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**Review Article**

# Nanoemulsions: A Promising Technology For The Development Of Innovative Products

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## ABSTRACT

Nanoemulsions are submicron-sized emulsions under extensive investigation as drug carriers for improving the delivery of therapeutic agents. They are the most advanced nanoparticle systems for the systemic delivery of biologically active agents for controlled drug delivery and targeting. Nanoemulsions are thermodynamically stable isotropic systems formed by mixing two immiscible liquids (water and oil) with suitable surfactants or their mixture to obtain a single phase with a droplet diameter ranging from 0.5 to 100 um. The size distributions of nanoemulsion droplets are narrow and usually lie between 20 and 200 nm. Nanoemulsions possess significant potential for advancing cosmetics, diagnostic tests, medicinal therapies, and biotechnology. This review aims to provide a concise overview of the investigation of the formulation, preparation process, and characterization techniques of nanoemulsions. It especially emphasizes the diverse applications of nanoemulsions in several fields including cancer treatment, drug targeting, mucosal vaccination, transdermal drug delivery, lipophilic drug delivery, self-nano emulsifying, and solid self-nano emulsifying drug delivery systems.

## INTRODUCTION

Nanoemulsions/ Submicron emulsions (SMEs)/Mini-emulsions are thermodynamically stable, transparent or translucent dispersions of oil and water protected by an interfacial layer of surfactant and cosmetic molecules of less than 100 nm globular scale. Nanoemulsions are commonly used to supply vaccines, medications associated with DNA, medicines, cosmetics, and topical

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preparations. These are delivered via various routes, such as oral, pulmonary, intranasal transdermal, etc.1 Classified as multi-phase colloidal dispersion, nanoemulsions are distinguished by their stability and clarity Small particles or droplets usually make up the dispersed process, and there is relatively little interfacial stress between the oil and the water. generates nanoemulsions readily and spontaneously, or occasionally with high-energy inputs.

A cosurfactant or cosolvent is used in many cases as opposed to the surfactant, the oil process, and the water cycle. Nanoemulsions have benefits as they have relatively high kinetic stability for many years. They can be made from deformable droplets into monodisperse structures that are highly uniform. The small droplets and thermal excitation action make them stable against creaming and prevent them from joining due to high surface load. Because of their long life and clear appearance, they are ideal for cosmetics, personal care products, and coatings. due to their tiny size and ability to enter target areas through lipid membranes and oil recovery, where they have high infectivity and penetration without filtration into the reservoir rocks, they are ideal for medication delivery systems. Nanoemulsions are also an interesting form of dispersion to be studied. These have special optical and rheological properties compared to microscale emulsions. (1,2,3,4)

**Type of nanoemulsion [5,6]**

Three types of nanoemulsions are most likely to form based on their composition:

- Oil in water Nanoemulsions in which oil droplets are dispersed in a continuous aqueous phase;
- Water in oil Nanoemulsions in which water droplets are dispersed in a continuous oil phase;
- Bi-continuous nanoemulsions in which oil and water microdomains are interspersed in witnesses.

In all three types of nanoemulsions, the interface is stabilized by an appropriate surfactant and/or co-surfactant combination. The primary distinction between emulsions and nanoemulsions is that, while the former may have excellent kinetic stability, they are fundamentally thermodynamically unstable and will eventually separate. Another significant difference is their appearance: emulsions are cloudy, whereas nanoemulsions are transparent or translucent in addition, there are distinct differences in their preparation process, as emulsions involve a high input of energy during nanoemulsions.


**Fig. 1: (A) Nanoemulsion and (B) Macroemulsion With Droplet Diameters of Less Than 100 Nm and More Than 1000 Nm, Respectively5**

**Advantages of nanoemulsion: [7,8]**

1. Nanoemulsions have a larger surface area and free energy, making them an efficient transport system.
2. They do not demonstrate the problems of inherent creaming, flocculation, coalescence, or sedimentation.
3. It can be used in a variety of formulations, including foams, creams, liquids, and sprays.
4. They are non-toxic and non-irritant, so they can be easily applied to the skin and mucous membranes.
5. It can be administered orally if the formulation includes biocompatible surfactants.
6. It does not harm healthy human or animal cells, making it suitable for human and veterinary therapeutic purposes.

