Formulation of Solid Lipid Nanoparticles Loaded Nasal Drop Containing Kalanchoe pinnata (Lam) Pers Extract

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ABSTRACT

The present study was aimed to formulate solid lipid nanoparticles loaded in nasal drops containing Kalanchoe pinnata by cold technique to impart better antidepressant activity. It can improve penetration of drugs to the CNS and show faster pharmacological action. Nasal drops were prepared by sodium chloride and benzalkonium chloride. Nasal drug delivery systems are better at imparting the antidepressant activity. The pH of the formulation was found to be within the range of 4.5 to 6.5. The viscosity of SLN-loaded nasal drops was found to be around 05-30 cp.

Keywords: SLN-loaded nasal drop, benzalkonium chloride, sodium chloride, phosphate buffer, etc.

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INTRODUCTION:

Kalanchoe pinnata is one of the exceptional medicinal plants belonging to the family Crassulaceae, grown in various parts of Asia. It has a lot of phytochemicals, which have played an important role in many biomedical applications. It has a good antimicrobial capacity against microbes like *Bacillus subtilis, Staphylococcus aureus, E. coli, Pseudomonas aeruginosa, S. dysenteriae, E. coli, Candida albicans, Rhodococcus rhodochrous,* and *Arthrobacter protophormial. Bacillus megaterium, Salmonella typhi,* and *Vibrio cholera.* It reduce the blood pressure chloroform, methanolic and aqueous extract of *K. pinnata* was having significant anthelmentic activity quercitrin flavonoid isolated from *K. pinnata* having good anti-allergic activity , the compounds like flavonoids, polyphenols, triterpenoids isolated from *K. pinnata* having good antinociceptive, anti-inflammatory and antidiabetic properties , the aqueous extract of this plant, have good effect in the inhibition of cell mediated and humoral immune responses in mice. *Kalanchoe pinnata,* formerly known as *Bryophyllum pinnatum,* is a herbaceous species native to tropical regions such as Africa. In Brazil, it was successfully introduced and propagated, being commonly used in communities far from large capitals. The juice of the leaves is usually used in the treatment of inflammatory diseases, gastric ulcers, burns, diarrhea, vomiting, insect bites, and body aches. In the literature, compounds such as anthocyanins and flavonoids are reported that have different biological activities, such as antimicrobial, antioxidant, cytotoxic, antitumor, antiparasitic, antiallergic, and hepatoprotective. The nasal route is an alternative route to parenteral since it has good bioavailability and fewer side effects. The aim of this research was to study the formulation of solid lipid nanoparticles containing Kalanchoe pinnata extract for nasal delivery using cow ghee as lipid core. reported where researchers ensured longer retention time of solid lipid nanoparticles at the site of deposition and avoidance of hepatic metabolism, resulting in improved bioavailability

MATERIALS AND METHODS:

Materials:

Kalanchoe pinnata leaves were obtained from the local market from Umarga. Cow ghee as Lipid Core i.e all ingradients used i.e Polaxomer 188, PEG-400, Tween-80, Triethanolamine,Benzalkonium chloride,Phosphate buffer, Sodium chloride,distilled water were pharmaceutical grade.

Table -1 Formulation table

Ingradients	F1	F2	F3
SLN dispersion	Equi to 1%	Equi to 1%	Equi to 1%
Sodium Chloride	0.85 gm	0.9 gm	0.91 gm
Benzalkonium chloride	0.01 gm	0.01 gm	0.01 gm
Phosphate Buffer	Q.S	Q.S	Q.S
Distilled Water	Up to 100 ml	Up to 100 ml	Up to 100 ml

Developing *Kalanchoe pinnata* leaf extracts using the maceration method

1.5 kg of fresh leaves were cleaned with water. The leaf material was then allowed to air dry for two days. In order to obtain extracts, a specific amount of dried material was macerated with ethanol by soaking 500 g of dried powdered plant in a bottle with two liters of ethanol for seventy-two hours. After that, the ethanol mixture was filtered and concentrated by utilizing a rotary evaporator to evaporate the alcohol under low pressure.

Preparation of SLN Loaded Nasal Drop

Take required quantity SLN dispersion and add sodium chloride (0.9%) and Benzalkonium chloride (0.01%) Adjust the PH to 5.5 to 6.5 using Phosphate buffer and make final volume with distilled water stir gently to obtain uniform Nasal drop formulation and then fill formulation into sterile amber coloured nasal dropper bottles, label properly and store refrigerated conditions at (4-8^{0}C).

Evaluation of Nasal Drop

1. Physical Appearance
2. PH Determination
3. Volume Uniformity
4. Osmolarity/ Isotonicity
5. In-vitro drug release study
6. Drop Charecterstics
7. Stability studies

1 . Physical Appearance

Solid Lipid Nanoparticle (SLN) loaded nasal drops are generally described as liquid, white, or opaque-white, slightly viscous dispersions or suspensions, often appearing similar to a white liquid emulsion. They are designed to be homogeneous (uniform in appearance) with no visible particulate matter or agglomeration.

