

Formulation And Evaluation of Niacinamide Nanoemulgel for Enhanced Topical Delivery

Ms. Rajeshwari D. Pawar^{*1}, Dr. Jitendra V. Shinde², Dr. Ashok Bhosale³

^{*1}Student at P.D.E. A's Shankarrao Ursal college of pharmaceutical sciences and research Centre, Savitribai Phule Pune University, Pune-411014, Maharashtra, India.

²HOD of Pharmaceutics at P.D.E. A's Shankarrao Ursal college of pharmaceutical sciences and research Centre, Savitribai Phule Pune University, Pune-411014, Maharashtra, India

³Principal at P.D.E. A's Shankarrao Ursal college of pharmaceutical sciences and research Centre, Savitribai Phule Pune University, Pune-411014, Maharashtra, India

* Corresponding Author

Ms. Rajeshwari Pawar

Email ID: rajeshwaripawar23032000@gmail.com

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ABSTRACT

Objective: The objective of this study was to develop and evaluate a nanoemulgel-based transdermal drug delivery system (TDDS) to enhance the skin permeability and bioavailability of niacinamide (a BCS Class III drug with high solubility and low permeability) for the treatment of pellagra, a disease caused by vitamin B3 deficiency. The formulation aimed to overcome the limitations of poor skin permeability and first-pass metabolism associated with conventional delivery.

Method: Niacinamide-loaded nanoemulgels (NEG) were formulated using an oil-in-water nanoemulsion incorporated into a gel base. Various batches were prepared and evaluated for physicochemical parameters including particle size, zeta potential, drug release, entrapment efficiency, spreadability, and in vitro skin permeability. The optimized formulation was identified based on performance metrics and subjected to further evaluation for toxicity and irritation.

Results: The optimized batch (F2) exhibited a particle size of 85 ± 0.14 nm and a zeta potential of -25.1564 mV, indicating stability of the formulation. In vitro drug release reached $95.7 \pm 0.38\%$ over 24 hours. The nanoemulgel demonstrated high entrapment efficiency ($92.40 \pm 0.007\%$), excellent spreadability ($16.69 \pm 0.035\%$), and favorable flow properties. In vitro skin diffusion studies showed a permeability of $98.1 \pm 0.26\%$ for batch NEG2. The formulation was found to be non-toxic and non-irritant upon evaluation.

Conclusion: The niacinamide-loaded nanoemulgel formulation represents a novel, stable, and effective approach for enhancing transdermal drug delivery. It significantly improves skin permeability, drug release, and bioavailability while minimizing first-pass metabolism and adverse effects, making it a promising strategy for the topical treatment of pellagra.

Keywords: Nanoemulgel, (TDDS)Transdermal drug delivery system, Nanosized droplet, Pellegra, Nanoemulsion, Permiability, BCS (Biopharmaceutical Classification System)

1. INTRODUCTION

The Pellegra is Nutritional Deficiency of Vitamin B3 also known as 3D disease and it stands for Diarrhea, Dementia, Dermatitis and death if untreated. Sunburn develops into thick, scaly, darkly pigmented markings on the skin after being exposed to sunlight.⁽¹⁾ Inflammation of the mouth and tongue, vomiting, constipation, abdominal pain and diarrhea may be seen due to gastrointestinal inflammation.⁽²⁾ Pellegra was first declared in Europe and US between 18th and 20th centuries. The (NAD) and (NADP) are the active forms of Niacinamide. These molecules used as vital coenzymes, playing provital roles in several metabolic pathways. This is why pellegra affects tissues with high metabolic rate, such as the skin, brain, and digestive system⁽³⁾. The neuropsychiatric symptoms may be occur, apathy, fatigue, psychosis and memory loss, depression, confusion, hallucinations. ⁽⁴⁾ Niacinamide is also known as Vitamin B3, Nicotinamide or Nicotinic acid. It gives Anti-inflammatory action and also reduce inflammation. The oral bioavailability is low hence the transdermal drug delivery of this drug is formulated. It also improves pigmentation, redness, itchiness and reduce inflammation and pain. ⁽⁵⁾

Topical drug delivery is one of the most promising methods for drug application. The topical drug delivery system defined as it is self-contained discrete dosage form which, when applied to the skin. Topical drug delivery systems involve applying

drugs directly to the skin or mucous membranes to treat local or sometimes systemic conditions. There are Some advantages of topical drug delivery systems are as follows:⁽²⁷⁾

1. Targeted Action: They deliver the drug directly to the affected area, ensuring higher local drug concentration.
2. Minimized Side Effects: Systemic absorption means fewer side effects compared to oral or injectable routes.
3. Non-invasive: No need for injections, making them painless and more acceptable to patients.
4. Bypasses First-pass Metabolism: Drugs avoid liver metabolism, increasing their effectiveness.
5. Improved Patient Compliance: Easy to apply and convenient for long-term use.

