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Formulation, Optimization and Evaluation of Organogel of Dapsone

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ABSTRACT:

Objective: The objective of present research work was to formulate organogel of Dapsone for the treatment of leprosy. By using 3^2fullfactorial design optimizations of Dapsone Organogel was done and optimized organogel was formulated. Ratio of Organogelator, Surfactants and non-polar organic solvents are selected on the base of the Preliminary study for the determination of the aqueous to organic phase ratio.

Significance: This project demonstrates the formulation of a Dapsone-based organogel for the topical treatment of leprosy, offering improved drug diffusion, stability, and application properties. The optimized formulation achieved high drug release (90.67% at 6 hours) presenting a promising alternative to conventional Dapsone delivery with better patient compliance and reduced systemic side effects.

Method: Dapsone Organogels were prepared by Direct approach method. 3^2full factorial design were applied. Concentration of SoyLecithin(X_1) and Concentration of Pluronic F127(X_2) were chosen as independent variables, while viscosity(Y_1) and % drug diffusion at 6 hr(Y_2) were selected as dependent variables. Organogel was evaluated for viscosity and %drug diffusion at 6 hr.

Result: Organogel was subjected to stability study under accelerated condition for one month. From the experimental design, OG-7 batches containing 30 % soya lecithin and 20 % Pluronic F127 exhibited highest 94.82 % Drug diffusion at 6 hr and good 8442 cps viscosity. Organogel optimized organogel showed great 90.67 % drug diffusion at 6 hr and it remained consistently stable over one month stability study.

Conclusion: It showed acceptable outcomes with respect to homogeneity, consistency, pH, viscosity, Spreadability, extrudability, %drug diffusion and %drug content.

Keywords: Leprosy, Dapsone, Organogel, 3^2full factorial design.

I. INTRODUCTION

Leprosy is a neglected infectious disease caused by Mycobacterium Leprae.Leprosy is also known as Hansen's disease.It is an acid-fast, gram positive obligate intracellular bacillus that demonstrates tropism for phagocytes in the skin and Schwann cells within peripheral nerves.Leprosy is believed to spread through respiratory means, primarily through the nasal mucosa. It can also be transmitted through skin erosions, blood, breast milk and insect bites. However, it's not spread through casual contact like shaking hands or sharing meals. It infects over 2,00,000 people each year all over the world.The highest rates for the detection of new cases are reported by countries in African Regions and Southeast Asia Regions.Leprosy affects patient both physically and emotionally.A gel is defined as semi-solid, cross-linked system containing of agglomerated particles interpenetrated by a liquid. Organogels are semisolid materials that are made up of an organic liquid phase and a three-dimensional network of gelator fibres.Organogels are thermodynamically stable, visco-elastic biphasic system comprising of a gelator and a non-polar phase, with or without the presence of water molecules within the network formed by gelator systems.Organogel can swell and retain large amount of the liquid phase, absorb and release substances and respond to various physical and chemical stimuli such as temperature, light, pH and mechanical deformation.

Advantages of Organogel [7,8,9]

- Thermodynamically stable
- Naturally thermos reversible
- Insensitive to moisture
- Resistance to microbial contamination
- It has viscoelastic behaviour
- Enhance drug delivery efficiency by improving skin penetration
- Longer shelf life

International Journal of Pharmaceutical Research and Applications
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- More stable than other form of gels
- Easy to prepare
- Economically beneficial

Limitations of Organogel [10,11]

- Drugs must have a molecular weight of less than 500 Dalton.
- On storage some of water will come out of gel and it will shrink also known as Syneresis.
- Any impurities will inhibit the gelling process.
- This method is not suitable for chemicals that cause irritation or sensitize the skin.

Experimental work:

Materials:

Dapsone is used as API. Soya Lecithin, Pluronic F127, Propyl Paraben, Methyl Paraben and lemon oil are obtained from the Astron Chemicals India. Isopropyl Myristate (IPM) and Isopropyl Palmitate (IPP) are purchased from the Arish Chem (Mumbai).

