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## Abstract

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*Eur J Pharm Biopharm.* 2014 Feb;86(2):167-77. doi: 10.1016/j.ejpb.2013.04.001. Epub 2013 May 2.

## In vivo toxicological evaluation of polymeric nanocapsules after intradermal administration.

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### Abstract

Polymeric nanocarriers have shown great promise as delivery systems. An alternative strategy has been to explore new delivery routes, such as intradermal (i.d.), that can be used for vaccines and patch-based drug delivery. Despite their many advantages, there are few toxicity studies, especially in vivo. We report a safety assessment of biodegradable poly( $\epsilon$ -caprolactone) lipid-core nanocapsules (LNC) with a mean size of  $245 \pm 10$  nm following single and repeated intradermal injections to Wistar rats. Suspensions were prepared by interfacial deposition of polymer. The animals ( $n=6$ /group) received a single-dose of saline solution (1.2 ml/kg) or LNC ( $7.2 \times 10^{12}$  LNC/kg), or repeated-doses of two controls, saline solution or Tween 80 (0.9 ml/kg), or three different concentrations of LNC (1.8, 3.6, and  $5.4 \times 10^{12}$  LNC/kg) for 28 consecutive days. Clinical and physiological signs and mortality were observed. Samples of urine, blood, and tissue were used to perform toxicological evaluation. There were no clinical signs of toxicity or mortality, but there was a slight decrease in the relative body weights in the Tween 80-treated group ( $p < 0.01$ ) after repeated administration. No histopathological alterations were observed in tissues or significant changes in blood and urinary biomarkers for tissue damage. Mild alterations in white blood cells count with increases in granulocytes in the Tween-80 group ( $p < 0.05$ ) were found. Genotoxicity was evaluated through the comet assay, and no statistical difference was observed among the groups. Therefore, we conclude that, under the conditions of these experiments, biodegradable LNC did not present appreciable toxicity after 28 consecutive days of intradermal administration and is promising for its future application in vaccines and patch-based devices for enhancing the delivery of drugs.

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**KEYWORDS:** Biodegradable nanocapsule; Genotoxicity; Nanotoxicology; Poly-( $\epsilon$ -caprolactone); Repeated-dose treatment; Single-dose treatment; Tween 80

PMID: 23643792 [PubMed - indexed for MEDLINE]

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