In the topical drug delivery, the particle size of nanoemulsion should be in the range of 20 to 200 nm. A nano emulsion can be divided into 2 types as follows oil-in-water (o/w) nano emulsion and water in oil (w/o) nano emulsion. It is a kinetically stable mixture of two immiscible liquids, such as oil and water, stabilized by surfactants or emulsifying agents. Nanoemulsions are characterized by their clarity or translucency, small droplet size, and enhanced stability compared to conventional emulsions. Nano emulsion is formulated by using Aqueous phase titration method. Nano emulgels are chosen over other formulations because they enhance drug solubility, improve skin penetration, provide controlled release, are more stable, non-greasy, and cosmetically elegant.^(19,23) For formulation of nano emulgels the gelling agents is use to give it thick, viscous nature. Nano emulgels improve skin penetration, controlled release, non-toxic, reduce first pass metabolism of drug through liver.^(6,20)

For formulating the nano emulsion, the biphasic system is important. In that the oil phase, Smix, and water is required to get the homogeneous, turbid, clear nano emulsion. The smix (Tween20:PEG200) is the mixture of surfactant and co-surfactant in the specific ratio to get the perfect consistency of nano emulsion. The peppermint oil is used as the oil phase in nano emulsion. It also used as penetration enhancer in the gel. In between the Carbopol 934 and Carbopol 940 the Carbopol 940 shows more viscous and more transparent gel than the Carbopol 934, so the Carbopol 940 is used as gelling agent for nano emulgel. The triethanolamine is used as the pH adjuster and the sodium benzoate is used as the preservative^(12,13,28). For formulation of the nano emulsion the simultaneous emulsification method is used. This method is required low energy, simple, cheap, very easy to formulate, less time consuming than high energy method.

2. MATERIALS AND METHODS

Materials

Niacinamide were purchased from Yarrow chem products, Mumbai. Tween 20, PEG-200, Peppermint oil, Triethanolamine, Carbopol 940, triethanolamine, sodium benzoate, were procured from Research lab fine Chemicals Industry, Mumbai. All other chemicals and solvents were of analytical reagent grade.

Methods

For formulation of nanoemulgel the spontaneous emulsification method is used. There are 4 steps for formulation of Niacinamide nano emulgel are as follows:

- 1: Construction of Pseudo ternary phase diagram
- 2: Preparation of nano emulsion
- 3: Preparation of Gel base
- 4: Incorporation of nano emulsion into gel base with continuous stirring.

Construction of Pseudo ternary phase diagram

In screening of excipients study, Peppermint oil, Tween 20, and PEG 200 are selected as oil phase, surfactant, co-surfactant respectively. The Distilled water was used as Aqueous phase. The Smix ratio (surfactant: co surfactant) were taken in 1:1, 1:2, 2:1, 3:1 ratio. Different concentrations of Smix were used to formed pseudo ternary phase diagram. Aqueous titration method is used for the Pseudo ternary phase diagram. After each water addition, the Appearance should be clear, transparent, turbid. Consistency (fluid, gel-like).^(17,21)

Method of preparation of Niacinamide Nano emulsion

The formulation was prepared by accurately weighed Niacinamide and mix in appropriate amount of Peppermint Oil, Smix (Tween20: PEG-200) and also add preservative in the oil phase. Mix the formulation until drug completely dissolved and get uniform oil phase. Then add Distilled water in oil phase dropwise by using aqueous phase titration method until the nano emulsion gets clear, turbid Nano emulsion.⁽³⁰⁾

