A Review: An Overview of Nanosuspension

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***Abstract*:**
In the world of medicine, nanotechnology has become a huge field. A particle's size range of 1-100 nm is referred to as Nano. Nanotechnology includes nanosuspensions. The solubility of many medications in water is poor. Drug nanosuspension is a generic formulation strategy that can be used to improve a drug's therapeutic efficacy using any delivery method. When it comes to drug delivery applications, such as oral, topical, parenteral, ocular, and pulmonary routes, nanosuspensions are defined as extremely finely colloid, biphasic, dispersed, solid drug particles in an aqueous vehicle with a size below 1um and no matrix material. They are stabilized by surfactants and polymers. Nano suspensions offer enhanced drug solubilization and dispersibility, greater therapeutic efficacy, and decreased toxicity. Consequently, the current review.

Keywords: Nanosuspension, bioavailability, poorly soluble drugs, drug delivery, high pressure homogenization

1. Introduction:

According to definitions, a pharmaceutical nanosuspension is characterized as "very finely dispersed solid drug particles in an aqueous vehicle, stabilized by surfactants, for either oral and topical use or parenteral and pulmonary administration, with reduced particle size, leading to an increased dissolution rate and therefore improved bioavailability." The average size of a particle is 200–600 nm. The solubility of solution velocity and saturation is increased by nanosized particles due to the vapour pressure effect. Additionally, as compared to a micronized product, the diffusional distance on the surface of drug nanoparticles is shortened, which results in a higher concentration gradient and a much more noticeable rise in the dissolution velocity. Since over 40% of medications are not well soluble in water, there are issues when manufacturing them in The vapor pressure effect allows for the expansion of the saturation solubility and solution velocity by nanosized particles. The drug's surface experiences a decrease in nanopartical in addition to diffusional distance, which amplifies the concentration gradient. The dissolving velocity increases in comparison to the micronized product due to the increased surface area and concentration gradient. By nano, we mean one billionth of a factor of 10-9. The following lists a few nanoscale comparisons. The diameter of one hydrogen atom is 0.1 nm. A DNA molecule's width is 2.5 nm. 1000 nm is one micron.
10-9m = 10-7cm = 10-6 mm is equal to 1 nm.
Micron: 10 – 6 m = 10 – 4 cm = 10 – 3 mm. In [3]
Polymers and surfactants created using appropriate techniques stabilize nanosized particles and enable their transport through multiple channels.

1.1.Necessity of nanosuspension :

The preparation of nanosuspensions is recommended for compounds with high log P values that are insoluble in water. When a drug is soluble in both organic and water media, nanosuspensions are utilized as a

formulation approach rather than lipidic systems, as they are most appropriate for drugs with high log P values, high melting points, and high doses.

2. Advantage of nanosuspension:

- It can be administered by any route and improves the solubility and bioavailability of substances.
- It is suitable for hydrophilic compounds and allows for higher drug loading and possible do
- se reduction.When administered subcutaneously or intramuscularly, less tissue irritation occurs.Via the IV approach, tissue targeting and rapid disintegration are possible.
- A possible alteration in the crystalline structure and increased solubility can result from increasing the amorphous fraction in the particles.
- possibility of large-scale manufacture

3.Disadvantage of nanosuspension :

- Compaction, sedimentation, and physical stability are problematic.
- Because it's heavy, handling and transportation require extra care.
- Incorrect dosage.
- It is impossible to obtain a precise and uniform dosage.

4.Formulation Consideration:

Following agent are used in the preparation of Nanosuspension

- Stabilizer
- chemic solvents
- Surfactant
- Co-surfactant
- Other additives.

4.1. Stabilizer :

In the absence of a suitable stabilizer, the high surface energy of nanoparticles may cause the drug crystals to aggregate or clump together. In order to produce a formulation that is physically stable, a stabilizer must first completely wet the drug particles and then provide steric or ionic barriers to prevent Ostwald's ripening and agglomeration of nanosuspensions. The physical stability and in-vivo behavior of nanosuspensions are significantly influenced by the kind and concentration of stabilizer.

Sometimes, to get a stable result, a combination of stabilizers is needed. The use of nanosuspensions Polysorbate (Tween/Span series), povidone, cellulose, poloxomers, and lecithin are examples of commonly used stabilizers.