7. It improves the uptake of oil-soluble supplements in cell culture technology, allowing for better cell growth and toxicity studies on oil-soluble drugs.
8. It may be applied as a substitute for liposomes and vesicles and it is possible to build lamellar liquid crystalline phases around the nanoemulsion droplets 1

**Disadvantages of Nanoemulsion [7,8]**

1. Use a high concentration of surfactant and co-surfactant to stabilize nanodroplets. High-melting substances have a limited solubility capacity.
2. The surfactant must be nontoxic when used in pharmaceutical applications.
3. Nanoemulsion stability is affected by environmental factors such as temperature and pH. These parameters change when nanoemulsions are delivered to patients.

**Components of Nanoemulsion [9,10]**

Main three components of Nanoemulsions are

1. Oil
2. Surfactant/Co surfactant
3. Aqueous phase

The correct ratios of an oil phase, an aqueous phase, a surfactant, and cosurfactants type form colloidal dispersions known as nanoemulsions. Nanoemulsions are based on low interfacial tension, Similarly, coarse emulsions are micronized by external energy. This was achieved by adding cosurfactants, which led to the spontaneous formation of a thermodynamically stable nanoemulsion. Due to the minuscule droplet size typically under 140 nm in diameter—in the dispersed phase. Nanoemulsions are transparent liquids. They employ techniques to give patients their medications, although topical application of Nanoemulsions has garnered some interest. Three main aspects influenced the transdermal permeation of medications: drug mobility inside the vehicle, drug release from the vehicle, and drug penetration into the skin. Therefore, in the transdermal administration of medications, they perform better than conventional topical treatments like emulsions and gels. When compared to nanoemulsions containing gel, which increased viscosity and further reduced absorption into the skin, the mobility of medicines in nanoemulsions is easier. It has been established that nanoemulsions' higher transdermal flow is primarily a result of their strong drug solubilization capacity for both lipophilic and hydrophilic compounds. As a result, the skin experiences enhanced thermodynamic activity.

**METHOD OF PREPARATION OF NANOEMULSION [5,11,12]**

Nanoemulsions have a tiny particle size range; they can be most effectively produced using high-pressure equipment. The most commonly used methods for producing nanoemulsions are High-pressure homogenization and Micro fluidization used at laboratory and industrial scales. Other methods, like the solvent evaporation technique, in-situ emulsification, and ultra-sonification phase inversion method, are also suitable for the synthesis of nanoemulsion.

**1. High Pressure Homogenization**

Nanoemulsion preparation requires the use of a high-pressure homogenizer. This technique produces nanoemulsions of low particle size i.e. 10-100nm. In this technique, a mixture is forced to pass through an orifice at a very high pressure ranging from 500 to 5000 psi. The resultant product is further subjected to intense turbulence and hydraulic shear resulting in emulsion with extremely fine particles. This has been proven to be the most efficient method for nanoemulsion preparation, but the only drawback associated with this technique is high energy consumption and the rise in temperature of the emulsion during processing.

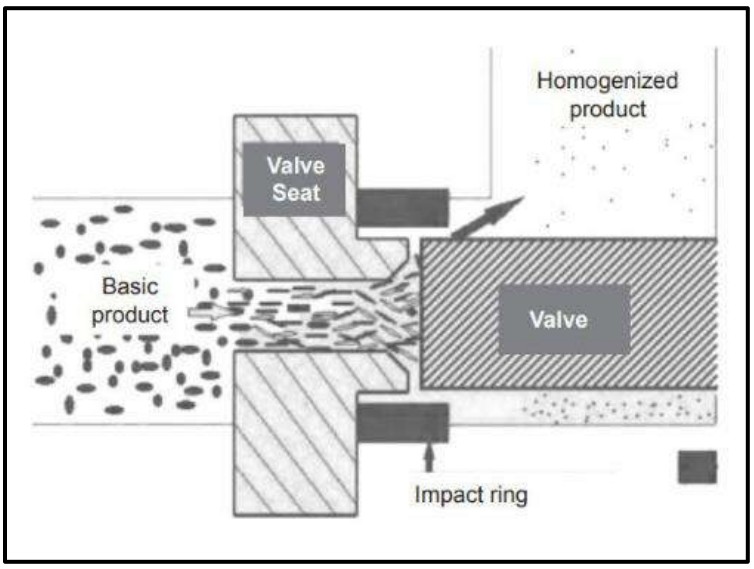


**Fig. 2: High Pressure Homogenization**

## 2. Microfluidization

Microfluidization is one of the most commonly used high-energy techniques. Initially, a high-shear mixer is used to create a coarse oil/water emulsion by combining oil, emulsifier, and water. The coarse emulsion is then forced through the microfluidizer's interaction chamber under pneumatic pressure. The microfluidizer works on the principle of dividing a pressure stream into two parts, passing each part through a fine orifice, and directing the flows at each other in the heart of the microfluidizer, namely the interaction chamber. The microfluidizer uses high pressure upto 500 to 20000psi to guide the flow stream through microchannels toward the impingement area, which creates a very high shearing action that provides an exceptionally fine emulsion. In the interaction chamber forced cavitation along with share and impact reduces emulsion to the desired droplet size.