Method of Preparation: [12,13]

The Pluronic lecithin organogel was prepared at room temperature by first taking the specified amount of soyabean lecithin in Isopropyl Palmitate (IPP) and then keep the mixture over night for complete dissolution of lecithin. In the solution the Sorbic acid was added as preservatives.Later pluronic gel was prepared by dispersing a weighed amount of Pluronic F127 and potassium sorbate in cold water. The dispersion was stored in a refrigerator at 2-4° C overnight for effective dissolution of Pluronic F127.The next day, API was dissolved in lecithin-Isopropyl Palmitate solution directly or firstly in PEG 600 and then mixed with the lecithin-isopropyl palmitate solution.Finally, aqueous solution was slowly added to oil phase with stirring at 400 rpm using a mechanical stirrer.

Determination of Aqueous to organic phase ratio:

Both soy lecithin and pluronic F127 are present in three distinct concentrations: 20%, 30%, and 40%, and 10%, 20%, and 30%, respectively. Additionally, three distinct aqueous to organic phase ratios3:1, 4:1, and 5:1were chosen.

Experimental design:

The effects of two important independent parameters on the batches of organogel were investigated using a 3-level complete factorial design. While (X1) and the concentration of pluronic F 127 (X2) were regarded as the variables, the amount of lecithin in the proposed design, viscosity (Y1), and in vitro drug diffusion in 6 hours (Y2) were selected as answers. The 32 full factorial design was used to develop a total of nine formulations.

3^2 Full factorial design:

The results of 9 experimental batches designed using a 3^2 factorial design were analyzed using DESIGN EXPERT software. The data were fitted to an appropriate model, and based on regression analysis criteria and ANOVA at a 5% significance level, a quadratic model was selected due to its low PRESS value. This confirmed a good model fit. The viscosity (Y1) ranged from 6000 to 9000 cps, and % drug diffusion (Y2) varied from 80% to 96%, indicating dependence on selected factors. ANOVA helped identify the insignificant factors affecting the responses.

Evaluation parameters:[14,15]

1. Physical appearance
- Organogel's hue, homogeneity, and consistency were visually assessed.

2. pH
- A pH meter was used to measure the pH. Readings were obtained at room temperature when the pH meter electrode was submerged in 1 g of organogel combined with 30 ml of purified water.

3. Viscosity
- The rheological properties of the microemulsion were ascertained by measuring its viscosity. Using spindle number 63 at 100 rpm, the Brookfield viscometer was used to measure viscosity.

4. Extrudability
- A collapsable tube was filled with organogel. The formulation's extrudability was evaluated by measuring the weight in grammes needed to extrude a 0.5 cm ribbon of organogel from the tube in 10 seconds. It is calculated using a certain formula:

Extrudability= applied weight to extrude the organogel from tube (gm) / Area(cm^2)

5. Centrifugation study
- To determine whether phase separation of any type had taken place, organogel was centrifuged for 30 minutes at 3500 rpm.

6. In-vitro drug release study
- Franz-diffusion cell was used to evaluate the in vitro drug release of organogel. There are

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donor and receptor compartments in a Franz-diffusion cell. The pH 6.8 phosphate buffer was added to the receptor compartment, which was continuously stirred and kept at 32±1ºC. The membrane between the Franz-diffusion cell's donor and receptor compartments was constricted. The membrane was coated with 1 g of organogel. To maintain the sink condition, 0.5 ml of sample was periodically removed from the receptor compartment and its volume was equal to that of pH 6.8 phosphate buffer. The amount of dapsone in each sample was then measured at 249 nm using a UV-visible spectrophotometer.

