation was applied on the skin and then eases and extent of washing with water was checked.

Extrudability

The extrudability was checked by filling the formulation in Aluminum foil tube and was pressed to extrude the product.

Drying time

The formulation was applied on the skin and drying time was determined.

Homogeneity

The formulation was tested for homogeneity by visual inspection after the gel has set in the container. It was tested for its appearance and presence of any aggregates.

Viscosity

The viscosity of the prepared gel was measured with a viscometer at different rpm in room temperature.

Drug Content

Formulations were diluted to 125 ppm with mobile phase (as per USP). The filtered solution was measured using HPLC. Firstly, 1.25 gm of all samples along with the optimized sample was weighed and dissolved in 100ml mobile phase and sonicated for 5 minutes. Around 1 ml of solution was poured into HPLC vials by filtering it using a membrane filter. It was then poured into the vials using a membrane filter and then the drug content was determined using HPLC at 201nm.

Drug Release Test

Drug release test of thirteen samples along with optimized sample was carried out using dissolution apparatus.

100 ml of Phosphate buffer (p^H 7.4) was taken in each six baskets and temperature was maintained at 37±℃. The speed was adjusted to 100 RPM. 1.25 gm of the samples was weighed and each sample was added into the six baskets containing a 100 ml phosphate buffer. After 30 minutes, few ml of solution was withdrawn and poured into the vials by filtering it out using a membrane filter.

The standard solution of 125 ppm was also prepared by dissolving 25 mg (0.025 gm) of clindamycin phosphate powder in a 100 ml phosphate buffer. Drug release study was performed using HPLC at wavelength of 201 nm.

Permeability Test

100 ml of Phosphate buffer (p^H 7.4) was taken in each basket and temperature maintained at 37±°C. The speed was adjusted to 100 RPM. 1.25 gm of all the samples were weighed. Each weighed samples were added into the baskets wrapped with cellophane membrane and rotated in 100 ml of phosphate buffer. The timer was set for 30 minutes. Then around 5 ml of each solution were withdrawn and poured into vials by filtering out with membrane filter. The permeability study was determined using HPLC at wavelength of 201 nm.

Result and Discussion

Organoleptic Properties

Colour of all the formulations were translucent-white while the texture were soft / smooth. Grittiness was present in F1, F8 and was slightly present in F2 and F7 while it was absent in rest of the formulations due to low concentration of polymers and the phase separation wasn't seen in any of the formulation which shows that all the components were equally mixed and were compatible with each other. Grittiness was absent in rest of the formulations and the phase separation wasn't seen in any of the formulations.

Table 2: Organoleptic properties

F.N.	Color	Texture	Grittiness	Phase separation
F1	Translucent white	Soft	Present	None
F2	Translucent white	Soft	Slightly Present	None
F3	Translucent white	Soft	Absent	None
F4	Translucent white	Soft	Absent	None
F5	Translucent white	Soft	Absent	None
F6	Translucent white	Soft	Absent	None
F7	Translucent white	Soft	Absent	None
F8	Translucent white	Soft	Absent	None
F9	Translucent white	Soft	Slightly Present	None
F10	Translucent white	Soft	Absent	None
F11	Translucent white	Soft	Present	None
F12	Translucent white	Soft	Absent	None
F13	Translucent white	Soft	Absent	None

Spreadability

Lesser the time taken to separate two slides, better is the spreadability so the formulations whose viscosity was higher showed bad spreadability while those that had low viscosity showed good spreadability. From this it is clear that, spreadability has inverse relationship with film forming agent (PVA) and viscosity

Table 3: Spreadability of various formulations

F.N.	Length of glass slide (cm)	Weight taken (gm)	Time (sec)	Spreadability (gm*cm/sec)
F1	7.5	50	225	1.66
F2	7.5	50	173	2.16
F3	7.5	50	97	3.86
F4	7.5	50	140	2.67
F5	7.5	50	140	2.67
F6	7.5	50	140	2.67
F7	7.5	50	76	4.93
F8	7.5	50	54	6.94
F9	7.5	50	48	7.81
F10	7.5	50	140	2.67
F11	7.5	50	153	2.45
F12	7.5	50	140	2.67
F13	7.5	50	38	9.86