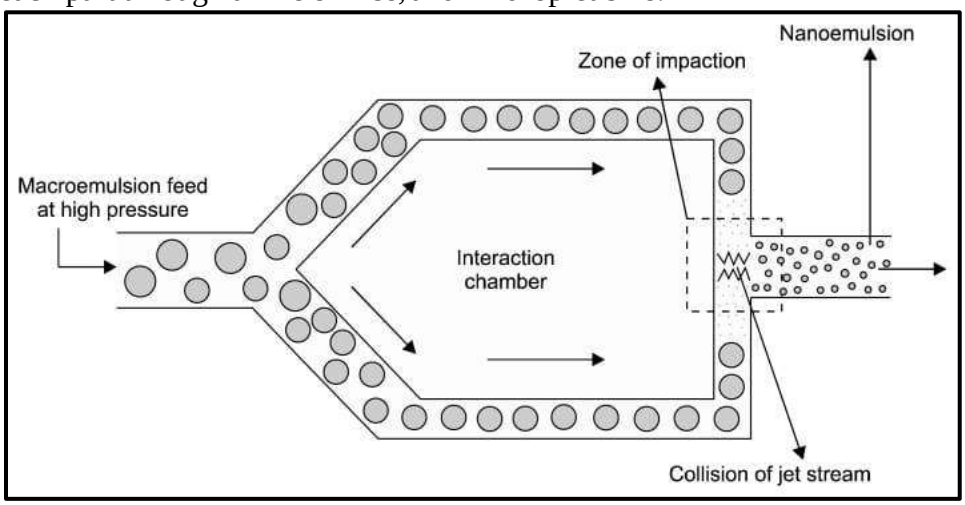


**Fig. 3: Micro Fluidizer with The Mechanism of Working**

## 3. Ultrasonication

Nanoemulsions can be created using ultrasonic sound frequency to reduce globule size. Another approach is to use a constant amplitude sonoprode at system pressures higher than the ambient value. It is well known that increasing external pressure raises the cavitation threshold within an ultrasonic field, resulting in fewer bubbles. However, increasing the external pressure raises the collapse pressure of cavitation bubbles. This means that

when cavitation occurs, the bubbles collapse more violently than when the pressure is atmospheric. As cavitation is the most important mechanism of power dissipation in a low-frequency ultrasonic system, these changes in navigational intensity can be related directly to changes in the power density. The system also uses a water jacket to control the temperature to the optimum level.

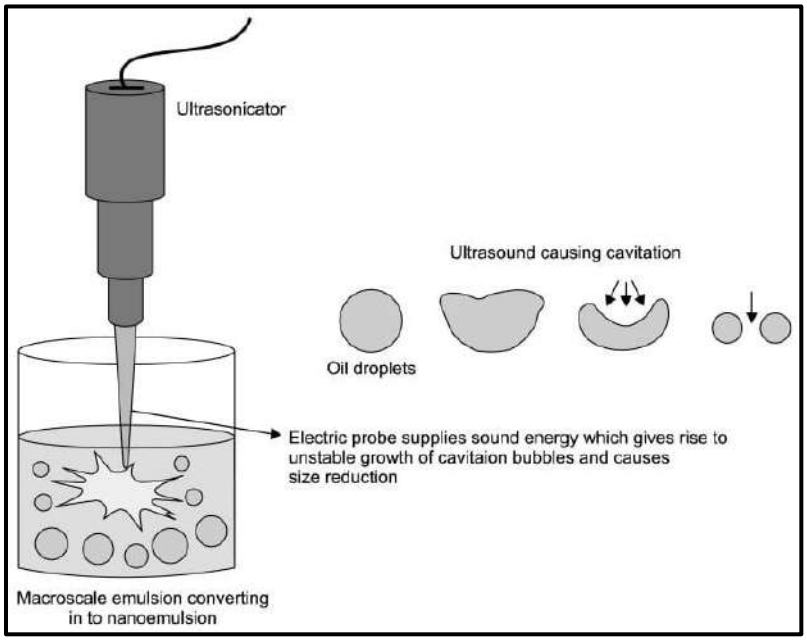


**Fig. 4: probe sonicator used in laboratory scale for preparation of nanoemulsion**

4. Phase inversion method

This involves the formation of fine dispersions when phase transitions occur by changing either the temperature or composition while keeping the alternate parameter constant. The persuasion method can be broadly categorized as

