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(57) Abstract :

The present invention relates to controlled-release microsphere composition comprising fluvastatin or a salt thereof having a bilayer shell structure comprising an outer polymer layer and an inner layer, and a core comprising the fluvastatin or a salt thereof, wherein the microspheres have a mean size diameter in a range from 100 um to 500 um; and wherein, the drug to polymer ratio is in the range of 1:1 to 1:5. The present invention also relates to optimization of the process for preparation of controlled-release microsphere by response surface methodology such that high entrapment efficiency and high yield of the microspheres is obtained.



FIGURE 1

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