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### **QbD development of a liposomal co-formulation with Doxorubicin and Simvastatin for an enhanced antiproliferative effect on T47D-KBluc cell line**

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The aim of the research was to develop a liposomal co-formulation with doxorubicin (DOX) and simvastatin (SIM). DOX is known for its high toxicity and thus, its association with a compound that also presents antiproliferative properties, like SIM, was explored in order to obtain a synergic/ additive effect.

The Quality by Design (QbD) concept was applied for liposomes development to get a better understanding of how the selected formulation factors and process parameters (PPs) can influence the quality attributes (QAs) of the liposomes. In accordance with this, risk assessment was performed and hence, three formulation factors and two PPs were selected to be studied in a screening experimental design. The results showed that all three formulation factors, namely phospholipids, DOX and SIM concentration, had a great influence on the liposomes QAs like encapsulated drug concentration and encapsulation efficiency (EE%). As regards the PPs, only the pH of the ammonium sulphate solution was pointed out to have a slight influence on DOX EE%.

Considering the results from the screening study, the optimization process was performed by means of a design of experiments with the aim of obtaining a design space and an optimal formulation which fulfils all our requirements.

The antiproliferative effects of the combined administration of SIM and DOX was studied on T47D-KBluc breast cancer cell line, indicating a strong inhibitory activity.

In conclusion, the co-administration of DOX and SIM in a liposomal formulation is a promising solution to inhibit the proliferation of T47D-KBluc breast cancer cells.

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