(i) Phase transition from the near-optimum state via a change in a single variable, which includes changing one formulation variable, such as temperature or salinity, to bring it closer to the optimal value. The optimal hydrophilic-lipophilic deviation (HLD) for a system, such as microemulsion at a higher temperature, is near the center.

(ii) Phase transition from near-optimal state through modification of many formulation factors, i.e., more than one variable change. For instance, using a greater temperature and adding more salt to a microemulsion.

(iii) Catastrophic inversion, an inversion of low internal phase emulsion so that the internal phase converts to the external phase.

(iv) Phase transition stabilized by liquid crystal formation, which includes nanodroplets stabilization from a state close to HLD-0 by liquid crystal formation.

6. Solvent Evaporation Technique

This technique involves preparing a solution of the drug followed by its emulsification in another liquid that is non-solvent for the drug. Evaporation of the solvent leads to precipitation of the drug. High-shear forces can be produced to control both crystal growth and particle aggregation by using a high-speed stirrer.

7. Hydrogel Method

In this technique, the drug solution is prepared and emulsified into another liquid (non-solvent for the drug) and then the solvent is evaporated, which leads to drug precipitation. A high-speed stirrer can be employed to regulate the crystal growth and particle aggregation. The Hydrogel method is very similar to the solvent evaporation method. The only difference from the solvent evaporation

method is that the drug solution in this case is miscible with the drug antisolvent.

## PHYSICOCHEMICAL CHARACTERIZATION OF NANOEMULSION

### 1. Dye Solubilization

A water-soluble dye is solubilized within the aqueous phase of the w/o globule but is dispersible in the o/w globule. An oil-soluble dye is solubilized within the oil phase of the o/w globule but is dispersible in the w/o globule. [5,11,12]

### 2. Dilutability Test

O/w Nanoemulsions are diluted with water whereas w/o are not and thus they undergo phase inversion into o/w Nanoemulsion. [5,11,15]

### 3. Conductance Measurement

The conductance of nanoemulsion is measured by a conductometer. In this test, a pair of electrodes connected to a lamp and an electric source is dipped into an emulsion. If the emulsion is o/w type, water conducts the current, and the lamp gets lit due to the passage of current between the electrodes. The lamp does not glow when the emulsion is w/o oil being in the external phase and does not conduct the current. [16,17]

### 4. Dynamic Light-Scattering measurements

The DLS measurements are taken at 90° in a dynamic light scattering spectrophotometer which uses a neon laser of wavelength 632 nm. The data processing is done in the built-in computer with the instrument. [15,18]

### 5. Polydispersity index

The average diameters and polydispersity index of samples were measured by Photon Correlation Spectroscopy. The temperature here used is about 25ºC. The He-Ne laser is used for this measurement. [11,19]

### 6. Phase analysis

Phase analysis of nanoemulsion is determined by measuring the electrical conductivity using a conductometer. [6,20]

### 7. Droplet Size Analysis

Droplet size analysis of nanoemulsion is measured by a diffusion method using a light-scattering, particle size analyzer counter. It is also measured by correlation spectroscopy which analyzes the fluctuation in scattering of light due to Brownian motion. Droplet size analysis of nanoemulsion can also be performed by transmission electron microscopy (TEM). [12]

### 8. Interfacial Tension

Spinning-drop apparatus can be used to measure the ultralow interfacial tension. Interfacial tensions are derived from the measurement of the shape of a drop of the low-density phase, rotating it in a cylindrical capillary filled with the high-density phase. [12]

### 9. Viscosity measurement

The viscosity of nanoemulsion is measured by using a Brookfield-type rotary viscometer at different shear rates at different temperatures. [11]

### 10. pH

The apparent pH of the formulation was measured by a pH meter. [5]

### 11. Refractive Index

It was determined using an Abbes-type refractometer at 25±0.5°C [5,12]

### 12. in vitro skin studies

Keshary Chiendiffusion cells were used for in vitro skin permeation investigations. It was carried out using 12 diffusion cells, a recirculating water bath, and abdomen skins taken from male rats weighing 250±10 g. Vertical diffusion cells' donor and receiver chambers were separated from one another by the skins. Freshwater containing 20% ethanol was poured into the receiver chambers. The solution in the receiver chambers was constantly agitated at 300 rpm and heated to 37°C. The mixtures were filled into the donor chamber. 0.5 ml of the solution in the receiver chamber was removed for analysis at 2, 4, 6, and 8 hours and immediately replaced with a new solution of the same volume.

