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A Comprehensive Review on Nanosuspension-Based Formulations to Improve Oral Bioavailability of BCS Class II Drugs

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ABSTRACT: Poor aqueous solubility remains a major challenge in the formulation of many newly developed drugs, particularly those belonging to Bio pharmaceutics Classification System (BCS) Class II and IV, leading to low dissolution rates and reduced oral bioavailability. Nanosuspension technology has emerged as a promising and commercially viable approach to overcome these limitations by reducing drug particle size to the nanometer range, thereby increasing surface area and saturation solubility. Nanosuspensions are biphasic colloidal dispersions of submicron drug particles stabilized by suitable surfactants or polymers. This review highlights the fundamentals of nanosuspension technology, including its rationale, preparation methods such as bottom-up, top-down, and combinative approaches, and characterization techniques used to evaluate physicochemical and performance-related parameters. The advantages, limitations, and diverse pharmaceutical applications of nanosuspensions in oral, parenteral, pulmonary, ophthalmic, topical, and targeted drug delivery systems are discussed. Overall, nanosuspensions offer an effective strategy for enhancing the bioavailability of poorly soluble drugs and hold significant potential for future advancements in drug delivery.

KEYWORDS: Nanosuspension; Poor aqueous solubility; BCS Class II and IV drugs; Bioavailability enhancement; Particle size reduction.

I. INTRODUCTION

The development of novel drugs with surface areas and rates of dissolution between 200 and 600 nanometres has garnered more attention in the past ten years. Because of this characteristic, delivery techniques that use particulate carriers, such as nanoparticles [(7)]. A novel drug delivery method, nanoparticles can deliver therapeutic substances in a targeted and regulated manner [(21)]. Nanosuspensions have drawn a lot of attention among the various nanotechnology-based methods for improving the solubility and bioavailability of medications that are poorly soluble [(32)].Drug particles smaller than a micron are stabilised by surfactants to form biphasic colloidal dispersions known as nanosuspensions [(20)Generally speaking, the drug's particle size in nanosuspensions is particularly helpful for medications in Biopharmaceutical Classification System (BCS) Class II, such as Glibenclamide, which have a log P value of about 2 and poor solubility in both organic and aqueous solvents [(5)]. For these medications, the rate of dissolution is typically the limiting element in intestinal absorption, making their effectiveness highly reliant on the patient's size, shape, and physiological state, including whether they are fed or fasting [(24)The preparation of nanosuspensions is based on nanotechnology, which entails research and development at the atomic, molecular, or macromolecular levels, frequently below the sub-100 nanometre size range [(26)]. The National Nanotechnology Initiative (NNI) defines nanotechnology as the creation of materials, devices, and systems whose fundamental unique and beneficial properties result from the confinement of photons and their interactions with matter at the nanoscale [(16)]. Nanotechnology is still a developing multidisciplinary field with enormous promise to

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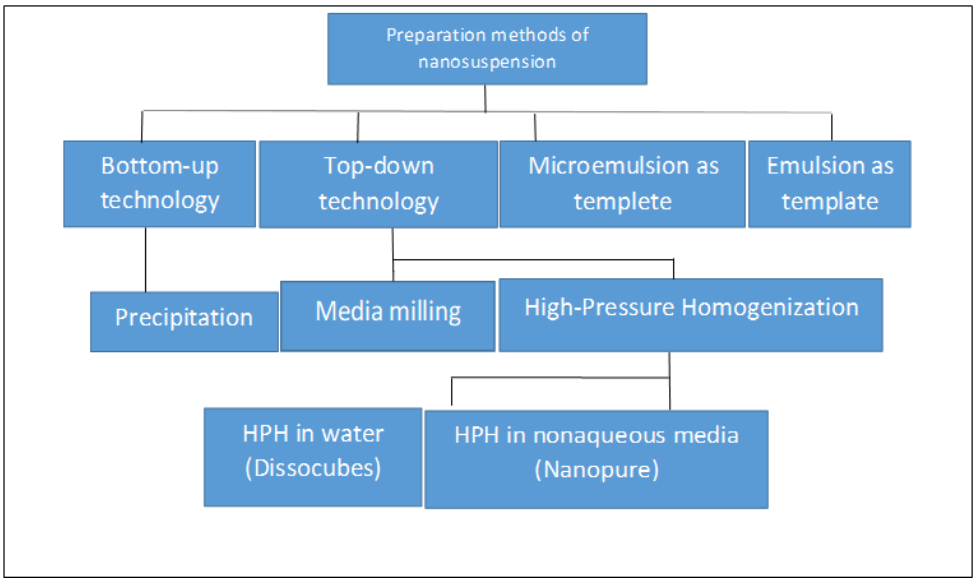
revolutionise medication administration through improved treatment efficacy, patient compliance, and overall clinical result, despite some difference in definitions between disciplines [2].