4.2. Chemical Solvents :

When creating nanosuspensions with emulsions or microemulsions as templates, it is important to take into account the organic solvents' acceptance in the pharmaceutical industry, their potential for toxicity, and how simple it is to remove them from the formulation. In the formulation, it is preferable to use less hazardous and pharmacologically acceptable water-miscible solvents like ethanol and isopropanol as well as partially water-miscible solvents like triacetin, propylene carbonate, ethyl lactate, ethyl acetate, and ethyl formate rather than traditional hazardous solvents like dichloromethane.

4.3. Surfactants in Water :

The addition of surfactants to formulations enhances The dispersion by a decrease in interfacial tension.Additionally, surfactants have wetting or deflocculating properties. Tweens and Spans are common surfactants used in Small-scale suspension.

4.4. Co – surfactant :

When utilizing microemulsions to create nanosuspensions, the co-surfactant selection is crucial. The impact of co-surfactant on drug loading and internal phase uptake for certain microemulsion compositions should be studied, as it can significantly affect phase behavior. Various solubilizers, including transcutol, glycofurol, ethanol, and isopropanol, can be safely employed as co-surfactants in the formation of microemulsions, despite the literature describing the usage of bile salts and dipotassium glycocerrhizinate as co-surfactants.

4.5 Additional Additives :

Depending on the drug's characteristics or the mode of administration, nanosuspensions may include additives such buffers, salts, polyols, osmogent, and cryoprotectants.

5. The characteristics of nanosuspensions :

The qualities of nanosuspensions include the following: increased drug saturation solubility and dissolution velocity; passive targeting; crystalline state and particle morphology; internal structure of the nanosuspension; physical long-term stability; adhesiveness; and more.

5.1. Physical Stability over the Long Term :

The crystal development that results in the formation of microparticles in scattered systems is caused by Ostwald ripening, which causes physical instability. Large and tiny particles have different saturation solubility and dissolving velocities, which results in Ostwald ripening. Due to the homogeneous size of all the particles in nanosuspensions, Ostwald ripening is completely absent, meaning that there is little variation in the saturation solubility of drug particles.

5.2. The Internal Organization of Nanosuspensions:

Internal structural alterations in the drug particles are brought about by the high-energy input during the disintegration process. Particles in the medication undergo a change from crystalline to amorphous forms when subjected to high-pressure homogenization. The hardness of the medication, the quantity of homogenization cycles, the chemical makeup of the drug, and the power density applied by the homogenizer all affect the state change.

5.3. adhesiveness :

Compared to coarse powders, ultra-fine particles have more adhesiveness. Improved oral administration of poorly soluble drugs can be achieved by utilizing the adhesiveness of tiny drug nanoparticles.

5.4. Particle Morphology and Crystalline State :

Understanding the polymorphism or morphological changes that a medicine may experience when treated to nanosizing is made easier by evaluating the crystalline state and particle morphology jointly. High-pressure homogenization can cause nanosuspensions to undergo a change in their crystalline structure, which could lead to an amorphous form or other polymorphic forms .Differential scanning calorimetry can be used in addition to X-ray diffraction analysis to determine the changes in the drug particles' solid state and the amount of the amorphous portion. In Scanning electron microscopy is the method of choice for actually understanding particle morphology.

5.5. Increases in the Drug's Saturation Solubility and Dissolve Speed

The surface area of the drug particles increases from micrometer to nanoscale size, increasing the drug's dissolution. The Noyes-Whitney equation states that as particles get smaller—from microns to nanometers—the surface area increases and so does the rate of dissolution.

Dx/dt D x A / h Cs X / V = − □ □ ( ) [ ] □ □

Where; D is diffusion coefficient,

A is surface area of particle,

Dx/dt is the dissolution velocity,

V is volume of dissolution medium and
H is the thickness of the diffusion layer and X is the
Concentration in surrounding liquid.

5.6. The Passive Targeting of Nano Suspension :

Due to their inability to reach the intended site of action, the majority of medications have not produced the desired results. Administered drugs frequently cause severe side effects because a large portion of the drug is dispersed throughout normal tissues or organs that are not involved in the diseased process. A successful strategy to address this important problem with the creation of tailored medication delivery systems. Adjustability Because of their adaptability in terms of changing surface characteristics and particle size, as well as how simple it is to process nanosuspensions after manufacturing, they can be used in a variety of dosage forms, including tablets, pellets, suppositories, and hydrogels, for a range of administration routes.