Three runs of each sample were performed. To determine the total number of drugs distributed at each time interval, cumulative adjustments were made. Plots were made as a function of time showing the total amounts of medication that passed through the skin of rats. [7]

**14. Studies on thermodynamic stability**

**a. Heating Cooling Cycle**

The temperature range for the six cycles of the nanoemulsion formulations was 4°C to 45°C.[14]

**b. Centrifugation**

The nanoemulsion formulations that did not exhibit any phase separation after being centrifuged at 3500 rpm were chosen for the freeze-thaw test.[13]

**c. Cycle of Freeze-Thaw**

Three freeze-thaw cycles between 21°C and +25°C held under standard laboratory conditions were performed on the formulation in this experiment. Three months were spent doing these studies. [11,12]

**APPLICATION OF NANOEMULSION**

**1. Parenteral Infusion**

the stringent requirements of this mode of administration, particularly the requirement for formulation droplet size less than 1 micrometer, nanoemulsion has advantages in intravenous administration. Parenteral (or injectable) administration of nanoemulsion has several applications, including nourishment, such as the injection of fats, carbohydrates, vitamins, and so on. When administered parenterally, nanoemulsion formulations have distinct advantages over macroemulsion systems because nanoemulsions clear more slowly than coarse particle emulsions and remain in the body for longer periods. Nanoemulsions can be administered parenterally in either O/W or W/O form. [7,12]]

**2. Oral Delivery 21**

For oral administration, nanoemulsion formulations provide several advantages over conventional oral formulations, including improved clinical potency, increased absorption, and reduced drug toxicity. As a result, Nanoemulsion is effective in delivering medications like steroids, hormones, diuretics, and antibiotics. Peptide and protein pharmaceuticals have very high potencies and are targeted in their physiological effects. [21]

**3. Topical Delivery**

One benefit of topical medication administration over other approaches is the avoidance of the drug's hepatic first-pass metabolism and associated adverse consequences. Another is the drug's capacity to distribute itself directly to the skin or eyes that are afflicted. Only systemic antibiotics could previously attain the high level of topical antibacterial activity that the nanoemulsion can. The nanoemulsion has broad-spectrum activity against bacteria and fungi. [22]

**4. Ocular Delivery**

The majority of drug delivery for the treatment of eye disorders is topically. For ocular delivery, to dissolve poorly soluble medicines, to increase absorption, and to provide a prolonged release profile, nanoemulsions have been researched. [6,23]

**5. In Cosmetics 20**

The aesthetic qualities of nanoemulsions, such as their low viscosity and transparent visual characteristics with droplet sizes below 200 nm, as well as their high surface area, which enables effective transport of the active component to the skin, make them particularly alluring for use in cosmetics. Because there is no intrinsic creaming, sedimentation, flocculation, or coalescence, which is seen with macro emulsions, nanoemulsions are suitable in cosmetics. Using high-energy machinery during manufacture will help prevent the incorporation of potentially irritating. [24]

**6. Transdermal**

In rats with carrageenan-induced paw edema, the anti-inflammatory effects of real optimized

nanoemulsion formulation were compared with those of commercial gel. Transdermal Indomethacin is a strong NSAID. There is a great potential for indomethacin transdermal application because the inhibition value was significant for produced Nanoemulsion. Celecoxib was delivered transdermally using nanoemulsions made of 2% celecoxib, 10% oil phase, 50% Tween 80 and Transcutol-P, and 40% water. In comparison to celecoxib gel (43.7%) and nanoemulsion gel (64.5%), the anti-inflammatory efficacy and percent inhibition value after 24 hours of dosing were shown to be higher for nanoemulsion formulation (81.2%). The in vitro-in vivo experiments showed that Aceclofenac nanoemulsion (82.2%) had significantly greater anti-inflammatory effects than nanoemulsion gel formulation (71.4%) and conventional gel (41.8%). [25,26]

