Title: Impact of the adequability of plastic sachets in the administration of parenteral solutions

In: on Wednesday, 5 September 2018, 12:00-14:30
Type: Poster
By: ACEVEDO, Maria (ANMAT-INAME and UBA-Facultad de Farmacia y Bioquímica, Galénica y Biofarmacia / Tecnología Farmacéutica)
Co-author(s): Maria Eugenia Acevedo
Maria Florencia Lopez: Galénica y Biofarmacia, ANMAT-INAME, Ciudad Autonoma de Buenos Aires, Argentina
Federico Lerner: Galénica y Biofarmacia, ANMAT-INAME, Ciudad Autonoma de Buenos Aires, Argentina
Graciela Pesce: Galénica y Biofarmacia, ANMAT-INAME, Ciudad Autonoma de Buenos Aires, Argentina
Matthias Gomez: Directorate of auditing and risk management , ANMAT-INAME, Ciudad Autonoma de Buenos Aires, Buenos Aires, Argentina, ()

Abstract:
BackgroundHospitalized patients in critical care settings are at risk for bloodstream infections and open infusion containers may increase the risk of contamination and administration-related because they allow the entry of air into the system it was imperative to minimize risk factors related to mechanical properties of plastic container. Switching from open system to close, fully collapsible, plastic infusion containers would be the solution.MethodsQuality determinations were made to samples taken from five different local laboratories: performance assays required in normative Mercosur A- 1/91 - GMC Nº 52/94 y 57/96 and ANMAT Regulation Nº 1149/97.ResultsThe results show that one laboratory needs to change the plastic material or manufacturing process of containers to provide against water vapour permeation, and the other four laboratories must re-examine the material composition so as to meet draining capacity and collapsibility requirements of their containers, otherwise a warning remark on the label must be included.ConclusionTaking into account all the above ANMAT approved the regulation ANMAT-11857E-2017 about the obligation of using closed system containers for large volume solutions for Injection.