Preparation and different sterilization approaches for Nanostructured Lipid Carriers (NLC): Towards industrial production

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Statement of the Problem: The transition of the production process of lipid nanoparticles from laboratory scale to industry could be difficult. Firstly, when manufacturing lipid nanoparticles, i.e. Nanostructured Lipid Carriers (NLC), it is important to obtain a homogeneous particle size. Secondly, for sterile products, aseptic manufacturing production is required, which implies high costs (class A clean rooms, qualified personnel) and a tedious process validation. To tackle these problems, High Pressure Homogeniser (HPH) could be a feasible equipment suitable for homogeneous industrial production of NLC (1) and, γ-radiation could fulfill sterilisation requirements when carried out as a final sterilisation method (2). The purposes of this study are: (i) to optimise the scaling-up of NLC production by using HPH and (ii) to demonstrate the suitability of γ-radiation as a simple and fast final sterilisation method, maintaining chemical and physical integrity of the loaded drug. Methodology: NLC were produced using the melt-emulsification method (3) including a homogenisation step by using the GEA PANDA HPH (Niro Soavi, USA) at 500 and 1,000 Bar pressure conditions (and 0, 3, 7 and 10 number of cycles. The homogenised emulsions were collected, lyophilised and obtained NLC were irradiated with a dose of 25kGy from 60Co following the European Pharmacopeia recommendations (4). The resulting NLC were then characterised in size, Poly Dispersity Index (PDI) and zeta potential. The drug release profile and chirality were also analysed before and after γ-sterilisation by circular dichroism. Findings: The increase on the number of cycles resulted in a lower particle size and PDI; and 500 Bar were enough to obtain monodisperse samples (Figure 1). Size, PDI, zeta potential, release profile and chirality were not affected by γ-radiation. Conclusion & Significance: HPH and final γ-radiation may be useful to produce NLC in an easy and cost-effective manner at industrial scale.

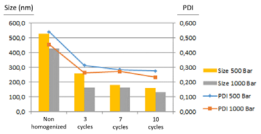

Figure 1. Size (nm) and PDI of nanostructured lipid carriers (NLC) at different pressure conditions (500 and 1000 Bar).

Biography

Claudia Vairo has completed his Degree in Pharmacy (2012) from University of Salerno and a Second level master's in pharmacology from University of the Basque Country (2015). She works as R+D researcher in BioPraxis Research AIE pharmaceutical company and she is completing her PhD studies in Pharmaceutical Technology, in collaboration with NanoBioCel Group from University of the Basque Country. She has published 2 papers in reputed journals concerning medical devices, such as lipid nanoparticles, especially nanostructured lipid carrier (NLC), and gelatin scaffolds, for the treatment of wound healing. Her investigation is recently focused on NLC nanosafety.

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