Method of preparation of Gel base

The weighed quantity of Carbopol 940 was mixed in distilled water in 0.1 % to 2 % w/w. After this, add triethanolamine to

maintain the pH of the formulated gel base. Then mix the gel base uniformly to maintained its consistency and then the gel was kept for 24 hrs. ⁽²⁵⁾

Formulation of Niacinamide Nanoemulgel

The prepared Niacinamide loaded nano emulsion was mixed with the gel base with constant stirring till the clear homogeneous nano emulsion gel obtained. The prepared Niacinamide loaded nano emulsion gel stored at room temperature for further evaluations. ^(24,28)

Characterization of Niacinamide Nano emulsion

Thermodynamic Stability study^(6,29)

In this study the nano emulsion were passes through different test for checking the stability. Such as Freeze thaw cycle, centrifugation and Heating cooling cycle.

Particle size and Zeta potential

The Malvern Particle size analyzer, USA, was used to examine prepared Niacinamide nanoemulsion using DLS method. After diluting nano emulsion to 200 µL in water, 50 µL was diluted to 2ml with water. The results are shows in table no.2

Polydispersity index (PDI)

The nano emulsion was measured by photon correlation spectroscopy using a Malvern Zetasizer. Samples were diluted appropriately with the water to get clear appearance. The measurements were carried out at 25 °C in 75% - 100% intensity. The samples were analyzed and result shows in table no 2.

DSC (Differential scanning Colorimetry)

Thermal analysis of final excipients with drug and pure drug was carried out using Mettler Toledo Company, Model- SW920. The thermal endotherm was shown in figure 1.

SEM

By the scanning electron microscopy the morphology of nano emulsion can be determined. SEM gives a 3-dimensional image of the particle. Various magnifications are used to analyze the samples at an appropriate accelerating voltage, often 20 kV and result were shows in figure no.7. ⁽¹⁸⁾

EE%

It is determined by calculating the concentration of free drug (un-entrapped) in aqueous medium. The weighed amount of nanoemulsion firstly centrifuge in centrifugation machine at 2000 rpm for 5-10 min. after filtration the supernatant were collected and check under UV spectrometer at 262nm diluting with phosphate buffer 7.4 pH. ⁽²²⁾

$$EE\% = \frac{\text{Total Drug} - \text{Free Drug}}{\text{Total drug}} \times 100$$

In-vitro Drug Release study of nano emulsion

In in-vitro dissolution study Cellulose membrane was used for in-vitro drug release. Soaked the cellulose membrane in hot distilled water for overnight. A sample of 1gram of nano emulsion was poured in a cellulose membrane and tie the other end with the help of rubber to prevent leakage of the sample. Then the membrane was immersed into the dissolution vessel it contains 500ml of phosphate buffer 7.4 pH and maintained at 37°C ± 0.5°C. The rpm sets at 50 rotations per min, and 1 ml of sample is withdrawn from the release medium at specific time intervals and make up the volume of release medium with fresh solution. The samples were assayed at λ_{max} 262 nm in UV spectrophotometer. After that calculate the % drug release of drug in release medium. ⁽¹¹⁾

Evaluation of Nano emulgel

pH

The pH meter was calibrated using a standard buffer solution. About 0.5gm of the nano emulgel was weighed and dissolved in 50ml of distilled water and the pH of the solution was measured in Digital pH meter (Model EQ-610). Result were shows in Table no 4.

Viscosity

For determining the rheological characteristics of formulation, the viscosity is measured by using Brookfield viscometer at CPE spindle 91 and at 50 rpm and 30°C. The results are displayed in Table No. 6.

Spreadability ⁽¹⁵⁾

For determining the Spreadability of gel the gel is placed between the two layers of glass slides with definite weight. The

one end of glass slide which is place on the gel is tied with specific amount of weight and the weight will increase or decrease as per necessary. The time taken to separates the slide completely were recorded. The spreadability is calculated by using the formula:

$$S=M.L/T$$

Where,

S= Spreadability

M= weight tied to upper slide.

L= length of glass slide.