2. pH Determination

The pH determination of Solid Lipid Nanoparticle (SLN) loaded nasal drops is a critical quality attribute (CQA) to ensure stability, minimize irritation, and maintain efficient drug delivery. The ideal pH for nasal formulations is typically between 4.5 and 6.5, which matches the natural pH of nasal secretions.

3. Volume Uniformity

Volume uniformity refers to ensuring that each administered drop (or delivered dose) from a nasal drop formulation contains a consistent and reproducible volume, which is crucial for accurate dosing of SLN (Solid Lipid Nanoparticle) dispersions. and using dropper calibration method.

4. Viscosity Measurement

Viscosity measurement is an important evaluation parameter for Solid Lipid Nanoparticle (SLN)–loaded nasal drops, as it determines the flow behavior, sprayability/drop formation, and nasal residence time of the formulation.

5. Osmolarity/ Isotonicity

Osmolarity (or isotonicity) is an important quality control parameter for SLN (Solid Lipid Nanoparticle)–loaded nasal drops. It ensures that the formulation has a similar solute concentration as nasal fluids, preventing irritation and improving patient tolerance. Normal Nasal Osmolarity Nasal fluid is approximately isotonic with blood

Ideal range: 270–320 mOsm/kg Equivalent to 0.9% NaCl solution

6. *In-vitro* drug release study

The in-vitro drug release study of SLN (Solid Lipid Nanoparticle)–loaded nasal drops is performed to evaluate the rate, extent, and pattern of drug release from the nanoparticles into a simulated nasal environment.

Table no:2 % drug release nasal drop (F1)

F1			
Time (min)	**Absorbance**	**Dilution**	**% DR**
0	0.000	1	0.00
30	0.004	1	6.82
60	0.010	1	14.14
120	0.022	1	28.79
180	0.036	1	45.88
240	0.048	1	60.53
360	0.062	1	77.62
480	0.067	1	83.72
720	0.071	1	88.61

Table no:3 % drug release nasal drop (F2)

F2			
Time (min)	**Absorbance**	**Dilution**	**% DR**
0	0.000	1	0.00
30	0.006	1	9.26
60	0.014	1	19.02
120	0.028	1	36.11
180	0.042	1	53.20
240	0.054	1	67.85
360	0.070	1	87.39
480	0.075	1	93.49
720	0.078	1	97.15

Table no: 4 % drug release nasal drop (F3)

F3			
Time (min)	**Absorbance**	**Dilution**	**% DR**
0	0.000	1	0.00
30	0.005	1	8.04
60	0.013	1	17.80
120	0.026	1	33.67
180	0.041	1	51.98
240	0.052	1	65.41
360	0.068	1	84.94
480	0.072	1	89.83
720	0.074	1	92.27

7. Drop Characteristics

Drop characteristics refer to the physical properties of individual droplets formed from SLN (Solid Lipid Nanoparticle)–loaded nasal formulations, which directly influence dose accuracy, nasal deposition, and patient comfort.

Drop Size (Volume per Drop)

Indicates volume of a single drop (µL or mL) Ideal nasal drop volume: 25–50 µL per drop

Must be uniform across all drops

8. Stability Studies

Kalanchoe Pinnata Loaded SLN nasal drop Stability studies for ensure their physical, chemical, and microbiological integrity over time, determining shelf life and storage conditions. Key assessments include pH (4.5–6.5), viscosity, drug content uniformity, and sterility. Accelerated studies often show increased degradation at 40°C, with stability enhanced by preservatives or antioxidants.

Table no: 5 Evaluation of Nasal drop formulation

Formulation code	pH	Viscosity	Osmolarity/Isotonicity
F1	5.4	5 cp	290 mOsm/kg
F2	5.7	7 cp	295 mOsm/kg
F3	6.1	9 cp	300 mOsm/kg

CONCLUSION:

Various formulation (F1, F2 and F3) were developed by using a Sodium Chloride and phosphate buffer . To Formulate Solid lipid nanoparticles Loaded Nasal drop containing *Kalanchoe pinnata* extract were evaluated for the physiochemical parameters such as drug content, pH, viscosity, *in vitro* drug diffusion. Viscosity studies of various formulations revealed that formulation F2 was better to compare to others. From among all the developed formulation, F2 shows better drug diffusion, did good Rheological properties. pH of the F2 formulation is sufficient enough to improve the penetration of drug to CNS and show faster pharmacological action Thus, SLN Loaded nasal drop can be successfully prepared using sodium chloride as Isotonicity/Osmolarity suitable for Nasal application Hence formulation F2 should be further developed for scale-up to industrial production.

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CONFLICT OF INTEREST:

The authors declare that there is no any conflict of interest.

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