We studied the stability of 1-10 mg/mL Mycophenolate Mofetil (MMF) in polypropylene (PP) 5% dextrose infusion bags prepared from Cellcept® and a generic brand name (Micofenolato de Mofetilo Accord) at different storage temperatures. To ensure chemical compatibility during preparation, we also tested MMF sorption to the EQUASHIELD® closed-system drug transfer device (CSTD) used in this step.” Ezquer-Garin et al (2019).

Abstract:

Stability studies are necessary in healthcare settings as they facilitate fast, cost-effective and efficient work related to batch manufacturing and availability of supplies. We studied the stability of 1-10 mg/mL Mycophenolate Mofetil (MMF) in polypropylene (PP) 5% dextrose infusion bags prepared from Cellcept® and a generic brand name (Micofenolato de Mofetilo Accord) at different storage temperatures. To ensure chemical compatibility during preparation, we also tested MMF sorption to the EQUASHIELD® closed-system drug transfer device (CSTD) used in this step. For this, a validated stability-indicating high-performance liquid chromatography method (HPLC) was developed for the quantification and identification of MMF in the infusion bags. The analytical selectivity of the assay was determined by subjecting a MMF sample to extreme values of pH, oxidative stress and heat conditions to force degradation. Protected from light, 1-10 mg/mL MMF prepared infusion PP bags from reconstituted Cellcept® 500 mg or Accord 500 mg in 5% dextrose were stable for at least 35
days when stored at 2-8°C or between -15 and -25°C, and 14 days when stored at 25°C. MMF loss due to chemical sorption to EQUASHIELD® CSTD set was negligible.

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