Validation of paediatric parenteral nutrient solutions production with Baxa MM12 automated compounder

F. Sadeghipour, H. Ing, C. Sierro, B. Meier, V.-M. Herrera, J.-F. Saâdi, P. Bonnabry
Pharmacy, University Hospitals, Geneva, Switzerland

Rationale

Replacement of a manual production method with final sterilising filtration of Total parenteral nutrition (TPN) in EVA bags by

A fully validated production method using a Baxa MM12 automatic compounder and filling system under aseptic filling conditions (horizontal laminar flow cabinet)

Methods

Automated Compounder & Filling System: Qualification

Baxa MM12 uses a volumetric method of measurement

Volumes of sterile water (1-100 ml) are pumped and results verified by gravimetric method for each channel

TPN Production Validation

Microbiology

MEDIA FILL TEST (MFT) : 104 bags (8 bags/day over 13 days by 3 different operators) filled under standard conditions with sterile nutrient medium (TSB)

PN control bags, filled by 10 different operators over a period of 3 months were tested for sterility.

Chemistry

Development of Method : PN bags (101 bags) were produced in parallel using both manual and Baxa MM12 methods. The Sodium and Potassium content were determined and the results were compared.

Routine Production : PN control bags (121 ml containing Glucose, NaCl, KCl, WFI) were filled as the first and last bags of every paediatric PN production session and analysed for Glucose, Na^+ & K^+ content.

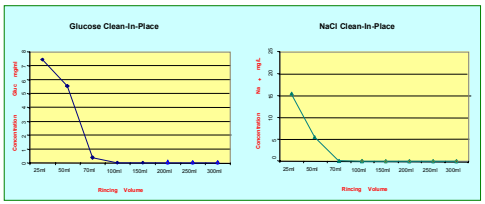
Results

Precision & Accuracy (WFI) 100 ml

ml	0.5*	1.0	5.0	10.0	20.0	100.0
Precision CV [%]	3.1	1.1	0.4	2.4	1.6	0.3
Accuracy [%]	96.0	98.1	98.4	98.3	98.4	100.5

* Lowest determined volume

Minimum Rincing Volume between 2 Bags



Microbiological Validation

- All MFT bags (104 bags) filled with sterile nutrient medium (TSB) were found to be *sterile* after 14 days of incubation (7 days 25°C & 7 days 32.5°C)
- All routine PN (121 ml) Control bags (> 250 bags) were found to be *sterile* after sterility testing (in accordance with Ph. Eur. 3)

Chemical Validation

Routine PN 121 ml Control Bags

(n = 132; p<0.05)

	Volume [ml]	Theoretical &	Practical [mmol/l]	Accuracy
Glucose	9.63	0.31	0.32 (CV = 3.8 %)	[94.0 - 109.6 %]
Na^+	1.56	25.8	25.0 (CV = 2.8 %)	[91.5 - 102.3 %]
K^+	0.7	11.9	11.2 (CV = 5.0 %)	[85.0 - 103.9 %]

Automatic vs Manual Methods

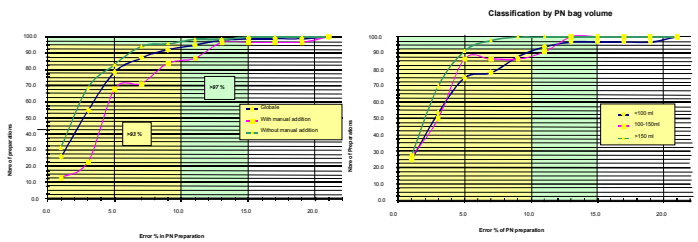
	Bag Volume [ml]	n	Manual Precision CV [%]	Manual Accuracy [%] p<0.05	n	Baxa MM12 Precision CV [%]	Baxa MM12 Accuracy [%] p<0.05
Sodium	< 150	16	4.2	[101.1 – 119.7]	24	3.7	[92.2 – 107.1]
	> 150	38	2.4	[95.2 – 104.9]	45	3.9	[89.9 – 104.9]
Potassium	< 150	14	2.6	[94.7 – 105.3]	20	4.8	[89.0 – 108.0]
	> 150	39	2.3	[95.9 – 105.2	46	4.4	[90.2 – 107.4]

Production Errors Analysis (Na^+ & K^+)

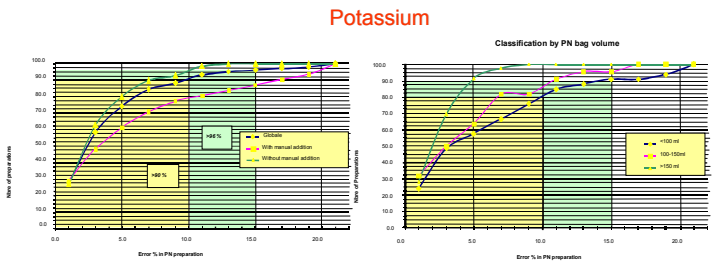
The error for the smaller bags (volume < 100 ml) was < 15% in 92% of the cases,.

The error for the bags produced fully automatically (without any manual addition), the error is < 10% in 98% of the cases.

Sodium



Potassium



Conclusions

- Good Accuracy and Precision was demonstrated in both automated and manual production methods
- Bag contents were found to be sterile in both routine and MFT
- **The automated method showed both a gain in time and cost-effectiveness in comparison with the manual method**

Process Re-engineering

- **Development of an online electronic prescription interface linked to the Baxa MM12 system via an automatic generation of a production file and individual PN bags labels**
- **A safer process avoiding re-transcription of medical orders**

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