T= time taken to separate the slides completely

Percentage Drug content

For calculation of % drug content take 1 g of the gel into 10 ml volumetric flask added methanol mix it well and make up the volume with methanol upto 10ml. the solution kept for 2hrs after that the solution passed through filter paper. then the supernant is use to measured absorbance by using spectrophotometer at 262 nm. ^(7,14)

In-vitro Diffusion study of Nano emulgel

The Franz diffusion cell apparatus is used for the in-vitro diffusion study. In this study the cellulose membrane is used. The membrane was The membrane was carefully attached to the dialysis cell's hollow glass tube, and then the glass tube is filled with 1 gm of Nano emulsion gel. Magnetic beads were used to agitate the phosphate buffer 7.4 pH solution that had been added to the receptor chamber. At specific interval of time, 1 ml of the sample was taken in aliquots, and the volume make to 10 ml. after the proper dilutions, the solution content was checked by using UV visible spectroscopy at 262 nm. ⁽⁸⁾

Stability

The Stability study of nano emulsion gel should be stable in various conditions. Stability studies was performed as per international council of harmonization (ICH). For the stability study of Niacinamide nano emulsion gel, it was stored at 25 °C, and 40 °C for 3 months. The gel was analyzed for various parameter like color change, pH, and viscosity. ^(10,16,22)

3. RESULT AND DISCUSSION

Characterization of Pure Niacinamide

Table1: Characterization of Niacinamide

Drug name	Melting point	Color	Appearance
Niacinamide	131 °C	White	Crystalline

DSC of pure drug (Differential Scanning Calorimetry)

DSC thermogram of Niacinamide represented events for melting endothermic peak at 136 °C.

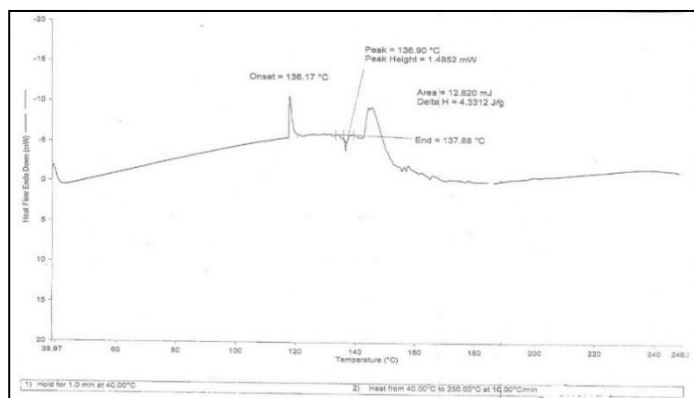


Figure1: DSC of Niacinamide Drug

Characterization of Nano emulsion

Pseudo ternary phase diagram studies

In the Pseudo ternary phase diagram, 4 ratio of Smix select for the preparation of Niacinamide loaded nano emulsion such

as 1:1, 1:2, 2:1, 3:1. From 4 formulations selected for preparation of Niacinamide nano emulsion from nano emulsion region of Smix ratio 2:1 and 3:1 is shows maximum solubility of oil in minimum amount of surfactant mixture. These are as follows

