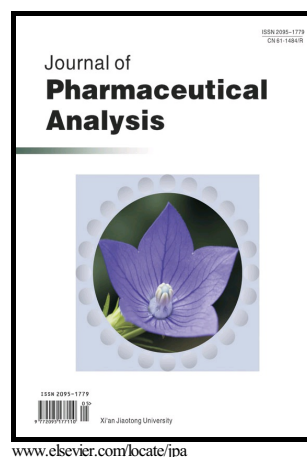


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The impact of storage conditions upon gentamicin coated antimicrobial implants

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Abstract

A systematic approach was developed to investigate the stability of gentamicin sulfate and gentamicin sulfate/poly (lactic-co-glycolic acid) coatings on hydroxyapatite surfaces. The influence of environmental factors (light, humidity, oxidation and heat) upon degradation of drug in the coatings was investigated using liquid chromatography with evaporative light scattering detection and mass spectrometry. Gentamicin sulfate coated rods were found to be stable across the range of environments assessed, with only an oxidizing atmosphere resulting in significant changes to the gentamicin composition. In contrast, rods coated with gentamicin sulfate/poly (lactic-co-glycolic acid) were more sensitive to storage conditions with compositional changes being detected after storage at 60 °C, 75% relative humidity or exposure to light. The effect of γ -irradiation on the coated rods was also investigated and found to have no significant effect. Finally, liquid chromatography-mass spectrometry analysis revealed that known gentamines C₁, C_{1a} and C₂ were the major degradants formed. Forced degradation of gentamicin coatings did not produce any unexpected degradants or impurities.

Keywords

Gentamicin, coatings, storage stability testing.

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