- 0.1nm = Diameter of one Hydrogen atom
- 2.5 nm = Width of a DNA molecule
- 1micron = 1000nm
- 1nm = 10-9m= 10-7cm = 10-6mm

Nano suspension technology is necessary since the majority of drugs that come from high screening are poorly soluble in water [25]. It is usually difficult to formulate drugs that are poorly soluble. Low bioavailability because of reduced absorption is one of the main issues related to them [32]. Nano suspension is a solution to these issues. Compounds having high log P values, high melting points, and high doses are best suited for the nanosuspension formulation method 15 [10]. Since a medication exists as pure solids, substantial drug loading can be accomplished and the administration volume of high dose 11 can be greatlydecreased [33]; Since they are in the solid form, nano suspensions can improve the physical and chemical stability of medications12,13. Lastly, they can offer passive targeting [1].

PREPARATION METHODS FOR NANOSUSPENSION

(Creation and characterisation of BCS class II and IV drug nanosuspensions using a combinative approach) (Expanding Nanosuspension Potential)Numerous techniques for creating nanosuspensions in the pharmaceutical sector have been developed by researchers in the field [1]. They can be broadly divided into three categories: top-down technology, bottom-up technology, and a hybrid that incorporates elements of both [33]. Furthermore, advanced study has produced effective preparation Some techniques for creating topical nanosuspensions for topically applying them include single methods or any combination of them, such as the "smart crystal" method, which combines high-pressure homogenisation (HPH) and wet milling. These techniques include supercritical fluid technology, an emulsification-solvent evaporation method, and a melt emulsification method [3]. The anti-solvent approach and HPH are two further ways to combine two techniques to create nanosuspensions [7].



Bottom-up technology

Anti-solvent precipitation: To cause precipitation and produce nanoparticles, a drug is dissolved in a solvent and then rapidly introduced to an antisolvent, which is a liquid the drug does not dissolve [27].

Solvent Evaporation: Nanoparticles are created when a medication is dissolved in an organic solvent, emulsified in a continuous phase, and the organic solvent evaporates [34].

Melt Emulsification: In order to promote quick lipid crystallisation and particle size reduction, a hot microemulsion (a blend of fatty acid, emulsifier, co-emulsifier, and water) is prepared and then dispersed in cold water while being stirred [2].

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Precipitation (Hydrosol)

The most used precipitation technique is the antisolvent addition approach, which involves dissolving the medication in an organic solvent and combining it with a miscible antisolvent [35]. The methods used for mixing differ greatly. High shear processing has also been linked to precipitation [28].The precipitation of friable materials for later fragmentation under high shear and/or thermal energy conditions is the basis of the NANOEDGE process, which is a registered brand of Baxter International Inc. and its subsidiaries [5].

Top-down technology

Media Milling: Coarse particles are homogenised in non-aqueous media (nanopure) or ground with a high-speed ball in a liquid medium: This is done in an organic or partially aqueous media at low temperatures (occasionally below freezing) for medications that are water-sensitive or thermolabile. Impact and attrition are used in media mills to reduce particle size [36].

High-Pressure Homogenization: Through a tiny opening, a liquid solution is exposed to extremely high pressure, causing the particles to disintegrate due to impact and shear forces.

Media Milling (Nanocrystals)

This technique was discovered in 1992 by Liversidge et al. It was initially patented by the "Nanosystems" group, and it has since been passed to "Elan drug delivery" [28].A high shear rate is used in this technique to minimise the particle size [37]. The entire process is carried out at a regulated temperature. Certain chemicals in the dosage form may deteriorate if the temperature increases excessively as a result of the high shear rate. This machinery is referred to as pearl mills or high-shear media milling [7]. The three primary parts of this mill are the recirculation chamber, the milling chamber, and the milling shaft [38].