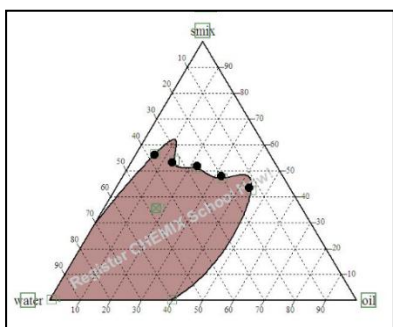


Figure 2: Smix 2:1

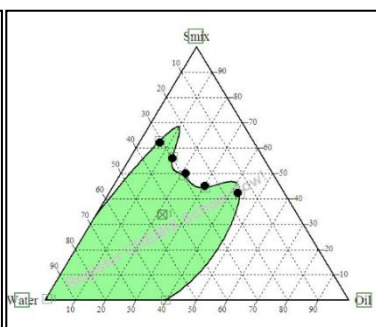


Figure 3: Smix 3:1



Figure: Nanoemulsion

Compatibility of Niacinamide with Excipients

Figure 4: IR of Niacinamide with Excipients

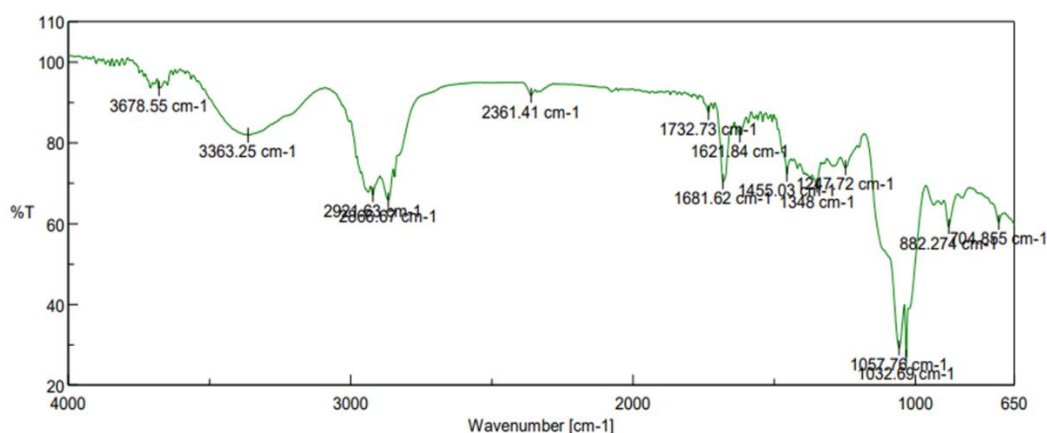


Figure 4: IR of Niacinamide with Excipients

Table1: Interpretation of Niacinamide with Excipients

Functional Group	Standard FTIR Range (cm ⁻¹)	Niacinamide (Observed)	Niacinamide + Excipients (Observed)
N-H stretching	3300–3180	3145.33	3363.25
C-H stretching	900-650	882.274	704.855
C=O stretching	1690–1630	1674.87	1681.62
C=C stretching	1600–1450	1591.95,	1621.84
C-N stretching	1350–1000	1338.36	1348

Particle Size, Zeta potential and Polydispersity Index

The particle size and polydispersity index were calculated from intensity, volume and bimodal distribution of spherical particles. Nano emulsion has various droplet size ranging from 50 to 200nm. The PDI value should be less than 1.0.

Table2: Particle Size, Zeta potential and PDI

Formulation	Particle size	PDI	Zeta potential
F1	203.3	0.4551	-16.511
F2	85.33	0.2955	-25.1564

F3	173	0.3354	-10.6722
F4	172.5	0.5372	-15.7877
F5	206.4	0.2843	-17.3815

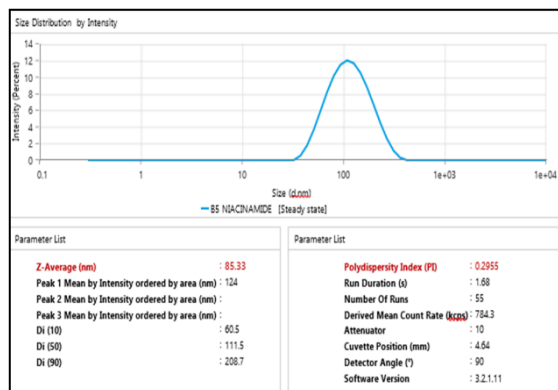


Figure5: Particle size and PDI

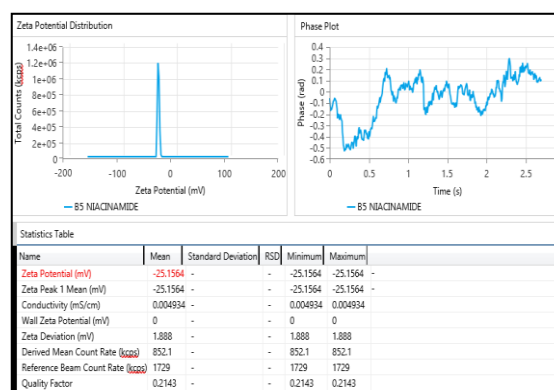


Figure 6: Zeta potential

SEM

The fig no. 7. Shows nano emulsion scanning electron microscopy. The nanoemulsion shows 3D spherical image and it was less than 1 micrometer. The showed some agglomeration of nano emulsion, which may cause due to evaporation of water in formulation during sample preparation before the examination.