Other Parameters

Table 4: Result of other parameters

F.N.	Washability	Extrudability	pH	Dryingtest (minutes)	Peel test	Homogeneity
F1	Washable	Bad	5.9±0.1	35	Bad	Good
F2	Washable	Bad	6.1±0.1	30	Bad	Good
F3	Washable	Good	6.4±0.1	30	Good	Good
F4	Washable	Good	7.8±0.1	20	Good	Good
F5	Washable	Good	7.8±0.1	20	Good	Good
F6	Washable	Good	7.8±0.1	20	Good	Good
F7	Washable	Good	6.7±0.1	20	Good	Good
F8	Washable	Good	7.1±0.1	25	Good	Good
F9	Washable	Good	6.6±0.1	30	Good	Good
F10	Washable	Good	7.8±0.1	20	Good	Good
F11	Washable	Good	5.9±0.1	35	Good	Good
F12	Washable	Good	7.8±0.1	20	Good	Good
F13	Washable	Good	7.7±0.1	25	Good	Good

The above formulation showed good washability as they were all washable. The extrudability of all formulations was good except F1 and F2 due to high viscosity. The pH ranged from 5-7 so does not irritate the skin. The drying time of the formulation ranged from 15-35 minutes. The formulations were homogenous observed through visual inspection.The peel test was good except of F1

and F2.

Figure 1: Extrudability test of peel off mask gel

Viscosity

Viscosity study was performed to determine the consistency of gel. From this study, all the formulations were found to be of Pseudoplastic nature i.e., the viscosity of the gel decreased with increase in RPM. Pseudoplastic flow behaviour displayed by the gels facilitate the spreadability of gels and during static conditions, the gels are capable of returning to the viscous gel form.

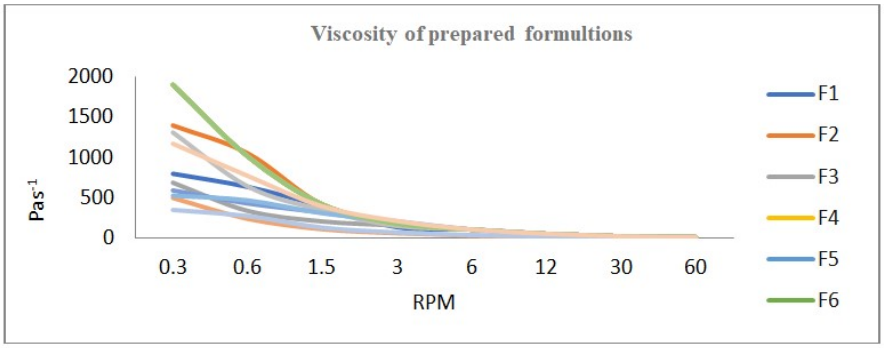

Figure 2: Graph showing viscosity of all formulations at different RPM

Drug Content

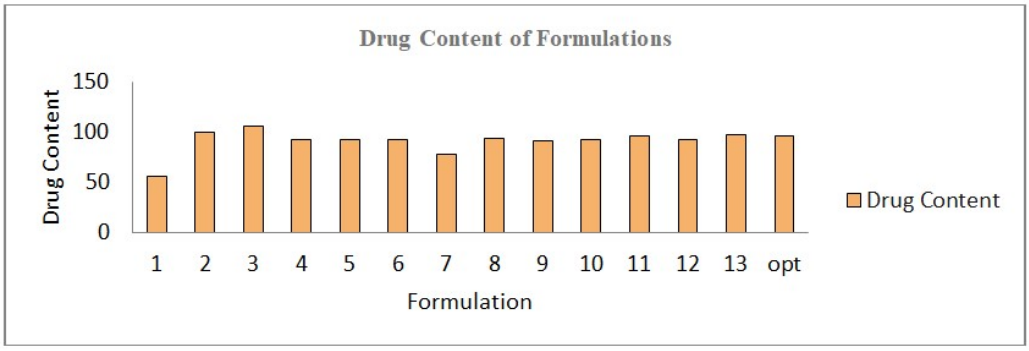

Figure 3: Bar graph showing Drug content of Formulations

All 13 formulations showed assay within the range of 56.49% – 105.92 % of labelled amount of drug. The result of the assay of optimized formulation has been reported as acceptable and indicates good assay profile.