II. RESULT:

Effect of independent variable on viscosity(Y1):

The analysis of multiple regression for response Y1 (viscosity) was done by quadratic model using Design Expert 22.0.3.0. The positive sign in X1 suggest that amount of Soya lecithin has direct relation with viscosity. It demonstrated that concentration of soya lecithin increases, viscositypositive. The positive sign in X2 suggest that amount of pluronic F127 has direct relation with viscosity. It demonstrated that concentration of pluronic F127 increases, viscosity also increases. Model p-value is 0.0009 which was less than 0.05 that indicates model is significant. The equation generated was per the following;

Full model:

$Y1=82.53+ 496.833(X_1) + 1010.83(X_2) + 133(X_1)(X_2) + 4.5(X_1)^2+ (-190.5)(X_2)^2$

Reduced model:

$Y1=82.53+ 496.833(X_1) + 1010.83(X_2)$

Effect of independent variable on % dug diffusion at 6 hr(Y2):

The analysis of multiple regression for response Y2 (%Drug release at 6 hr) was done by quadratic model using Design Expert 22.0.3.0. The negative sign in X1 suggest that amount of soya lecithin has inverse relation with % dug diffusion at 6 hr. It demonstrated that concentration of soya lecithin increases, % dug diffusion at 6 hr decreases. The positive sign in X2 suggest that amount of pluronic F127 has direct relation with %Drug release at 6 hr. It demonstrated that concentration of pluronic F127 increases, % dug diffusion at 6 hr also increases. Model p-value is 0.0070 which was less than 0.05 that indicates model is significant.The equation generated was per the following;

Full model:

$Y2= 86.3844+(-8.29)(X_1) +3.22(X_2) +(-0.6825)(X_1)(X_2) +(-1.95667)(X_1)^2+ (-1.91667)(X_2)^2$

Reduced model:

$Y2= 86.3844+ (-8.29)(X_1) + 3.22(X_2)$

Optimization of formulations:

OG-7 was selected as optimized batch, as it showed highest % dug diffusion at 6 hr: 94.82 5 and good viscosity: 8442 cps. So, it was further utilized for the formulation of Organogel.

Stability study:

One month stability study of dapsone organogel was carried out under accelerated condition (40±2ºC & 75±5% relative humidity). Organogel was evaluated for different parameters.

III. DISCUSSION

The present research work aimed to formulate topical organogel of dapsone for the treatment of leprosy. Dapsone is a sulfone class drug. Which is used for the treatment of leprosy. 3^2 full factorial design was applied for optimization of dapsone organogel. Concentration of soya lecithin (X1) and Concentration of pluronic F127 (X2) were chosen as independent variables, while Viscosity(cps) (Y1) and % Drug diffusion at 6 hr (Y2) were selected as dependent variables. Nine batches were formulated and evaluated for various parameters and statistical analysis of dependant variables were done.Check point batch (OG-10) was formulated and evaluated. All experimental responseswere near to predicted responses. So model was valid. Study concluded that factors likeconcentration of Oil and Smix played a significant role in the model.OG-7 batches containing 5% of drug, 30% of soya lecithin and 25 % of pluronic F127 was optimized because it shows 94.82 % drug release at 6 hr. and good 8442 cps viscosity.Prepared organogel has excellent homogeneity, good consistency, skin compatible 6.3 pH, 8327 cps viscosity, 5.8 cm Spreadability, 18 gm/cm2 extrudability. In vitro drug release study was carried out by using Franz diffusion cell and it demonstrated 90.67% drug diffusion at 6 hr.Stability study of organogel was conducted for one month. All the parameters of organogel were evaluated before and after the one month. They were almost similar. So prepared organogel was stable in stability study.It is concluded that topical organogel of dapsone can be effectively used for treatment of leprosy.

International Journal of Pharmaceutical Research and Applications
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Table 1- determination of aqueous to organic phase ratio

Batch no.	Concentrationof soy lecithin (%W/W)	Concentration of PluronicF127 (% W/W)	Aqueous to organic phase ratio	Formulation Of Organogel (Yes/No)	Viscosity (cps)
H-1	20	10	3:1	No	-
H-2	20	10	4:1	No	-
H-3	20	10	5:1	No	-
H-4	30	10	3:1	No	-
H-5	30	10	4:1	No	-
H-6	30	10	5:1	No	-
H-7	40	10	3:1	No	-
H-8	40	10	4:1	No	-
H-9	40	10	5:1	No	-
H-10	20	20	3:1	Yes	5923
H-11	20	20	4:1	Yes	6243

