

## Toxicology and Biocompatibility of Solid Lipid Nanoparticles

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### Abstract

Development of Solid Lipid Nanoparticles (SLNs) presents a highly effective nanocarrier system in drug delivery, diagnostic, cosmetic, and nutraceutical applications because of its special properties, such as controlled release, high biocompatibility and scalability. Although they have some benefits and are widely accepted as safe, their growing commercialization and biological exposure elevates the importance of the overall assessment of their toxicological profiles. This chapter gives a detailed discussion of the forces affecting SLN safety such as lipid composition, type and concentration of surfactant, particle size, surface charge, crystallinity, and degradation products. The major pathways of SLN toxicity, including oxidative stress, membrane damage, inflammation, and mitochondrial dysfunction, are discussed in reference to the results *in vitro* and *in vivo*. The chapter also explains the biocompatibility tests, regulatory aspects, and standard test methods that would be important in the provision of safe biomedical translation. The existing

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issues, gaps in knowledge, and future opportunities to develop safer and next-generation SLN systems are also indicated.

**Keywords:** Solid lipid nanoparticles, nanotoxicology, biocompatibility, drug delivery systems, lipid-based nanocarriers, cytotoxicity, oxidative stress, surface properties, biodistribution, safety assessment, *in vitro* toxicity, *in vivo* toxicity, regulatory considerations, nanomedicine.

## 1. INTRODUCTION

Solid lipid nanoparticles serve as colloidal drug delivery systems that have attracted a lot of attention because of their biocompatibility and capacity to improve bioavailability of drugs and targeted drug delivery [1]. These nanoparticles are made of physiological lipids and make the nanoparticles less toxic compared to synthetic carriers and has the ability to entrap both hydrophilic and lipophilic drugs [2,3]. Their main strength is in the fact that they consist of excipients already approved to be used by people, and the safety issue is reduced as compared to systems that use new materials [4]. Nevertheless, even though they appear to be safe, a thorough realization of the toxicological profile of SLNs, particularly in relation to their long-term outcome and their interactions with biological systems is essential before extensive clinical use can be implemented [5]. This requires stringent preclinical testing including acute and chronic toxicity, genotoxicity, hematotoxicity and immunogenicity tests to complete the safety profile description and assure regulatory compliance [4].

### 1.1 Introduction on solid lipid nanoparticles.

In this section, the nature, types and the overall importance of solid lipid nanoparticles used in the field of pharmaceutical research shall be explored [6]. Solid lipid nanoparticles: solid lipid nanoparticles, also known as solid lipid nanoparticle (SLNPs), are an alternative to conventional colloidal systems such as emulsions and liposomes, integrating the benefits and reducing the demerits [7]. The biocompatible lipid-based submicron particles which are stable by