High-Pressure Homogenization (HPH)

It is the most popular technique for creating nanosuspensions of numerous medications that are not very soluble in water (35–37) [29]. Dissocubes, Nanopure, Nanoedge, and Nanojet technology are some of the techniques for creating nanosuspensions that have been developed based on this idea [39]. A drug and surfactant suspension is forced through a high pressure homogenizer's nanosized aperture valve while it is under pressure using the high pressure homogenisation method [22]. This method's foundation is cavitation in the aqueous phase. The cavitation forces of the particles are significant enough to transform the drug microparticles into nanoparticles [11]. This method's drawbacks include the requirement for tiny sample particles prior to loading and the numerous homogenisation cycles needed (38–39 provides a graphic representation of the high-pressure homogenisation process) [40].

High-Pressure Homogenization in Water (Dissocubes)

R. H. Muller created the method, and DDS Gmbh obtained the first patent. Skype Pharmaceuticals later received the patent [10]. The APV Micron Lab 40 (APV Deutschland Gmbh, Lubeck, Germany) is a frequently used homogeniser [41]. Additionally, piston-gap homogenisers are another kind. Additionally, Avestin manufactures it. (Avestin Inc., Canada's Ottawa). Stansted (Stansted Fluid Power Ltd. Stansted, UK) is another [17]. High pressure, between 100 and 1500 bars, is the fundamental idea.We can readily transform micron-sized particles into nanoparticles under this pressure. Additionally, it requires particles in the micron range that are less than 25 micrometres, thus we must obtain the sample from a jet mill since it can reduce particle sizes to less than 25 micrometres [42]. HPH is a mechanical method that uses high pressure to break apart cells in a liquid media, reduce particle size, and produce stable emulsions. In the food sector, it is crucial [40].

Homogenization in non-aqueous media (nanopure)

This is done at low temperatures (occasionally below freezing) in an organic or partially aqueous media for thermolabile or water-sensitive medications [33].

Microemulsion as templete

Microemulsions, which are thermodynamically stable and isotropically transparent dispersions of two immiscible liquids, such water and oil, are stabilized by an interfacial layer of surfactant and co-surfactant[43]. This required making the microemulsion, combining it with the dug solution, and then evaluating the effectiveness of drug loading. The method of precipitation. Over the past ten years, precipitation has been employed to create submicron particles, especially for water-insoluble medications[44]. The drug is generally dissolved in a solvent first. Next, a miscible antisolvent is added to the solution while surfactants are present[35]. When a drug solution is

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added to the antisolvent (often water) more quickly, the drug in the combined solution becomes instantly supersaturated and forms ultrafine crystalline or amorphous drug solids. Nuclei creation and crystal development are the two phases. A high rate of nucleation but a low rate of growth is necessary to create a stable suspension with the smallest particle size[45]. Both rates are temperature-dependent; temperature optimization is possible since the ideal temperature for nucleation may be lower than that for crystal formation[42].

Emulsion as template

Nanosuspensions can also be created using these emulsions. Medications that were either insoluble in volatile organic solvents or just slightly soluble in water are prepared using this technique[29].This method uses an o/w emulsion system as a template, where the drug's solid nanoparticles are produced by solvent removal[46].

Drug Dissolution: The medicine that is poorly soluble in water is first dissolved in a volatile organic solvent that is immiscible with water, like ethyl acetate, methylene chloride, or chloroform[47].Using mechanical stirring, high-speed homogenization, or sonication, the organic phase is distributed into the aqueous phase that contains appropriate surfactants and stabilizers to create an o/w emulsion. The potential size of the final drug particles is directly determined by the size of the emulsion droplets [50].

Solvent Evaporation: Usually at low pressure or with constant magnetic stirring at room temperature, the organic solvent quickly evaporates from the emulsions[46].

Evaluation

Testing a nanosuspension's physical and chemical characteristics to verify stability, solubility, and enhanced drug release is known as characterization[8] [20]. Particle size and size distribution, zeta potential, saturation solubility, entrapment efficiency, drug content, and in-vitro dissolution are the main evaluation factors[32].To ascertain these values, analytical techniques including UV spectrophotometry, transmission electron microscopy (TEM), and dynamic light scattering are used[52].

Physical and chemical examination

Particle Size and Polydispersity Index (PDI): Assesses the size of the nanoparticles, typically by the use of digital microscopes, photon correlation spectroscopy, or laser diffraction[53].

The uniformity of the particle size distribution is indicated by the PDI. In most cases, smaller sizes and PDI values are preferred[53].

Zeta Potential: determines the electric charge at the particle's surface and serves as a crucial physical stability indicator[55]. A high zeta potential (e.g., >\(30\text{\ mV}\)) indicates good physical stability.