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 673-680 www.ijprajournal.com ISSN: 2456-4494

H-12	20	20	5:1	Yes	6851
H-13	30	20	3:1	Yes	6189
H-14	30	20	4:1	Yes	7447
H-15	30	20	5:1	Yes	8263
H-16	40	20	3:1	Yes	6739
H-17	40	20	4:1	Yes	8590
H-18	40	20	5:1	Yes	9841
H-19	20	30	3:1	No	-
H-20	20	30	4:1	Yes	15430
H-21	20	30	5:1	Yes	16177
H-22	30	30	3:1	No	-
H-23	30	30	4:1	No	-
H-24	30	30	5:1	No	-
H-25	40	30	3:1	No	-
H-26	40	30	4:1	No	-
H-27	40	30	5:1	No	-

Table 2- 3^2 Factorial design batches of Dapsone Organogel

Batch no.	**Concentration of Soya Lecithin (% W/W)(X_1)**		**Concentration of Pluronic F127 (% W/W)(X_2)**	
	Coded value	**Actual value**	**Coded value**	**Actual value**
OG-1	-1	30	-1	15
OG-2	0	35	-1	15
OG-3	+1	40	-1	15
OG-4	-1	30	0	20
OG-5	0	35	0	20
OG-6	+1	40	0	20
OG-7	-1	30	+1	30
OG-8	0	35	+1	30
OG-9	+1	40	+1	30

Table 3- Evaluation data of Dapsone Organogel

Formulation Code	**pH**	**Viscosity (cps)**	**Centrifugation Study**	**% dug diffusion at 6 hr.**	**% drug content**
OG-1	5.6	6731	No phase separation	87.91	97.44
OG-2	6.2	6955	No phase separation	80.56	97.31
OG-3	6.8	7478	No phase separation	71.36	96.72
OG-4	6.3	7728	No phase separation	91.59	97.68
OG-5	6.4	8357	No phase separation	85.97	97.36
OG-6	6.1	8683	No phase separation	77.68	98.85
OG-7	6.4	8442	No phase separation	94.82	99.27
OG-8	6.0	9066	No phase separation	88.79	98.66
OG-9	6.3	9721	No phase separation	75.54	96.23

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 673-680 www.ijprajournal.com ISSN: 2456-4494

Table 4- Evaluation parameters of stability study

Sr. no.	Evaluation parameter	Initial	After one month
1	Colour	Pale yellow	Pale yellow
2	Homogeneity	Excellent	Excellent
3	Consistency	Good	Good
4	pH	6.4	6.37
5	Viscosity	8442	8378
6	Spreadability	5.8 cm	5.5 cm
7	Extrudability	18	18.5
8	% drug content	99.27	98.79
9	% dug diffusion	94.82	93.05

Figure 1- Contour plot and response plot for Viscosity (Y1)

