

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

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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.

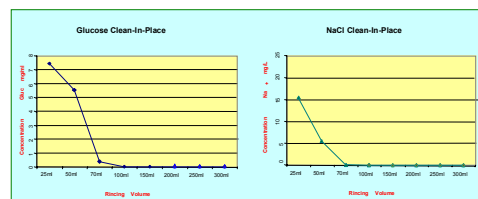
Results

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 Rinsing 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

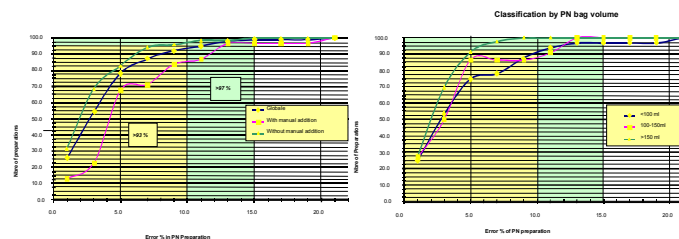
	Bag Volume [ml]	n	Manual		n	Baxa MM12	
			Precision CV [%]	Accuracy [%] p<0.05		Precision CV [%]	Accuracy [%] p<0.05
Sodium	< 150	16	4.2	[101.1 - 119.7]	24	3.7	[92.2 - 107.1]
	> 150	38	2.4	[95.2 - 104.9]	45	3.9	[89.9 - 104.9]
Potassium	< 150	14	2.6	[94.7 - 105.3]	20	4.8	[89.0 - 108.0]
	> 150	39	2.3	[95.9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

Production Errors Analysis (Na⁺ & K⁺)

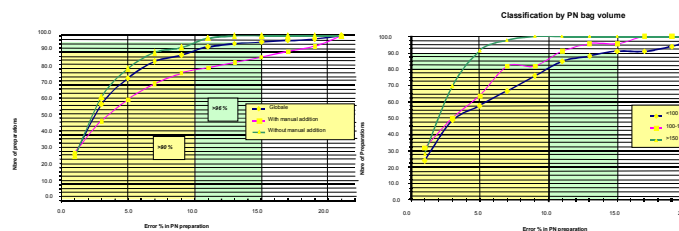
The error for the smaller bags (volume < 100 ml) was < 15% in 92% of the cases,.

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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