

PENGARUH SUHU DAN KELEMBABAN TERHADAP STABILITAS KOKRISTAL KALSIMUM ATORVASTATIN

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ABSTRAK

PENGARUH SUHU DAN KELEMBABAN TERHADAP STABILITAS KOKRISTAL KALSIMUM ATORVASTATIN. Kalsium atorvastatin adalah obat golongan statin sebagai inhibitor kompetitif selektif enzim HMG-KoA (hidroksi metil glutaryl koenzim A) reduktase, yang secara luas digunakan untuk pengobatan hiperkolesterolemia dan pencegahan penyakit kardiovaskular. Kalsium atorvastatin, yang memiliki kelarutan rendah dan permeabilitas tinggi. Hal ini berakibat pada menurunnya laju disolusi dan ketersediaan hayatinya. Untuk meningkatkan kelarutannya adalah dengan modifikasi kristal melalui kokristalisasi. Selain itu, kalsium atorvastatin sangat rentan terhadap panas, kelembaban, pH rendah dan cahaya. Penelitian sebelumnya, kokristalisasi dapat meningkatkan laju disolusi dan ketersediaan hayati obat dan meningkatkan stabilitas suatu obat. Tujuan penelitian ini untuk melihat pengaruh panas dan kelembaban serta pemilihan koformer terhadap stabilitas ko-kristal kalsium atorvastatin. Stabilitas suatu obat bisa dilihat melalui lamanya waktu daluarsa terhadap suhu dan kelembaban. Penelitian diawali dari pembuatan ko-kristal, karakterisasi ko-kristal, uji stabilitas pada kelembaban relatif 75% dan 98% pada suhu 25^o dan 75^o C dan analisis data. Berdasarkan hasil penelitian, ko-kristal kalsium atorvastatin – Nikotinamida merupakan ko-kristal yang paling stabil. Hasil menunjukkan bahwa suhu dan kelembaban memiliki pengaruh terhadap stabilitas ko-kristal kalsium atorvastatin tetapi tidak signifikan serta ko-former nikotinamida merupakan yang paling stabil karena memiliki waktu kadaluarsa yang lebih lama dibandingkan dengan atorvastatin baku.

Kata kunci : Kalsium atorvastatin, Ko-kristalisasi, ko-former, Uji Stabilitas, Kelembaban relatif, Suhu

ABSTRACT

EFFECT OF TEMPERATURE AND HUMIDITY ON STABILITY ATORVASTATIN CALCIUM CO-CRYSTAL. Atorvastatin calcium is statins as a selective competitive inhibitor of the enzyme HMG-CoA (hydroxy methyl glutaryl coenzyme A) reductase, which is widely used for the treatment of hypercholesterolemia and prevention of cardiovascular disease. Atorvastatin calcium, which has a low solubility and high permeability. This resulted in a decrease of the dissolution rate and biological availability. to improve solubility is the crystal modification through co-crystallization. Additionally, atorvastatin calcium is very susceptible to heat, moisture, low pH and light. The research earlier, co-crystallization can increase the rate of dissolution and bioavailability of the drug and increase the stability of a drug. The purpose of this study was to look at the effect of heat and humidity as well as the election of co-former on the stability of crystalline atorvastatin calcium. The stability of a drug can be seen through the length of time expired to temperature and humidity. The study begins from the preparation of co-crystals, co-crystals characterization, stability testing at a relative humidity of 75% and 98% at a temperature of 25^o and 75^o C and data analysis. Based on the results of the study, co-crystalline of atorvastatin calcium - Nicotinamide is the co-crystal of the most stable. Results showed that the temperature and humidity has an influence on the stability of the co-crystalline of atorvastatin calcium but not significantly, and the co-former nicotinamide is the most stable because it has a longer expiration time compared to standard atorvastatin.

Keywords: Atorvastatin calcium , Co-crystallization, Co-former Stability test, Relative humidity, Temperature