6. Procedure for Setting Up Nasosuspension :

The following techniques are used to prepare nanosuspension: micro-milling of media; homogenization (Dissocubes); homogenization in non-aqueous media (Nanopure); combined homogenization and precipitation (Nanoedge); nanojet technology; emulsification-solvent evaporation techniques; hydrosol method; supercritical fluid method; precipitation technique; dry-co-grinding.

6.1. Milling of Media:

High-shear media mills or pearl mills are used to create nanosuspensions. A recirculation chamber, a milling shaft, and a milling chamber make up the mill. The medication is then put into a mill that has tiny grinding balls or pearls in an aqueous solution.Under controlled temperature, these balls rotate at a very fast shear rate. They fly through the interior of the grinding jar and strike the sample on the opposite grinding jar wall. A significant amount of
particle size reduction is produced by the interaction of the forces of impact and friction. The balls or milling media are composed of strongly cross-linked polystyrene resin with high abrasion resistance, zirconium oxide, or aluminum oxide sintered in ceramic media. One piece of machinery that can be utilized to accomplish this is a planetary ball mill.

6.1.1. Advantages :

• Low cost of the milling process
• Simple technology
• Somewhat likely large-scale production

6.1.2. Disadvantages :

• The possibility of product contamination due to erosion from the milling material.
• The length of the process is not particularly conducive to manufacturing.
• The potential for microbial growth during extended milling periods in the water phase.

Time and expenses related to the process of separating the medication nanoparticle suspension from the milling material, particularly when creating parenterally sterile goods

6.2. Normalization Dissipatives:

In order to homogenize, the suspension must be forced through a valve with a small aperture while under pressure. Dissocubes were created in 1999 by Muller and associates. Here the drug suspension is allowed to pass through a tiny opening, lowering the static pressure below the water's boiling point and causing the water to boil and gas bubbles to develop.

The surrounding area holding the drug particles rushes to the center as the suspension exits the gap and normal air pressure is restored. In the process, colloids are created, which reduces the particle size.The majority of cases necessitate several passes or cycles through the homogenizer; this is contingent upon the drug's hardness, the intended mean particle size, and the necessary homogeneity. An Ultra Turrax T25, IKA-Werke

GmbH& Co. KG, Staufen, Germany was used to disperse an aqueous suspension of atovaquone, and a Gaulin Micron Lab 40 high-pressured homogenizer was used to further homogenize the mixture. A atovaquone nanosuspension with a mean diameter of 279 ± 7 nm and a mean polydispersity index of 0.18 ± 0.001 was formed after the samples were subjected to pressures of 1.5 x 107 (two cycles), 5 x 107 (two cycles), and 1.5 x 108 (twenty cycles) Pa. In order to generate a nanosuspension with a greater solids concentration, homogenization should ideally begin with extremely tiny drug particles,

6.2.1. Advantage:

• Facilitates aseptic production; can be used for both concentrated and diluted solutions.

6.3. Nanopure: Homogenization in Non-Aqueous Media :

In other words, the drug suspensions in the non-aqueous medium were homogenized at 0°C or even below the freezing point & hence are called "deepfreeze" homogenization. Nanopure is suspension homogenized in water free media or water mixes. Because the results were similar to dissocubes, thermolabile substances can be used successfully in milder environments.

6.4. Nanoedge-Based Combined Precipitation and Homogenization :

The medication is dissolved in an organic solvent, and to facilitate precipitation, this solution is combined with a miscible anti-solvent. The medication has low solubility and precipitates in the water-solvent mixture. Additionally, high shear processing has been linked to precipitation. The fundamental ideas behind homogenization and precipitation also apply to nanoedge. Smaller particle sizes and improved stability are produced in a shorter amount of time when these strategies are combined.

6.5. The Technology of Nanojets :

Opposite stream technology is another name for nanojet technology. This method reduces the size of the particles by passing a stream of suspension that has been separated into two or more sections under high pressure and causing them to colloid with one another. This is made possible by the strong shear forces created during the process.

6.5.1.Advantages:

• You don't need specialized equipment

• The size of the emulsion droplet can be easily changed to control the particle size.

• Scaling up will be simple if the formulation is well tuned.