Drug Release Study

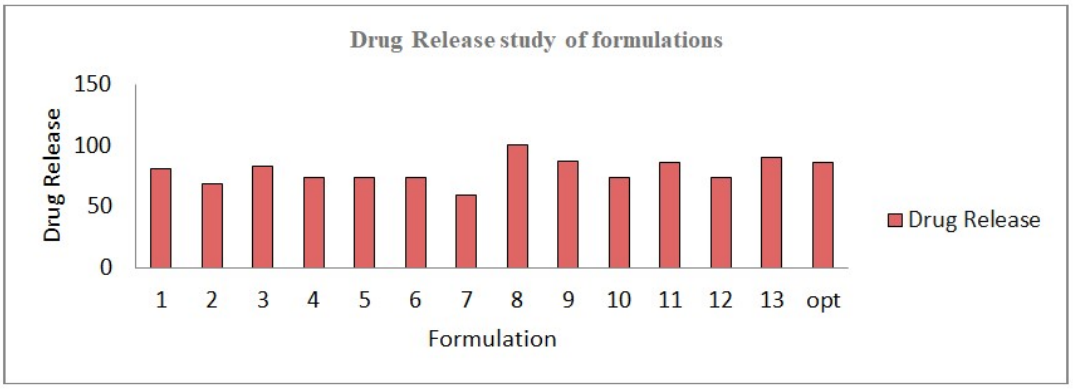

Figure 4: Bar graph showing Drug release study of formulations

The drug release table shows different release of drug of 13 formulations. The drug release varied from 59.24% to 100.99%. Highest drug release was seen in F8, F9,F11,F13 and the lowest drug release was seen in F1,F2,F4,F4,F7. This shows that the effect of polymer highly affects the release of drug from the formulation. Higher the quantity of polymers, lower the release rate.

Contour Plot of Drug Release Vs PVA and Carbopol

The contour plot generated indicated that the amount of Carbopol and PVA possess a significant influence on dissolution.