Morphology: The form and surface properties of the nanoparticles are determined using scanning electron microscopy (SEM) and transmission electron microscopy (TEM)[46].

Performance-related evaluation

Saturation Solubility: determines the maximum amount of medication that can dissolve in the solution[17]. Since the particles in nanosuspensions are smaller than those in pure drugs, they typically show greater solubility [29].

In-vitro Dissolution Rate: determines the rate at which the medication dissolves in the aqueous media from the nanosuspension. Higher dissolution rates are a prime objective, as they result in better bioavailability [13].

Stability Studies: To assess their long-term stability, nanosuspensions are commonly kept at regulated temperatures and humidity levels (accelerated stability tests, for example), with time-series monitoring for changes in particle size, drug content, and other parameters[54].

Drug Content/Entrapment Efficiency: Determines how much medication is successfully captured in the nanosuspension [29]. This is often assessed following centrifugation to remove free drug, and the concentration of remaining medication is quantified using the supernatant [51].

II. APPLICATION

Parenteral delivery of the drug:

The drug's nanocrystals must be produced aseptically in order to comply with the obviously more stringent regulations [17].

Alternatively, autoclaving or gamma radiation and sterile filtration can be used to sterilize nanosuspensions[20]. Omeprazole nanosuspension should be administered intravenously to prevent oral omeprazole from undergoing chemical breakdown. Compared to conventional solubilization techniques like surfactants, cyclodextrins, etc., the bioavailability of medicines with poor solubility, such as tarazepide, is improved in the nanosuspension state [8]. Potential benefits include tissue targeting, quick

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breakdown, and a longer stay in the systemic circulation [48].

Pulmonary Drug Delivery:

Commercial nebulizers can be used to nebulize the drug's nanosuspension. The size distribution of the generated aerosol droplets can be used to control lung disposition [56]. Because of their high mucoadhesiveness, drug nanocrystals stay on the lung's mucosal surface for a longer period of time. Hernandez-Trejo and colleagues created physically stable nanosuspensions to nebulize Bupravaquone at the lung infection site [5].

Ophthalmic Drug Delivery:

For the ocular administration of hydrophobic medications, nanosuspension achieves saturation solubility in the lachrymal fluid. A long residual time in cul-de-sac was demonstrated by the drug particles in nanoscale form, resulting in a prolonged release of the drug. Increased absorption, reduced discomfort, and more reliable dosage [38].

Oral drug delivery:

Potential advantages include quick dissolving, high bioavailability, and a lower fed/fasted ratio[49].

Subcutaneous and intramuscular:

Increased bioavailability Quick onset and less tissue irritation [7].

Target Drug Delivery:

Future targeted drug delivery systems will be stealth nanosuspensions designed with various surface coatings to target the place of interest either actively or passively [20]. Nanosuspensions offer a way to transfer poorly soluble medications to the brain with fewer adverse effects [8]. For example, surface-modified polyisobutyl cyanoacrylate nanoparticles were successfully used to deliver the peptide Dalargin to the brain [31].

Topical Formulations:

Additionally, water-free ointments and creams that have a higher saturation solubility and better drug absorption into the skin can incorporate drug nanoparticles[6]. Creams and water-free ointments can also contain drug nanoparticles [30]. The drug's saturation solubility in the topical dose form is increased by the nanocrystalline form, which enhances the drug's skin diffusion [1].

III. CONCLUSION

A novel and practical way to deal with hydrophobic drug issues including limited solubility and low bioavailability is using nanosuspensions [29]. High-pressure homogenization technology and media milling have been effectively used in the large-scale manufacturing of nanosuspensions. The applications of nanosuspensions for drug delivery by many routes of administration have increased due to their impressive properties, which include improved dissolution rate, improved saturation solubility, improved bioadhesivity, surface modification adaptability, and easy postproduction processing. Nanosuspensions have well-established applications in oral and parenteral routes; nevertheless, their potential for usage in pulmonary and ocular delivery has to be evaluated. However, it is still necessary to administer them topically, nasally, and buccally [5].

SOME OF THE ADVANAGES FROM THE ABOVE RESULTS

a) Enhance the solubility and bioavailability of drugs
b) Suitable for hydrophilic drugs
c) Higher drug loading can be achieved
d) Dose reduction is possible
e) Enhance the physical and chemical stability of drugs
f) Provides a passive drug targeting [5]

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