

Compounding and stability evaluation of atorvastatin extemporaneous oral suspension using tablets or pure powder

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Abstract:

Background Statins are the first-line therapy for lowering high lipid levels. Atorvastatin calcium (AtC) is the most commonly prescribed statin. It inhibits 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase which converts HMG-CoA into mevalonic acid, a cholesterol precursor.

Objective To compound and evaluate the stability of AtC suspension (0.4% w/v) using commercial tablets or pure AtC powder as the source of the active pharmaceutical ingredient.

Method Several AtC suspension formulations were produced using commercial AtC tablets or AtC pure powder as the source of the active ingredient. The most suitable one in terms of general organoleptic properties and dissolution was selected for stability studies. For this purpose, samples of final suspensions were stored at room temperature and in the refrigerator. Assay, pH, organoleptic properties and microbial contamination were evaluated according to the USP specifications. High performance liquid chromatography was used for the analysis and quantification of AtC in the studied samples.

Results The obtained suspension (S₄) had good organoleptic properties. It showed complete dissolution of AtC within 30 min. However, the suspension prepared from crushed tablet (S_{t4}) showed a better dissolution profile than that prepared from pure powder (S_{p4}). The prepared formula had unchanged pH, which remained around 9.9. S_t and S_p formulas were both free from microbial contamination. Both products showed good stability within at least the period of use of the 100 mL AtC bottles.

Conclusions AtC extemporaneous suspension was successfully prepared using tablets as a source of AtC or pure AtC powder. However, S_{t4} had a better dissolution profile than S_{p4}. This study provides a solution for patients with swallowing difficulties or feeding tubes who are unable to take medicines in solid oral dosage forms. Community pharmacists can prepare the suspension using AtC tablets as the source of the active ingredient.