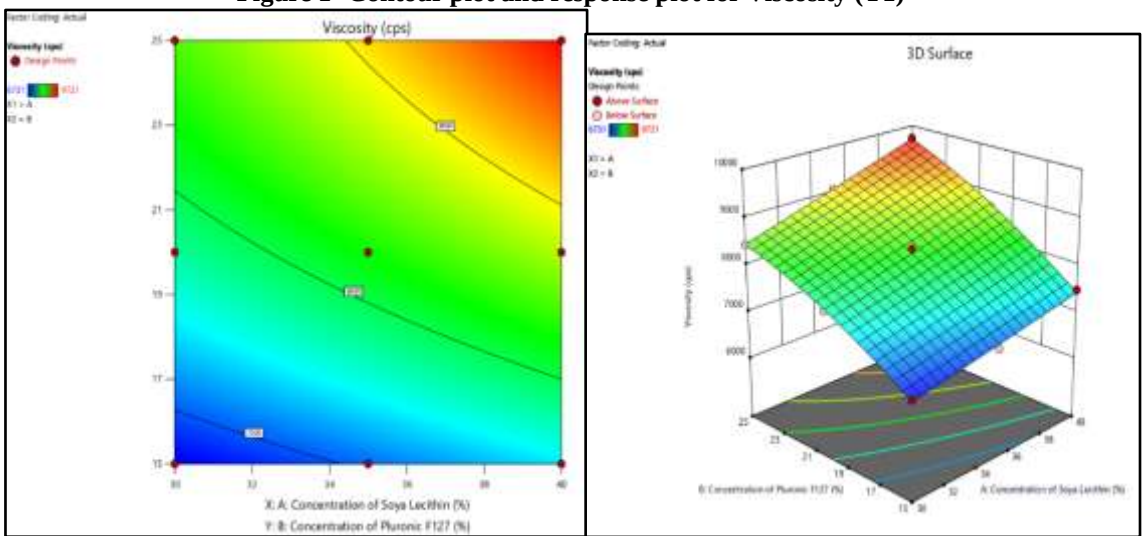
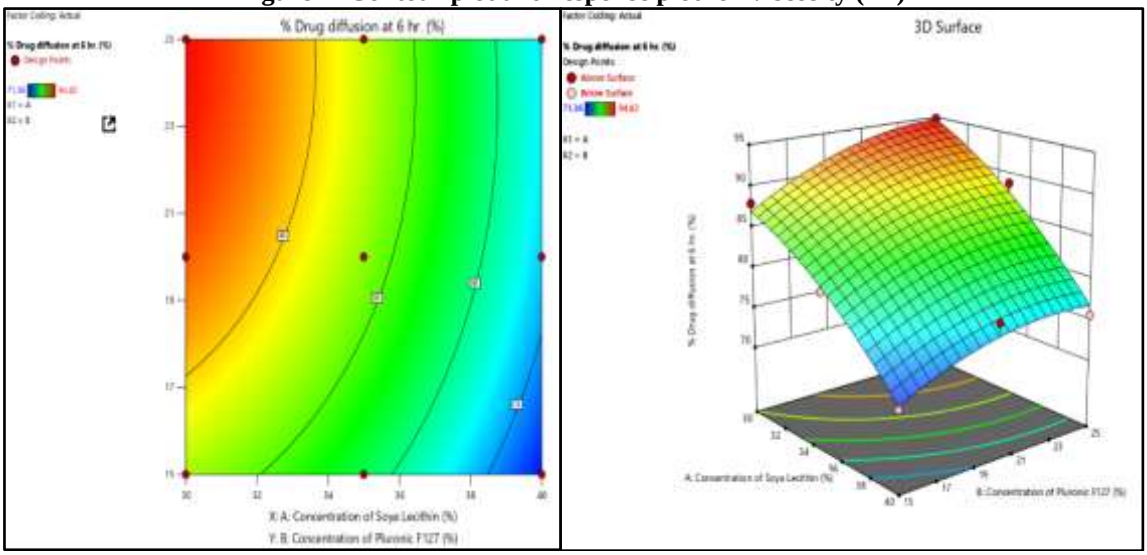


Figure 2- Contour plot and response plot for Viscosity (Y2)



International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 673-680 www.ijprajournal.com ISSN: 2456-4494

