

Development of an extraction method for the quantification of docetaxel loaded in PLGA nanoparticles

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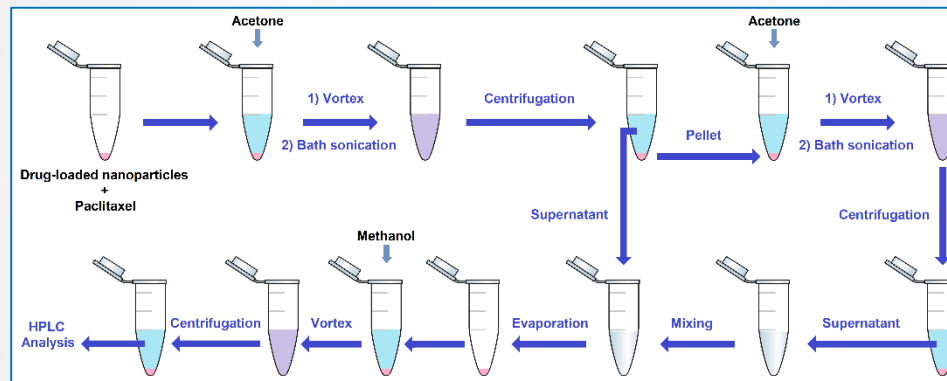
Purpose:

A critically essential step in the development of any drug-loaded nanoparticle formulation is the determination of the loading parameters [1]. Quantification might become feasible by the application of an extraction method. The purpose of this study is to develop an efficient extraction method to be used for the quantification of docetaxel in PLGA nanoparticles.

Methods:

PLGA nanoparticles were prepared using a solvent evaporation technique [2]. The extraction process was initiated by adding paclitaxel as the internal standard, and subsequent addition of acetone to the drug-loaded or drug-spiked nanoparticles to dissolve both the polymer and the drug. The obtained mixture was vigorously shaken and subsequently subjected to bath sonication. After centrifugation, the supernatant was separated and transferred to new Eppendorf tubes.

The same procedure was repeated by dissolving the precipitate in acetone. The collected supernatants from the first and the second centrifugation steps were mixed and evaporated. Methanol was added to the residue and vortexed for one minute followed by another centrifugation step. The supernatant was transferred to HPLC vials for quantification. Encapsulation efficiency, drug loading percentage, extraction efficiency, and extraction recovery percentage were determined to assess the effectiveness of the developed method.



Results:

The results showed that the extraction process was able to meet the criteria of the Food and Drug Administration (FDA) guidelines.

Moreover, the developed method was able to quantify docetaxel in the PLGA nanoparticle (mean size 170.2 ± 4.2 nm) matrix at a concentration as low as 15.6 ng/ml.

The encapsulation efficiency was calculated to be 40.83%. The drug loading percentage was 4.54% and the extraction efficiency was calculated to be 60%.

References:

1. Ganesan P, et al. *Sustain Chem Pharm.* 2017;6:37-56.
2. Rafiei P, et al. *Am J Anal Chem.* 2015; 6:164–175.

Conclusions:

The developed method of extraction of docetaxel was efficient in terms of providing an adequate lower limit of quantification (LLOQ) as well as recovering the analyte to a suitable percentage. We believe that the promising results are due to the use of acetone and methanol. Acetone dissolves both PLGA and docetaxel, while methanol efficiently dissolves the drug only.

The solvent evaporation method used to prepare the nanoparticles provided proper size of the particles and a proper loading percentage to make further *in vivo* studies possible.

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