**7. Nanoemulsion Therapy for Cancer**

In cancer treatment, nanoemulsions can be employed as a vehicle to delay the onset of drug release after intramuscular and intertumoral injection (W/O systems). Due to an increase in the transfer of anti-cancer medications via lymphatic permeation through the skin and the fact that It is a non-irritating system, it also improves transdermal drug delivery. [27]

**8. Nanoemulsions in intranasal drug delivery**

In addition to parenteral and oral methods, intranasal drug delivery systems are now recognized as a reliable method of medication administration. Nasal mucosa has become a therapeutically effective route for administering systemic medications, and it appears to be a promising method of overcoming barriers to direct drug delivery to the target site. [28] Furthermore, this approach is painless, non-invasive, and well-tolerated. Because of its low enzymatic activity, availability of immunoactivity sites, and relatively permeable epithelium, the nasal cavity is one of the most cost-effective sites.[29]

**9. Nanoemulsions in pulmonary drug delivery**

The lung is the most important target for drug delivery because it can be administered noninvasively through inhaled aerosols, avoid first-pass metabolism, directly treat respiratory diseases by going to the site of action, and has a large surface area available for both systemic and local drug absorption. Improved drug solubility from the drug's aqueous solubility, a sustained drug release that subsequently lowers the frequency of dosing, increases patient compliance, lowers the incidence of side effects, and the potential for drug internalization by cells are just a few advantages of using colloidal carriers—also known as nanocarrier systems—in pulmonary drug delivery.[30]

**10. Nanoemulsions in gene delivery vector**

Emulsion methods have increased in popularity as substitute vectors for liposome-to-liposome gene transfer. Other emulsion studies for gene delivery (non-pulmonary route) have shown that the binding of the emulsion/DNA complex is stronger than that of liposomal carriers. This stable emulsion technique provided genes more efficiently than liposomes.[31] The factors influencing DNA compaction in cationic lipid nanoemulsions were examined by Silva et al. These nanoemulsions contain stearyl amine, a cationic lipid that, when in solution, presents a primary amine group. This lipid can compact genetic material through electrostatic interactions, and in dispersed systems like nanoemulsions, it anchors on the oil/water interface, giving them a positive charge. Examined were various incubation temperatures, the length of the complexation process, and the stearyl amine inclusion phase (water or oil). The process of characterization used dynamic light scattering (DLS). The results show that after 120 min of complexation, at a low temperature (4±1°C), and after integration of the cationic lipid into the aqueous phase, the optimal DNA compaction

process takes place. Lipoplexes' zeta potential was lower than what was observed for fundamental nanoemulsions, but the granulometry remained the same. Furthermore, it was shown that lipoplexes are reliable delivery systems for genes.[32]

**Table no: 1 Marketed formulation and their respected manufacturer[33]**

| Drug/Bioactive | Brand | Manufacturer | Indication |
|---|---|---|---|
| Alprostadil palmitate | Liple | Mitsubishi pharmaceutical | Vasodilator |
| Dexamethasone | Limethason | Mitsubishi pharmaceutical | Steroids |
| Propofol | Diprivan, troypofol | Astra zaneca, troika | Anaesthetic |
| Flurbiprofen axtil | Ropion | Kaken pharmaceutical | NSAID |
| Vitamins A, D, E, and K | Vitalipid | Fresenius Kabi | Parenteral nutrition |
| Etomidate | Etomidatlipuro | B. Braun melsungen | Anesthetic |
| Cyclosporine | Restasis, gengraf | Allergen, abott | Immunosuppressant |
| Ritonavir | Norvir | Abbott | Antiretroviral |

## CONCLUSION

Nanoemulsion formulations offer several advantages for the delivery of drugs, biologicals, or diagnostic agents. Traditionally, NEs have been used in clinics for more than four decades as total parenteral nutrition fluids. Several other products for drug delivery applications such as Diprivan, Liple, and Ropion have also reached the marketplace. Although NEs are chiefly seen as vehicles for administering aqueous insoluble drugs, they have recently received increasing attention as colloidal carriers for the targeted delivery of various anticancer drugs, photosensitizers neutron capture therapy agents, or diagnostic agents. Because of their submicron size, they can be easily targeted to the tumor area. Even though many studies on enhancing medicine administration have been published, it is still important to stress its characterization, which includes in-vitro evaluation. Moreover, research indicates that a larger proportion of surfactant—much greater than the CMC level—is employed in the creation of nanoemulsions, irrespective of the mode of administration. Nevertheless, there aren't any toxicological evaluations of the finished product, which should be a major focus of future study.

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