Figure 3-Overlay plot

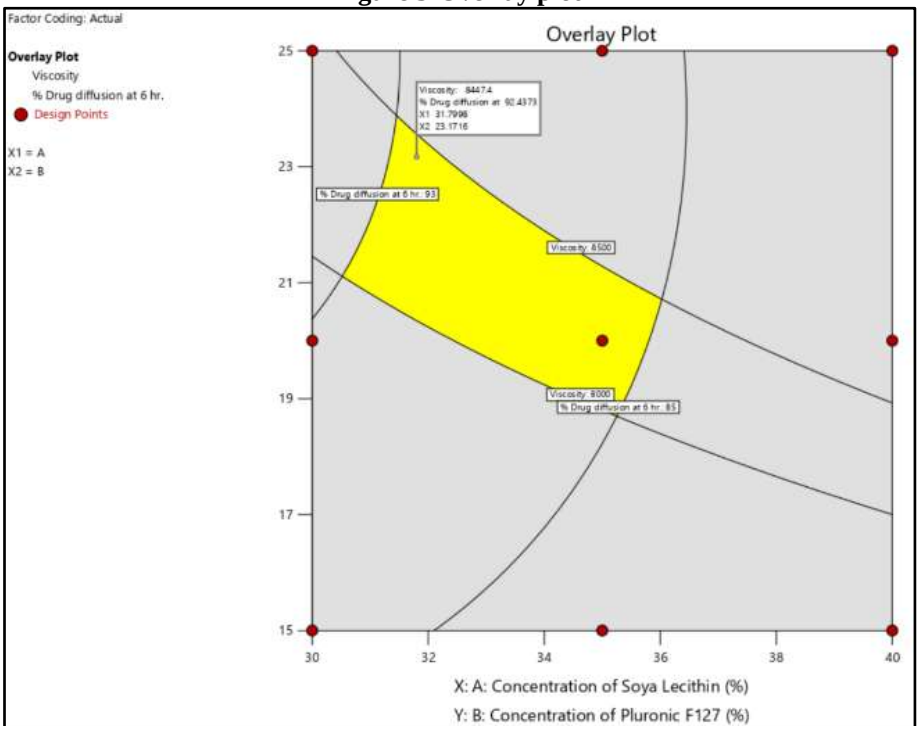
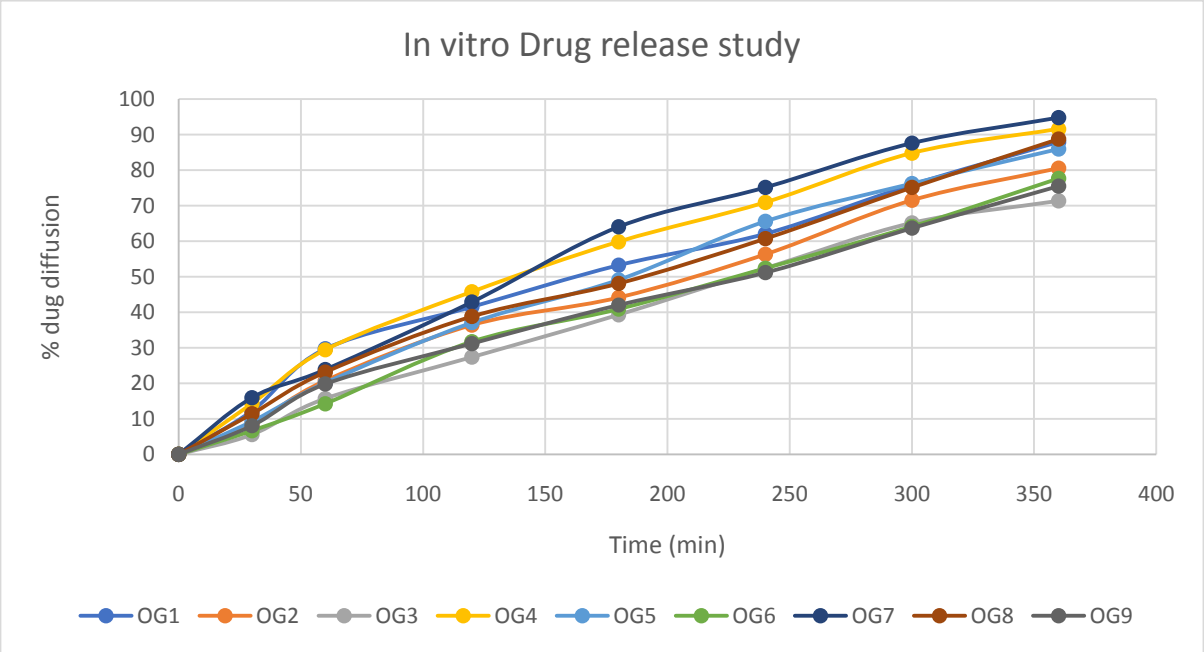


Figure 4- In Vitro drug release of dapsone Organogel



International Journal of Pharmaceutical Research and Applications
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Figure 5- SEM study of organogel of dapsone