6.5.2. Disadvantages :

• This approach cannot be used to synthesize compounds that are weakly soluble in organic or aqueous environments.

• Safety issues resulting from the method's usage of potentially dangerous solvents.

• Diultrafiltration is required to purify the drug nanosuspension, which could make the procedure expensive.

• A high stabiliser/surfactant concentration is needed.

6.6. Techniques for Emulsification and Solvent Evaporation :

Using this procedure, a drug solution is made and then it is emulsified in a different liquid that isn't the drug's solvent. The medication precipitates as the solvent evaporates.

6.7. Hydrosol Approach :

The emulsification-solvent evaporation process and this are comparable. The drug solvent and drug anti-solvent are miscible, which is the only distinction between the two procedures. Increased shear force guarantees that the precipitates stay smaller in size by inhibiting crystal development and Ostwald ripening.

6.8: The Supercritical Fluid Technique :

Organic solvents pose a risk to human health and the environment when utilized in the production of traditional techniques such solvent extraction evaporation, solvent diffusion, and organic phase separation. Because supercritical fluids are harmless for the environment, they have been researched as a potential solution to the issue with the standard method for the manufacture of biodegradable micro and nanoparticles.

The three most popular methods for working with supercritical fluids are rapid expansion of supercritical solution (RESS), precipitation with compressed anti-solvent process (PCS), and supercritical anti-solvent (SAS).The liquid solvent used in the SAS process, such as methanol, is fully miscible with the supercritical fluid (SC CO2) and is used to dissolve the solute to be micronized. Because the solute is insoluble in the supercritical fluid, the extraction of the liquid solvent by the supercritical fluid causes the solute to precipitate instantaneously, which results in the formation of nanoparticles. The SAS technique was used to create griseofulvin and dexamethasone phosphate medication nanoparticles (for microencapsulation). Unlike the SAS process, the RESS method dissolves the solute in a supercritical fluid and quickly expands the solution through a tiny nozzle into a lower pressure area, resulting in a significant drop in the supercritical fluid's solvent power and eventual solute.

6.9. Technique for Precipitation :

Using this procedure, the medication is first added to an aqueous surfactant solution after being dissolved in a water-miscible organic solvent.Drug precipitation occurs when the drug's solubility in the water-solvent mixture decreases. In order to achieve successful outcomes, this approach has also been used with high pressure homogenization, or HPH. Such a technique forms the basis of the patented NanoEdge process of Becker International. Rapid addition of the drug solution to the anti-solvent causes the mixed solution to suddenly become super saturated, which in turn causes the formation of sub-micron colloidal particles. When the amorphous phase's solubility is surpassed, precipitation is frequently preferred at high super saturation.

6.10 Grind-De-Deep:

Without the need for organic solvents, dry-co grinding is a simple, cost-effective process. Co-grinding enhances the physicochemical characteristics and solubility of poorly water soluble pharmaceuticals by changing the drug's surface polarity and transforming it from a crystalline to an amorphous state.

6.10.1 Benefits :

- Simple procedure that doesn't need an organic solvent.
- Require little time to grind.
- Boost the drug's inability to dissolve in water

7.Evaluation Parameter :

- The Distribution mean of particle size
- Particle Charge (Zeta Potential)
- Crystal Morphology
- Saturation Solubility and Dissolution Velocity
- Surface Hydrophilicity
- Adhesion Properties
- Interaction With Body Proteins..

7.1. The Distribution and Mean of Particle Sizes :

The saturation solubility, dissolution rate, physical stability, and even in-vivo behavior of nanosuspensions are all impacted by the mean particle size and the span of the particle size distribution (polydispersity index, or PI). These are two crucial characteristic characteristics. Using coulter counter multiplexer, laser diffraction, and photon correlation spectroscopy (PCS), one may ascertain the particle size distribution. Even the width of the particle size distribution (polydispersity index, or PI) can be calculated using PCS. For nano suspensions to remain stable over the long term, the PI, a crucial parameter that controls the physical stability of the suspensions, should be kept as low as feasible. In contrast, a PI number larger than 0.5 denotes a relatively wide size distribution. A PI value between 0.1 and 0.25.

