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Hollow calcium carbonate nanoparticles as pH-sensitive targeted delivery carriers in cancer therapy

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pH sensitive drug delivery systems can achieve targeted drug delivery and systemic control release. The studies in this area have been increased in recent years and more attention has been devoted to develop new methods for the preparation of new drug delivery systems especially in cancer therapy. Among the metal based anti-cancer drugs, copper complexes have shown remarkable potential in cancer therapy. Therefore, the aim of this study is to synthesize a pH-sensitive calcium carbonate-encapsulated copper bis-(8-hydroxyquinoline) anti-cancer drug delivery system starting from naturally occurring dolomite. In this novel research, first, copper bis-(8-hydroxyquinoline) is synthesized using copper(II) chloride dihydrate and 8-hydroxyquinoline as the reactants. The drug was loaded to the preformed hollow structures of precipitated calcium carbonate (PCC) by physisorption method. Hollow structures of PCC were suspended in prepared solution of Copper bis-(8-hydroxyquinoline) dissolved in Dimethylformamide (DMF). It was moderately stirred for five days. PCC products were collected by centrifugation followed by washing with acetone to remove the DMF. The obtained product was characterized using XRD, XRF and FTIR studies. XRD and FTIR studies revealed that copper bis-(8-hydroxyqunoline) incorporated inside the CaCO3 hollow PCC product. The release of drug is monitored in vitro in the pH values of 2.0, 4.0, 6.0 and 8.0. According to results, within first four hours, the cumulative release shows 100% in pH 2 and pH 4. However, no release is observed in pH 8 for 120 hours. Therefore, it is a good indication that the encapsulated drug releases at the pH trigger point. pH differences can be found at the subcellular level, late endosomes and lysosomes have much lower pH, in the range 4.5–5.5 . Due to high rate of glycolysis, tumors exhibit pH value 5.7 while the pH value of normal tissue is 7.4. This pH gradient is very important in internalization of drugs. Therefore this has potential applications in effective cancer therapy.

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Formulation design and development of solid self-micro-emulsifying drug delivery system (S-SMEDDS) for Bosentan monohydrate

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Liquid self-emulsifying system is prepared by employing Quality by Design (QbD) using D-optimal mixture design. Solubility of bosentan monohydrate is determined in long chain and medium chain triglycerides, surfactants and co-surfactants. Optimal mixture design is used for setting various levels of constraints for the excipient concentrations in preparing liquid SMEDDS and response surfaces such as globule size, polydispersity index, dissolution efficiency and time for 85% drug release (t85%) are evaluated. Optimized batch containing bosentan monohydrate 62.5 mg, capmul MCM (10.38%), labrasol/cremophor EL 1:1 (56.0%), transcutol P (33.62%) is predicted by the design which is validated by droplet size, PDI, dissolution efficiency and t85% . Solid powder form is prepared by adsorbing liquid SMEDDS onto solid carrier material neusilin US2. *In vitro* dissolution studies, comparative dissolution profiles of prepared solid SMEDDS and marketed preparation 'BOSENTAS' are carried out and reported. Ex vivo permeation study using chicken intestine showed improved permeability up to 0.0649 µg/cm2/min. Droplet morphology and solid state characteristics are determined using TEM, XRD and SEM. Zeta potential of the system was found to be -1.89 mV. Reconstituted S-SMEDDS had droplet size of 77.97 nm compared to liquid SMEDDS droplet size which was 47.00 nm. TEM images revealed the spherical shape and least globule size while XRD peaks reveal the transformation of crystalline polymorph A2 state of drug to amorphous state in S-SMEDDS. SEM images validate the integrity in shape. This study demonstrates a strategic way for development of S-SMEDDS for a drug with low solubility by QbD approach.

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