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Needle-free injection of vesicular phospholipid gels – a novel approach to overcome an administration hurdle for semisolid depot systems

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#### ACCEPTED MANUSCRIPT

Needle-free injection of vesicular phospholipid gels – a novel approach to overcome an administration hurdle for semisolid depot systems.

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#### **Abstract**

Vesicular phospholipid gels (VPGs) are depot formulations for the sustained release of drugs which are characterized by a high amount of phospholipids in the formulation. They consist of physiological excipients only and therefore display high biocompatibility. Their manufacture is simple, cheap, solvent free and ideal for the processing of proteins and peptides because of the low stress on the molecule e.g. by elevated temperatures. One major hurdle of VPGs is their high viscosity which makes them hard to almost impossible to inject with conventional, thin needles used for subcutaneous administration. However, so far no data is published to overcome this administration challenge. In the present study, needle-free injection (NFI) was investigated and successfully applied as a technology for the easy and elegant administration of VPGs. VPGs with different phospholipid content were injected with a Biojector 2000 into gelatin blocks and full thickness pig skin post mortem as in vitro models and the injection depth was determined after injection. The release behavior was tested after shearing the VPG with the device to evaluate the effect of shearing on the drug release from the formulation. No differences were observed when compared to an ejection with needle and syringe.

## **Keywords**

Vesicular phospholipid gels; needle-free injection; gelatin soft skin model; post mortem injection; sustained release; erythropoietin

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