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White paper: PolyVivo AK109 Accelerated Storage Stability

Purpose

Determine storage stability of PolyVivo AK109 in aqueous solution at accelerated conditions (room temperature) relative to suggested 4 C storage condition.

Method

Dissolution:

1 gram of Polymer PLCL-PEG-PLCL (AK109 lot# 60301ELH-A) dissolved in 5ml of distilled water. Dissolved from March 24, 2016 and tested at indicated times.

Storage:

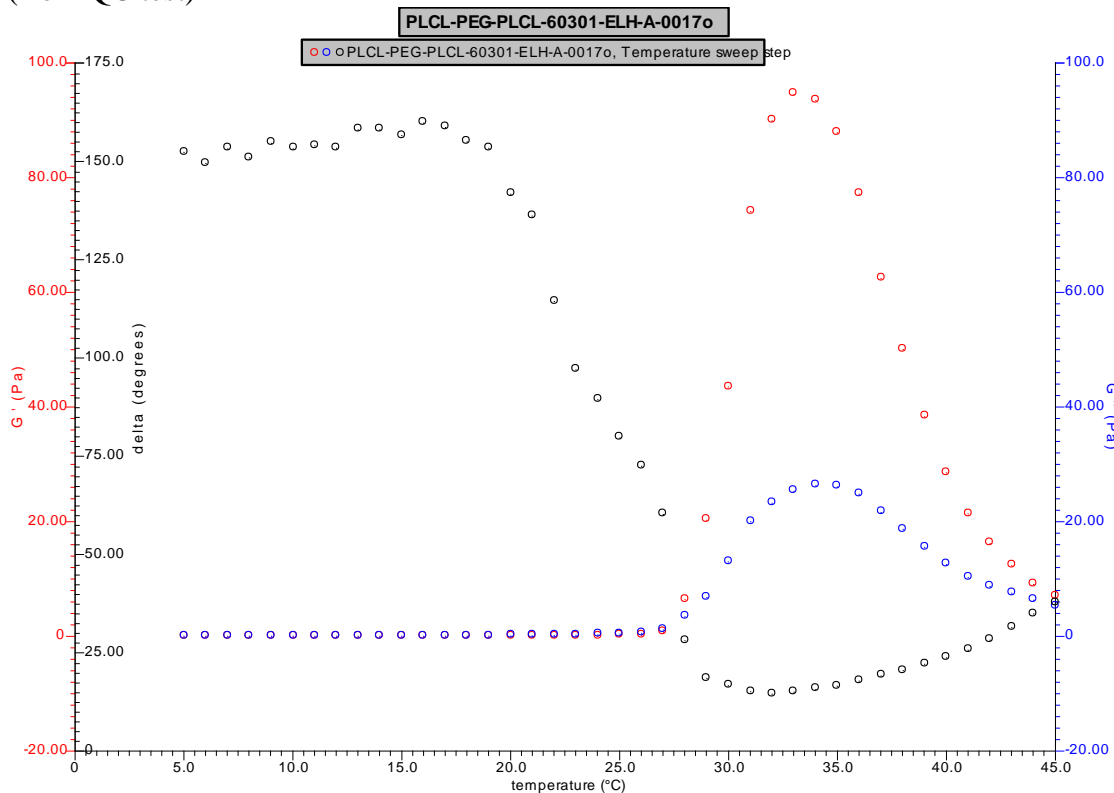
Solution stored at room temperature between 20-25 C.

Rheology:

Rheology performed on AR550 (TA instruments) with 60mm 2degree cone on 20% w/v polymer in distilled water dissolved over 2 days with shaking at 4C. Viscosity of solution at 0.1 (sec-1) and 5C was measured (1minute peak hold 5 second test intervals). Rheology performed by oscillating at constant 6.283 rad/s, 0.1% strain, in increments of 1C ranging from 5-45C with 2 minutes of temperature equilibration at each point.

Results:

