

# Qualification of an automated compounding device (IMF MediMix<sup>multi</sup>) for pediatric parenteral nutrition (PPN) production.

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**INTRODUCTION** The pharmacy manually manufactures PPN (≈2000/year) → 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<sup>multi</sup>

• 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<sub>4</sub>, 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 PPN, 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

| Genauigkeitskontrolle<br>Accuracy check     |                    |        |        |        |                       |                     |                        |                        |                            |
|---|--------------------|--------|--------|--------|-----------------------|---------------------|------------------------|------------------------|----------------------------|
| durchgeführt von / metered by: A. Thies     |                    |        |        |        |                       |                     |                        |                        |                            |
| Datum / Date: 09.12.17                      |                    |        |        |        |                       |                     |                        |                        |                            |
| Geräte-Typ / Device type: MediMix multi - 4 |                    |        |        |        |                       |                     |                        |                        |                            |
| Geräte-Nummer / Device number: G412CX50B    |                    |        |        |        |                       |                     |                        |                        |                            |
| Temp: 23.5°C Licht: 0.967417 g/ml           |                    |        |        |        |                       |                     |                        |                        |                            |
| Beutel / Bag: MF1663 / MU013                |                    |        |        |        |                       |                     |                        |                        |                            |
| Kanal<br>Station                            | Vorges.<br>Volumen | 1      | 2      | 3      | Mittelwert<br>Average | Dosierung<br>Dosing | min. Abw.<br>min drift | max. Abw.<br>max drift | Mittlere Abw.<br>av. drift |
| 1   | 5.0                | 5.000  | 4.991  | 4.993  | 4.99                  | 5.01                | 0.08                   | 0.26                   | 0.15                       |
| 2   | 50.0               | 50.023 | 50.023 | 49.995 | 50.00                 | 50.13               | 0.25                   | 0.26                   | 0.26                       |
| 3   | 5.0                | 5.014  | 5.017  | 5.012  | 5.01                  | 5.03                | 0.50                   | 0.60                   | 0.58                       |
| 4   | 50.0               | 50.011 | 50.025 | 50.022 | 50.00                 | 50.15               | 0.38                   | 0.50                   | 0.39                       |
| 5   | 1.0                | 1.003  | 1.002  | 1.002  | 1.00                  | 1.00                | 0.40                   | 0.55                   | 0.49                       |
| 6   | 20.0               | 20.029 | 20.006 | 20.010 | 20.02                 | 20.07               | 0.30                   | 0.43                   | 0.34                       |
| 7   | 1.0                | 1.007  | 0.998  | 1.001  | 1.00                  | 1.00                | 0.36                   | 0.56                   | 0.46                       |
| 8   | 20.0               | 19.970 | 20.041 | 20.039 | 20.02                 | 20.07               | 0.11                   | 0.48                   | 0.34                       |

### 5 volumes were tested on each channel

Error between the measured weight and the theoretical weight was calculated (from the density of the solutions)

→ 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.

