

## Validation of a once-a-week set up for an automated compounder device for parenteral nutrition solutions

Lucie Bouchoud, Farshid Sadeghipour, Sandrine Fleury-Souverain, Pascal Bonnabry

*Pharmacy, Geneva University Hospitals, Geneva, Switzerland and School of Pharmaceutical Sciences, University of Geneva, University of Lausanne, Geneva, Switzerland*

**Background:** Setting up an automated compounder device (ACD) takes time and money. Daily production of paediatric parenteral nutrition (PN) solutions in our pharmacy decreased after implementing standard PN for neonatology. To keep the production of a limited number of PN bags cost effective, we wished to set up the ACD weekly rather than daily.

**Objectives:** This study aims to validate (operational and performance qualification (PQ)) use of an ACD (Baxa MM12) for once-a-day and once-a-week set up.

**Methods:** Accuracy and precision of the ACD were evaluated using water (operational qualification) on a daily basis, and using the products for preparing PN solutions (PQ) on a daily and a weekly basis. Nutrient dosage was measured for specific PN solutions after daily or weekly ACD set ups. Particle contamination of PN solutions produced were controlled throughout the week. To validate the aseptic process, media-fill tests of the once-a-week set ups were carried out over three consecutive weeks.

**Results:** Accuracy and precision of the ACD were validated for small (0.5 ml) and high (100 ml) volumes. Precision improved when pumped volumes increased. Nutrient dosage in PN solutions following daily and weekly set ups were always in conformity with specification limits. No particles or microbiological contaminations were detected following the week-long set ups.

**Conclusions:** Validation proved good accuracy, precision and aseptic conditions existed throughout each week. PN solutions can be produced safely all week long with one set up. A week-long set up saves technician time and money.

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Contact: Lucie.Bouchoud@hcuge.ch

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