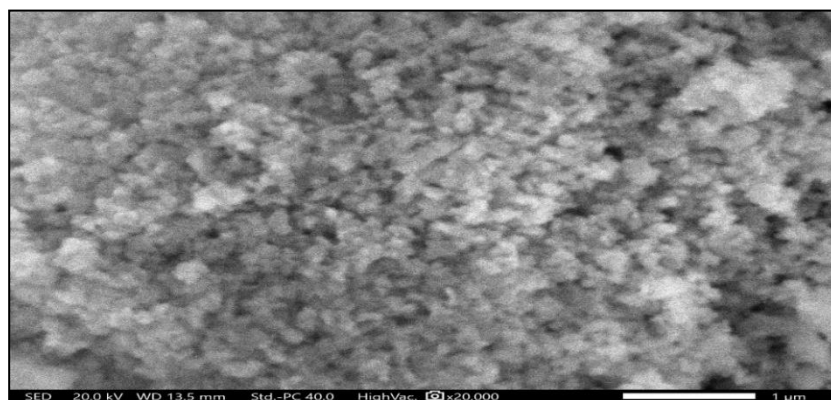


Figure 7: Scanning Electron Microscopy

In-Vito Drug Release study

In In-vitro drug release studies the different formulation shows different controlled release of drug. In that the F2 batch shows highest drug release.

Table3: In-Vitro drug release in 12hrs

Formulations	% Drug release (12hrs)
F1	91.3±0.30
F2	95.7±0.38
F3	89.3±1.04
F4	88.9± 0.50
F5	87.6±0.50

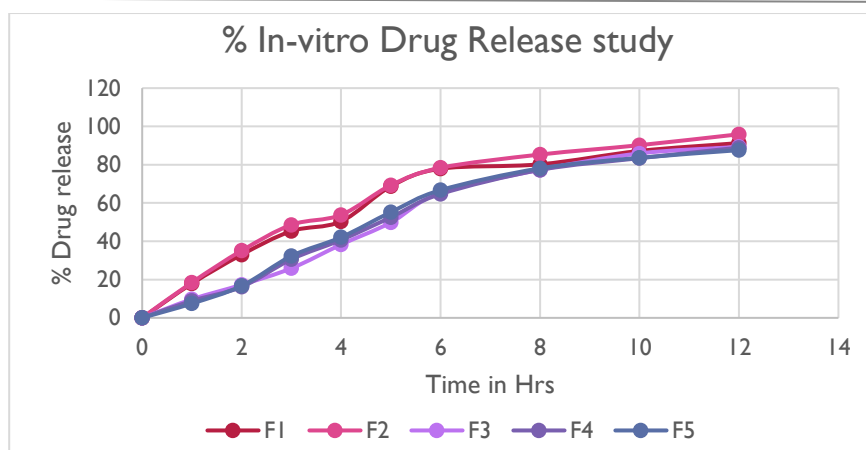


Figure 8: % In-vitro drug release

Formulation table of nanoemulgel

Formulation	Smix %	Oil %	Water%	Carbopol 940 %	Sodium benzoate %	Triethanolamine %
NEG1	55.94	13.98	30.06	0.5	0.1	Q.S
NEG2	55.94	13.98	30.06	1	0.1	Q.S
NEG3	55.94	13.98	30.06	1.5	0.1	Q.S
NEG4	55.94	13.98	30.06	2	0.1	Q.S

Evaluation of Nano emulgel

Organoleptic characteristics of gel

Nano emulsion gel's physical characteristics was determined to be transparent, uniform, turbid, clear and consistent.

pH , Spreadability and Viscosity

pH of all Nano emulsion gel was shown in the following table which was found to be in range of 4.8 ± 0.38 to 5.7 ± 0.1 and the The Spreadability of the Nano emulgel is ranging from 15.17 ± 0.025 to 16.69 ± 0.035 shown in the following table. The theological properties of the Nano emulgel are evaluated by Brookfield Viscometer. The Viscosity was found to be 18.22 ± 0.2 to 28.26 ± 0.4 shown in the following table.

Table 4: Determination of pH

Sr,no	Formulation	pH	Spreadability	Viscosity
1	NEG1	5.7 ± 0.1	15.17 ± 0.025	28.26 ± 0.4
2	NEG2	5.4 ± 0.1	16.69 ± 0.035	18.22 ± 0.2
3	NEG3	4.8 ± 0.38	15.78 ± 0.028	20.2 ± 0.2
4	NEG4	5.2 ± 0.42	16.44 ± 0.018	19.5 ± 0.3

% Drug content and Entrapment Efficiency %

UV vis. spectrophotometer was used to determine the % drug content and entrapment efficiency % of various gel formulations, and the results are shown in table no. 7.

