

# Parenteral formulations that use cyclodextrin as a delivery mechanism: A review and update

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### ABSTRACT

In clinical practice, parenteral formulations are essential and frequently the only way to provide medications that cannot be administered by other channels, such as proteins and some anticancer medications, which are essential to treat some of the most common chronic diseases in the world (like diabetes and cancer). Additionally, because they are the only ones that deliver a drug's immediate action after injection, parenteral formulations are important in emergency care. However, because of the unique quality and safety standards established for these preparations as well as the inherent characteristics of the medications, developing parenteral formulations is a challenging undertaking. One of the

most favorable methods for creating parenteral formulates been found to be the production of water-soluble host-guest inclusion complexes with Cyclodextrins (CDs). A number of compounds, especially medicines, can form water-soluble host-guest inclusion complexes with CDs, which increase their apparent water-solubility, chemical stability, and bioavailability and making them appropriate for parenteral administration. Additionally, CDs can be used as the foundation for more sophisticated injectable drug delivery systems with improved properties, like supramolecular hydrogels and nanoparticles, which have been demonstrated to be particularly effective for the administration of anticancer medicines.

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### INTRODUCTION

The market for parenteral pharmaceuticals, which is expected to reach a value of \$451 billion in 2019, is showing signs of expansion as the percentage of parenteral drugs approved as new molecular entities has increased to values of about 40% in recent years. The rise in the number of biologic medications that need parenteral administration, such as monoclonal antibodies, is mostly to blame for the parenteral drug market's expansion. A substantial component of the parenteral drug industry is made up of biological medications, which are used to treat some of the most common chronic conditions, including diabetes and cancer. Total parenteral drug sales have increased as a result of the rise of generic versions of medications and the appearance of multiple companies in the market as a result of the patent expiration of branded pharmaceuticals and fewer new product launches. Therefore, it is anticipated that the parenteral medication market would continue to expand in the

future. Parenteral formulations are an excellent tool for medication administration in a variety of situations, but creating them is a difficult task with many challenges. The drug's low water-solubility and stability in aqueous formulations, which are necessary to ensure biocompatibility with bodily fluids, are the most frequent issues when producing parenteral formulations. It is essential to find a safe and efficient solution to these problems, and Cyclodextrins (CDs) have been identified as an exceptional instrument for the task. A wide variety of hydrophobic medicines or their lipophilic moieties can form water-soluble drug-CD inclusion complexes with CDs, which have the ability to increase the apparent water-solubility and stability of these compounds in aqueous preparations like parenteral formulations. Additionally, CDs can self-assemble and interact with other polymers to create more sophisticated and effective injectable drug delivery systems, such as CD-based supramolecular hydrogels and CD-based Nanoparticles (NPs). CDs have long been a

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component of parenteral formulations; nevertheless, recently, their utilization in these formulations has increased. This phenomenon is primarily attributable to the commercialization of cyclodextrin derivatives with patent protection that can be administered parenterally and that are made with a high level of purity for use in the pharmaceutical industry, such as SulfoButylether-Cyclodextrin (SBE-CD), which is sold under the trade names Captisol® and Dexolve®. Along with the recently released monograph of SBE-CD (in 2019), the European Pharmacopoeia also contains monographs for alpha-, beta-, and 2-HydroxyPropyl-Cyclodextrin (HP-CD), making them recognized and certified pharmaceutical excipients by regulatory agencies. In light of these facts and the development of the parenteral medication industry, CDs may end up becoming the go-to solution for parenteral formulation development issues. This review article will therefore concentrate on the outstanding CD applications for improving parenteral formulations, including both small molecule drugs and biological products. These applications include both free CD applications as well as their incorporation into intelligent, multifunctional CD-based delivery systems. Our current work explores clinical trials as well as the regulatory issues surrounding goods that incorporate CDs, critically enhancing earlier material on this important topic of the pharmaceutical industry.

#### **Parenteral preparations: Advantages and disadvantages**

Parenteral medication preparations are dose forms designed for administration by a method that bypasses the digestive system. Parenteral formulations are sterile substances meant to be infused, implanted, or administered via injection into the body. These medications are typically injected Intravenously (IV), Subcutaneously (SC), or Intramuscularly (IM) to distribute them directly into the

bloodstream. The intrathecal route (for administration into the cerebrospinal fluid), the intra-articular route (for administration into the synovial cavity), the Intratumoral (IT) and Peritumoral (PT) injection (for administration, respectively, into the tumor and their periphery), among others, may be considered for specific drug delivery.

Parenteral formulations must adhere to stringent quality standards since they bypass the body's primary defenses (skin and mucous membranes) by being delivered directly into body tissues or fluids. In addition to being sterile, parenteral formulations must be isotonic, chemically and physically stable, and free of pyrogens (endotoxins) and visible particulates. Depending on the route of administration, the limits for particle contamination may range, being more lenient for the SC and IM routes and tougher for the IV route. Depending on the intended route of administration, parenteral formulations can be delivered in a variety of dosage forms but are often aqueous solutions. For instance, solutions and microemulsions are more frequently utilized for IV administration than suspensions, which are better suited for SC and IM administration due to the possibility of capillary occlusion by insoluble particles. To enhance or maintain the quality of these preparations, excipients may be required, such as vehicles, co-solvents, preservatives (especially in multi-dose preparations), antioxidants, surfactants, chelating agents, inert gases, and complexing agents. Injections, infusions, concentrates for injection or infusion, powders for injection or IV infusion, gels for injection, and implants are only a few examples of the different types of parenteral dosage forms. The capacity of parenteral formulations to bypass the gastrointestinal tract, as opposed to other formulations, particularly oral preparations, allows for a superior drug bioavailability.