7.2. Zeta Potential Particle Charge :

Zeta potential provides details on the qualities of surface charges and, in addition, the long-term physical stability of the nanosuspension. The stability of the nano suspension is determined by particle charge. A zeta potential of at least ±30 mV is required for electrostatically stabilized nano suspension, while at least ± 20 mV is required for combined steric and electrostatic stability.

7.3 Crystal Morphology :

Techniques like differential scanning calorimetric or differential thermal analysis in conjunction with X-ray diffraction analysis can be used to quantify the polymorphic changes brought about by the impact of high-pressure homogenization in the drug's crystalline structure.

Differential scanning calorimetry is used in conjunction with X-ray diffraction analysis to determine the change in the drug particles' solid state and the amount of the amorphous portion. Scanning electron microscopy is the method of choice for actually understanding particle morphology.

7.4 Dissolution Velocity and Saturation Solubility:

One significant benefit of using nanosuspension over other methods is its ability to accelerate both the rate of dissolution and the saturation solubility. Compound-specific constant saturation solubility is influenced by temperature and the characteristics of the dissolution media. The Ostwald-Freundlich equations and the Kelvin equation can explain an increase in saturation solubility.

7.5 .pH :

In order to reduce "pH drift" and electro surface coating with suspended particles, the pH value of the aqueous formulation should be measured at a certain temperature and only after settling equilibrium has been attained. It is not recommended to add electrolyte to the formulation's exterior phase in order to stabilize the pH. I took a prepared nanosuspension.

7.6.Osmolarity :

Using an osmometer, one may determine the osmolarity of a nanosuspension. To ensure that the nanosuspension formulation is tested for osmolarity, the intravenous dosage form should be isoosmolar with the blood. Osmolarity was determined theoretically using the following formula and practically tested with an osmometer. Gm/lit of weight equals osmolarity (mOsmol). Total number of species * 1000 molecular weight * 100

7.7 Hydrophilicity of the Surface :

One of the key factors influencing the in vivo organ distribution following intravenous injection is surface hydrophilicity/hydrophobicity. The surface hydrophilicity controls the contact with cells before phagocytosis and is an important feature for plasma protein adsorption, which is essential for the dispersion of organs. The inaqueous dispersion media, which is the initial environment of the drug nanoparticles, is where the surface hydrophobicity must be specified in order to prevent artifacts. Hydrophobic interaction chromatography (HIC), which was first used to assess bacteria's surface hydrophobicity before being applied to the assessment of drug carriers that are nanoparticulate, is an appropriate method.

7.8.Adhesion Characteristics :

Male Wistar rats are employed in in vivo bioadhesive studies. Every animal is generally given a single oral dose of 1 milliliter of an aqueous suspension containing 10 milligrams of the drug-loaded nanoparticles (or around 45 mg particles/kg body weight). Cervical dislocation is used to sacrifice the animal one and three hours after administration. After the stomach, small intestine, and cecum are removed, the abdominal cavity is opened longitudinally along the mesentery, and phosphate saline buffer (pH 7.4) is used to cleanse the organs. Additionally, the cecum, small intestine, and stomach are divided into 2-centimeter segments and digested for 24 hours in an appropriate alkali. Medication was removed from the digested samples by adding two milliliters of methanol, vortexing for one minute, and centrifuging.

7.9. Interaction with Proteins in the Body :

By culturing mucin and nanoparticles (1:4 weight ratio) in either an acidic or neutral media, the in vitro interaction between the two substances can be investigated. The incubation process is run at 37°C with constant stirring. After centrifuging the dispersions, 150µl of each supernatant is transferred to a test plate. Following the addition of the 150µl Micro BCA Protein Assay Reagent Kit to the supernatants, the plate is incubated for two hours at 37°C. Through this process, colorimeters may quantify the mucin absorbance at the drug's λmax. The quantity of mucin that has been adsorbed to the nanoparticles can be calculated by subtracting its original concentration from the concentration that was detected in the

8. Pharmaceutical Applications of Nanosuspensions in Drug Delivery:

• Oral Drug administration
• Parental Drug administration
• eye care provision
•Supply of Pulmonary medicines
• Targeted Drug Deliver
• administration medicine Topically
• Mucoadhesion of The Nanoparticles
• Bioavailability Enhancement.