Table 7: % Drug content and Entrapment Efficiency

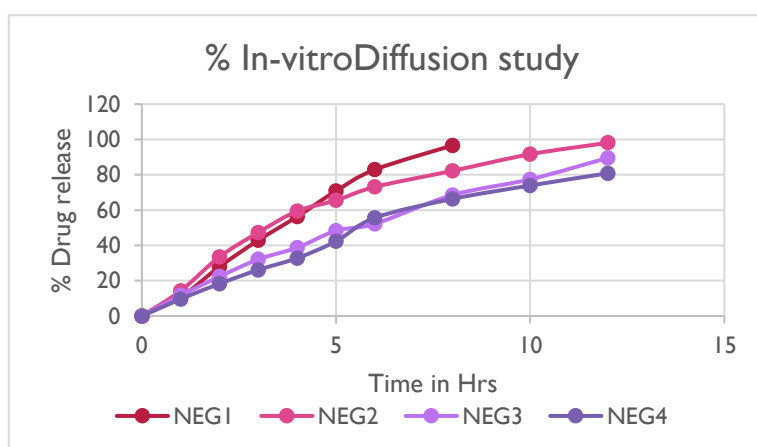
Formulation	% Drug content	Entrapment Efficiency%
NEG1	82.92 \pm 0.03	88.15 \pm 0.43
NEG2	90.24 \pm 0.02	92.40 \pm 0.007
NEG3	87.86 \pm 0.032	88.69 \pm 0.01
NEG4	78.96 \pm 0.038	89.66 \pm 0.017

In-vitro Diffusion study

In-vitro diffusion studies of gel were performed for different formulations, which shows controlled release of nanoemulgel formulation NEG1, NEG2, NEG3 and NEG4 as 96.6 \pm 0.2, 98.1 \pm 0.26, 89.5 \pm 0.2, 80.8 \pm 0.5, respectively after 12hrs. The NEG2 shows higher drug release of nano emulsion gel as 98.1%. The in-vitro Diffusion profile of Niacinamide Nano emulgel was represented in the table.

Table 8: In-vitro diffusion study

Formulations	In-vitro diffusion study (12 hrs)
NEG1	96.6 \pm 0.2
NEG2	98.1 \pm 0.26
NEG3	89.5 \pm 0.2
NEG4	80.8 \pm 0.53

**Figure9: In-vitro diffusion study****Figure10: Nanoemulgel****Stability study**

The accelerated stability study of the Niacinamide nanoemulgel was conducted as per ICH guidelines. The prepared formulation was stored at a temperature of 40 \pm 2°C and relative humidity of 75 \pm 5% in a stability chamber. After three months, the following observations were recorded:

Table 9: Stability study

Formulations NEG 2	0 Month	1 st Month	2 nd Month	3 rd Month
pH	5.49 \pm 0.1	5.4 \pm 0.1	5.3 \pm 0.1	5.3 \pm 0.1
Particle Size	85.33	86.01	87.45	87.89

Zeta potential	-25.1564	-24.968	-24.740	-24.512
Viscosity	18.22±0.2	18.15±0.3	18.08±0.2	17.70±0.3

4. CONCLUSION

In this present study of formulation and evaluation of Niacinamide nanoemulgel for enhanced topical delivery the Niacinamide nanoemulgel was successfully formulated and evaluated. In this study the formulated nanoemulsion shows low particle size 85.33 nm, high entrapment efficiency 92.40 ± 0.007 , high drug content 90.24 ± 0.02 , and the nanoemulgel shows high in-vitro drug release 95.7 ± 0.38 %, and also high in-vitro diffusion study 98.1 ± 0.26 %.

The conclusion of this study is that the Peppermint oil is act as a penetration enhancer and oil phase and it helps gel to pass through the membrane. The next conclusion is that as the Carbopol 940 quantity is increasing as well as the consistency become more thick and not good for gel to get absorbed in the skin. So, the conclusion is the less quantity of Carbopol 940 can formulate stable, homogeneous and clear, easily spreadable gel.

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