Qualification of an automated compounding device (IMF MediMix\textsuperscript{multi\textregistered}) for pediatric parenteral nutrition (PPN) production.

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INTRODUCTION
The pharmacy manually manufactures PPN (=2000/year) \rightarrow In order to improve safety of the production, we acquired an automated compounding device.

The aim is to perform its qualification before using it daily

MATERIALS and METHODS

**Automated compounding device IMF MediMix\textsuperscript{multi\textregistered}**
- 12-way processor-controlled device
- Syringes 10, 20 et 50 ml
- Predefined configuration

**Installation qualification (IQ)**
Performed by the manufacturer:
- Calibration
- Final device inspection

**Operational qualification (OQ)**

**Weighing test of volumes**
- Water for injection (Wfi) and D50\% (2 solutions of extreme density)
- Solutions that will be used in our daily configuration: Primene 10\%, Phocytan, MgSO\textsubscript{4}, Calcium, NaCl, KCl, wfi, D50\%

The filling speed test and lowest volume delivered were performed by the manufacturer

**Performance qualification (PQ)**

To design the PPN formulation, we used the average volume of each solution recorded over a two-month period.

**Repeatability**
1 formulation of PNN, by 1 operator, 6 times on the same day.

**Reproducibility**
5 bags of 5 formulations of PPN, by 3 operators, on 3 different days.

**Media fill test (MFT)**
3 batches of 4 bags of PPN, by 3 operators, on the same week.

The medium used is Soybean-Casein digest.

**RESULTS**

Manufacturer’s test report

5 volumes were tested on each channel

Error between the measured weight and the theoretical weight was calculated (from the density of the solutions) \rightarrow Compared to the deviation tolerated by the manufacturer

Problem in the delivery of small volumes
Solved by adjusting the filling speed for the channel concerned

**Bags weighing**

Precision < 3\% compared to the theoretical value

Analytical control - [Na], [K], Osmolarity
Precision < 10 \% compared to the theoretical value
Coefficient of variation < 5\%

**MFT**

No microbiological contamination was reported in the bags produced (14 days of incubation)

CONCLUSION

According to the results of the qualification process, the compounder meets our requirements for a daily use.

A staff training and an update of the quality manual will follow to allow its daily use.