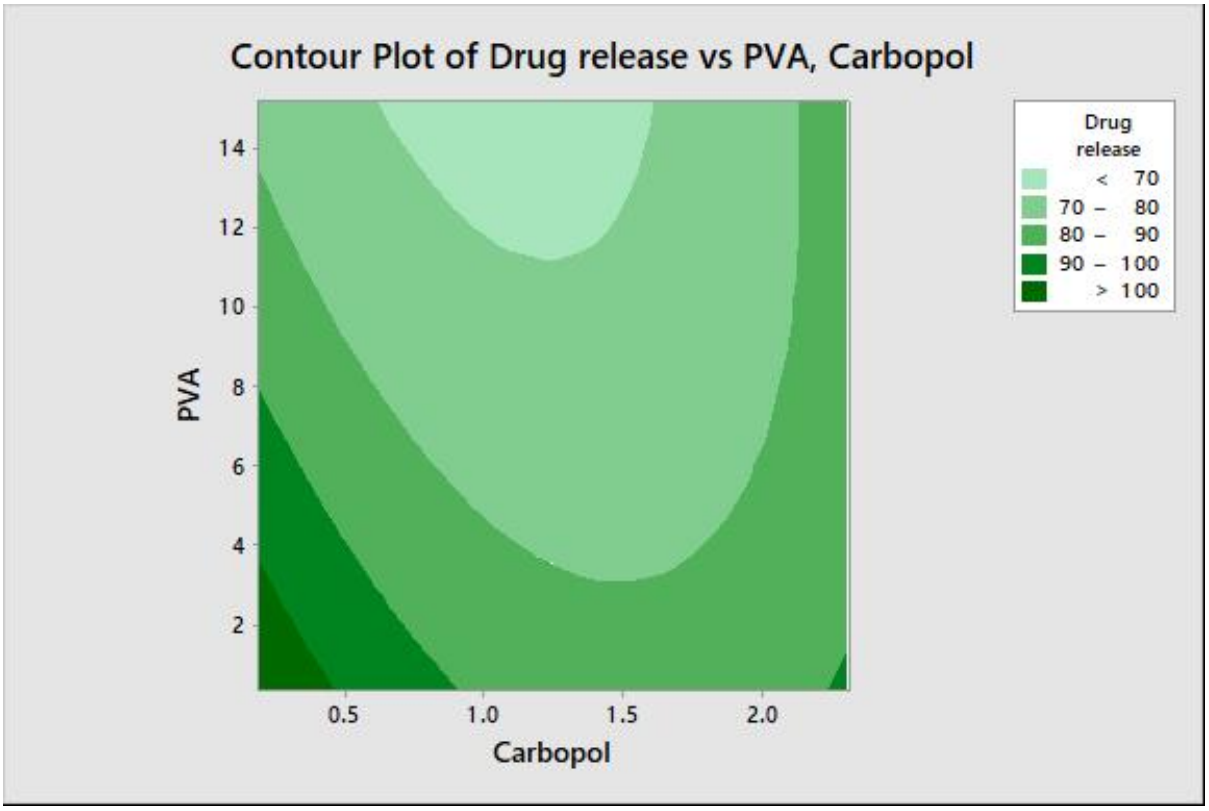

Figure 5: Contour Plot of Drug release vs PVA, Carbopol

From the contour plot in figure no., it was determined that a dissolution (90%-100%) can be obtained by maintaining Carbopol's concentration range from 0.4% to 0.9% and PVA concentration range from 3.9% to 8 % respectively.

Surface Plot of Drug Release Vs PVA, Carbopol

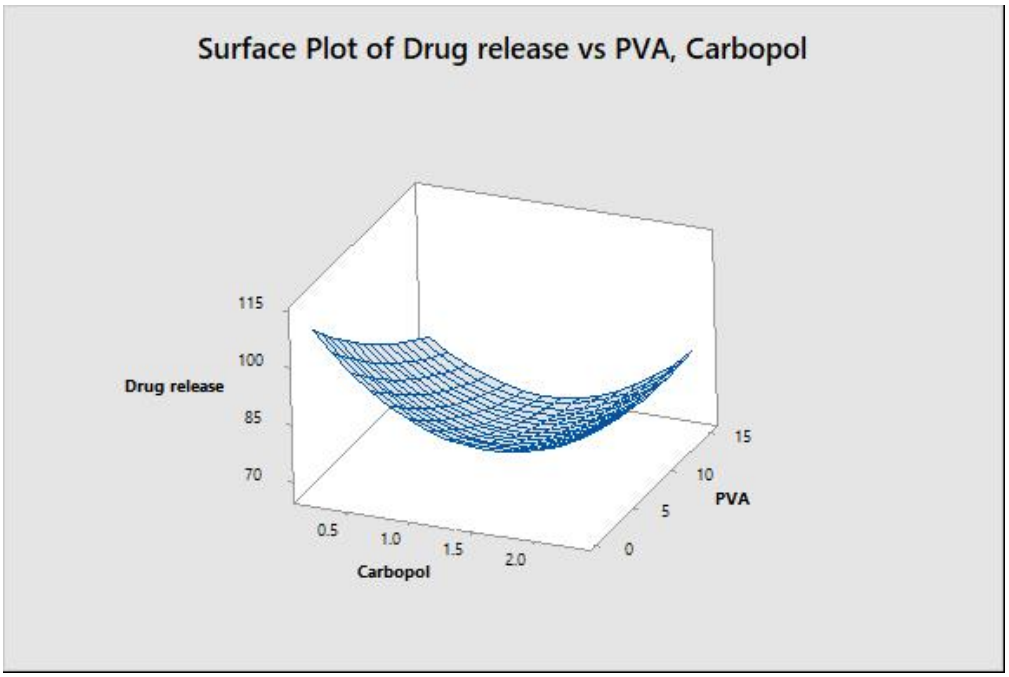

Figure 6: Surface Plot of Drug release vs PVA, Carbopol

The result of assay and drug release showed that formulations prepared with different concentration of PVA and Carbopol has drastic effect on preparation of gel as well as on film forming ability.The effect of PVA enhanced the film forming effect.

Higher the concentration of PVA much better film was formed that adsorbed greatly to the skin and the concentration of Carbopol determined the type of gel formed. This shows that the ratio of PVA and Carbopol in a formulation had a significant effect on the gel masks that were formulated.

Permeability Test

Table 5: Result of permeability test

F.N.	Permeability	Permeability per cm^2
F1	3.62	1.04
F2	5.10	1.47
F3	2.13	0.62
F4	4.69	1.35
F5	4.69	1.35
F6	4.69	1.35
F7	2.94	0.85
F8	10.53	3.04
F9	6.67	1.93
F10	4.69	1.35
F11	4.06	1.17
F12	4.69	1.35
F13	6.52	1.88

Permeability of the formulated peel off gel mask was found to be less than the normal range (2.5-6). This is because the formulation is hydrophilic in nature and polymer present in it affects the permeation of drug into the skin. Viscosity is inversely proportional to drug permeation. The lower the viscosity of formulation, the faster the drug release and the higher the drug permeation

This shows that the gel doesn't permeate through the skin per cm^2 but only works on the skin surface. So the benefit of this obtained result will be effective action on the bacteria present on the skin and doesn't get systematically absorbed within 30 minutes and has very less chance of causing side effects.