8.1.Oral Drug Administration :

Because of its many well-known benefits, the oral route is the recommended method for drug delivery. This issue is aptly reflected by oral antibiotics like atovaquone and bupravaquone. Such medications may exhibit a considerable increase in oral absorption and, consequently, bioavailability upon nanosizing. Compared to 44.7 mg/h/l for Naprosyn suspensions and 32.7 mg/h/l for anaprox tablets, the oral administration of naproxen nanoparticles results in an area under the curve (AUC) (0-24 h) of 97.5 mg/h/l. When taken orally as a nanosuspension, the gonadotropin inhibitor Danazol has an absolute bioavailability of 82.3, while the standard dispersion (Danocrine) only achieves 5.2%. When Amphotericin B was dissolved in water, a notable enhancement in its oral absorption occurred .

8.2: Parental Medicine Administration :

Different parenteral methods, including intraarticular, intraperitoneal, intravenous, etc., are used to give nanosuspensions. Furthermore, parenterally delivered medicines have greater efficacy when suspended in nanoparticles. There have been reports of superiority for paclitaxel nanosuspension in lowering the median tumor burden. In female mice infected with Mycobacterium avium, clofazimine nanosuspension demonstrated increased stability and efficacy over liposomal clofazimine.

8.3. Eye Care Provision :

Some medications don't dissolve well in lachrymal fluid. It will become more bioavailable and have a higher saturation solubility if it is prepared as nanoparticles. Used mostly with hydrophobic medications. The length of time spent in the cul de sac is increased. Ibuprofen is the greatest illustration of a nanosuspension. When compared to the aqueous formulation, ibuprofen's anti-inflammatory efficacy increased.

8.4: Supply of Pulmonary Medicines :

When it comes to administering medications that don't dissolve well in pulmonary secretions, nanosuspensions might be the best method. Mechanical or ultrasonic nebulizers can be used to nebulize aqueous nano suspensions for inhalation. A more even distribution of the medicine in the lungs is thought to result from the small size of the drug particles, which are probably contained in every aerosol droplet.

8.5. Targeted Delivery of Drugs :

If the infectious pathogen is still present intracellularly, targeted drug delivery can be employed to give anti-fungal, anti-mycobacterial, or anti-legitimacies medications to macrophages. An further strategy for the

targeted medication delivery system involves the use of different surface coatings for either passive or active targeting.in murine mice infected with toxoplasma gondii, atovaquone nanosuspension has enhanced therapeutic efficacy against toxoplasma encephalitis and has a high concentration in the brain, lungs, serum, and liver.

8.6. Administration of Medicine Topically :

It is possible to add drug nanoparticles to creams and water-free ointments. Increased saturation solubility of the drug in the topical dosage form due to the nanocrystalline forms improves the drug's diffusion into the skin

8.7.Mucoadhesion of the Nanoparticles :

Orally administered drug nanoparticles diffuse into liquid media through a nanosuspension and quickly come into contact with the mucosal surface. An adhesive mechanism known as "bioadhesion" immobilizes the particles at the gut surface. The concentrated dispersion now serves as a particle reservoir, and the adsorption process proceeds quickly. The initial stage prior to particle absorption involves the particles coming into direct touch with the intestinal cells via a bioadhesive phase. The nano suspensions' sticky properties aid in both better targeting of the parasites that are still present in the GIT and increased bioavailability.

8.8. Enhancement of Bioavailability :

Low solubility and low permeability across the membrane are the twin issues that nanosuspensions address in order to address the issue of poor bioavailability.A nanosuspension formulation was used to increase the bioavailability of poorly soluble oleanolic acid, a hepatoprotective drug. Higher bioavailability was demonstrated by the marked improvement in the therapeutic efficacy.

9. Conclusion

When it comes to delivering hydrophobic pharmaceuticals—that is, medications that are poorly soluble in both aqueous and organic media—nanosuspensions seem to offer a novel and yet economically feasible way to overcome issues like poor bioavailability. Production methods that have proven effective for producing Nano suspensions on a wide scale include media grinding and high pressure homogenization. Nano suspensions offer a wider range of applications because to their appealing properties, which include enhanced bioadhesivity, increased saturation solubility, increased velocity of dissolution, ease of post-production processing, and variety in surface modification. Applications for pulmonary and ocular distribution of nano suspensions have been realized, and their uses in parentral and oral routes have been thoroughly studied. Inadequate water solubility is quickly rising to the top obstacle.

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