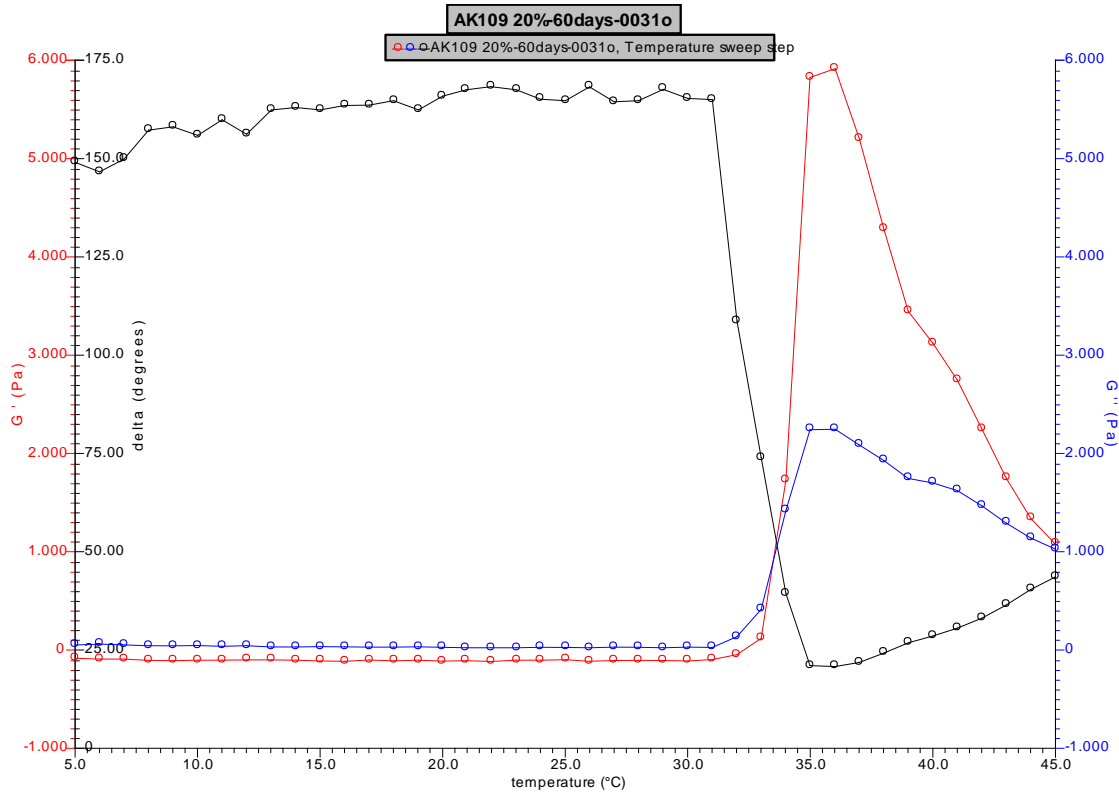
Initial result (from QC test)



Viscosity 20% w/v solution at 5C

0.09092

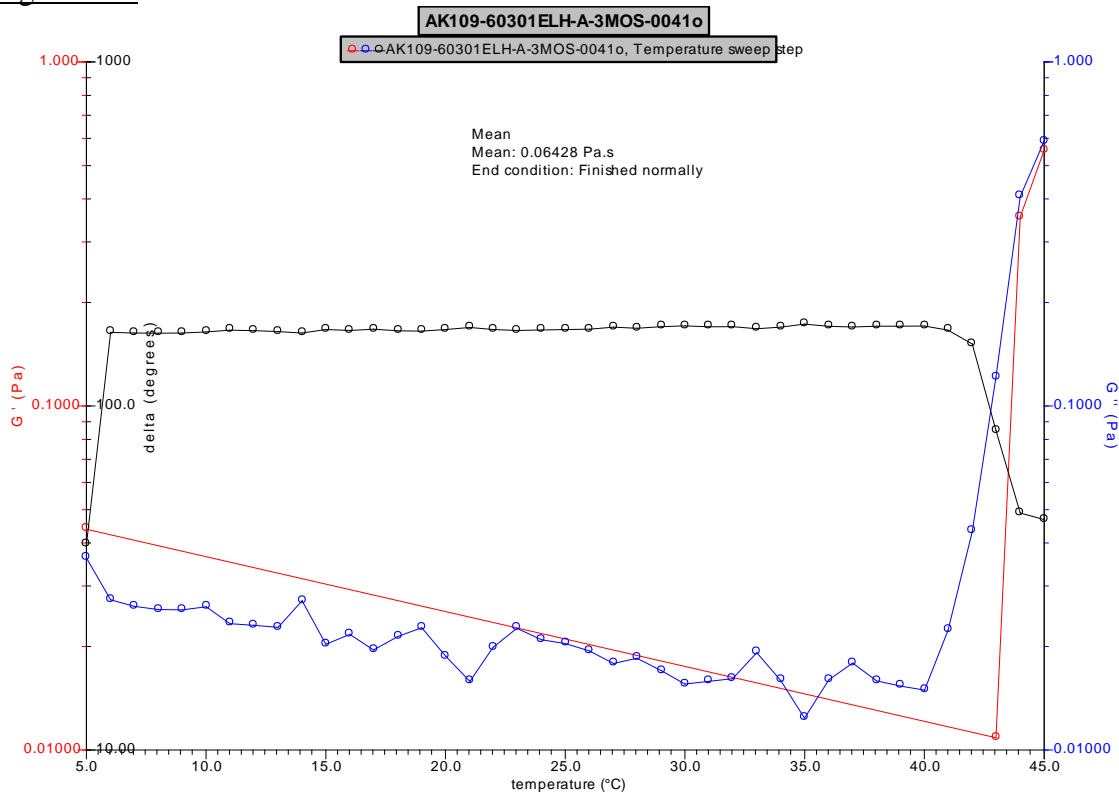
60-day storage result:



Viscosity 20% w/v solution at 5C

0.01926

120-day storage result:



Viscosity 20% w/v solution at 5C	0.06428
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Conclusion

PolyVivo AK109 eventually breaks down when stored in aqueous solution at room temperature to lose gelation property. By 60-days, it transitions through a stage of weaker gelation. By 120 days, it loses gel property all together. This is due to hydrolysis of the chains upon storage in aqueous solution.

By a generalized assumption that most reaction rates, including hydrolysis, double for every 10°C change in temperature [Pauling, L.C. (1988) General Chemistry, Dover Publications] it can be estimated that 60 days at 20°C is roughly equivalent to 150 days at 5 °C. This gives the maximum timeline for cold storage that allows gelation to still occur at 37 °C.