Response Optimizer Curve of Drug Release

Response optimizer model in minitab was used to obtain the optimized formulation. The drug release parameter was kept at maximum, drying rate parameter was kept at minimum and the assay parameter was set to the target of 100%. With all the above conditions, the analysis was performed which resulted in the optimized formulation that contain the concentration of Carbopol to be 0.832% and PVA to be 5.787%.

Optimized batch containing Carbopol (0.832) and PVA (5.787) was prepared experimentally using the procedure and same ingredients that was used for preparing 13 formulations of Clindamycin peel off gel face mask.

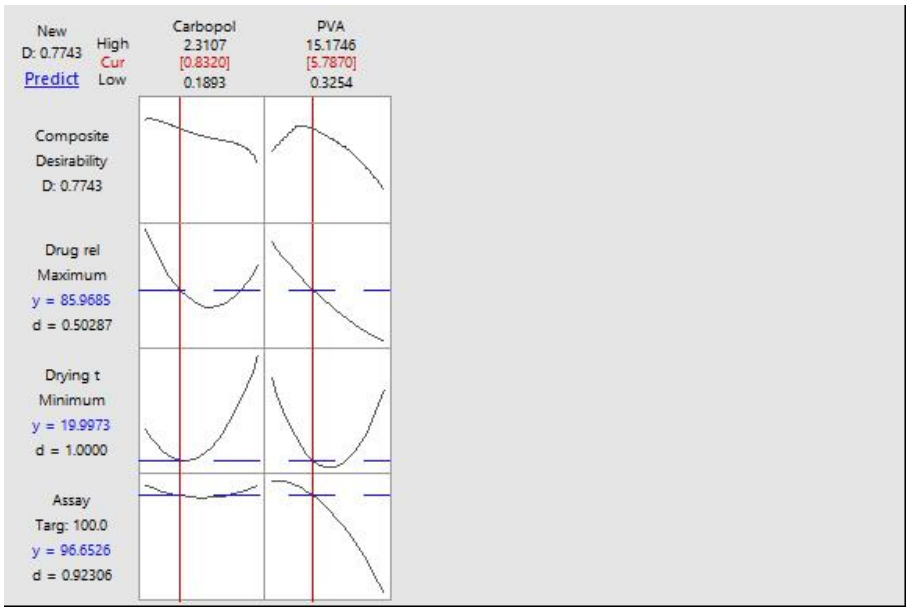

Figure 7: Response optimizer curve

Regression Equation

Drug release = 116.8 - 40.0 Carbopol - 3.02 PVA + 12.60 Carbopol*Carbopol + 0.050 PVA*PVA + 0.79 Carbopol*PVA

As per equation, Carbopol and PVA shows retarding effect on drug release whereas combined effect of Carbopol and PVA shows accelerating effect. The interaction of Carbopol and PVA also shows positive effect in drug release.

Composition of Optimized Formulation

Table 6: Composition of optimized formulation

S.N.	Ingredients	Amount
1.	Carbopol	0.83 gm
2.	Polyvinyl alcohol (PVA)	5.78 gm

3.	Xanthan gum	1.5 gm
4.	Active drug (Clindamycin Phosphate)	1 gm
5.	Glycerin	5 ml
6.	Triethanolamine (TEA)	1 ml
7.	Benzyl alcohol	1 ml
8.	Distilled water	83.88 ml

Result of Optimized formulation

Table 7: Result of optimized formulation

Parameters	Color	Texture	Grittiness	Phase separation	Peel test	P^H	Drying time	Drug content	Drug release
Observation	Translucent white	Soft	Non-gritty	None	Excellent	7.2±0.1	20 min	98.35% ±0.01	85.69% ± 0.01
RPM	**Viscosity(Pas^{-1})**								
0.3	1169.1								
0.6	770.7								
1.5	392.8								
3	211.7								
6	105.9								
12	52.9								
30	21.2								
60	10.6								

Conclusion

The ideal formulation is the one that contains low concentration of both Carbopol and PVA which was proven by the optimized formulation designed using MINITAB software. The formulation of Clindamycin peel-off gel face mask thus could be used to treat acne, prevent acne scars along with that remove dead skin cells, blackheads and keep the skin hydrated.

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