

# MEASUREMENT OF THE PARTICULATE LOAD IN PARENTERAL NUTRITION SOLUTIONS PREPARED USING AN MM12

## MICROMACRO<sup>R</sup> COMPOUNDER

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### BACKGROUND AND OBJECTIVES:

There is an increasing demand for parenteral nutrition (PN) prepared in the hospital environment. Between 2000 and 2500 bags are manufactured annually at the University Hospitals of Geneva for paediatric patients. Since 2002, the preparation of these solutions has been automated using a MM12 MicroMacro<sup>R</sup> compounder (Baxa UK). Recent studies<sup>1,2</sup> have shown that PN prepared using such automatic systems may generate important quantities of particulate matter which can exceed the limits laid down in the European Pharmacopoeia (EP). The objective of this study was to measure the particulate load of PN prepared by this method and to determine the possible causes of contamination.

### METHOD

The components tested were: the fluid selector valve with pump tube set and all the various tubing including connectors and adapters used for the MM12 system, the ingredients used for the preparation of the PN, the EVA bags, the pooled initial flushing volume (at the beginning of a session) and the finished product

On average 6 determinations were made for each of the 25 components. They were rinsed with filtered water (0.22µm) and the resulting solutions were analysed for particle content using a Hiac/Royco 9064 optical counter.



### RESULTS

The particulate load of the test solutions obtained from both the components and the finished PN was within the required limits but not in the case of the flushing volume where the results were outside the norm. The average number of particles (10 determinations)  $\geq 10\mu\text{m}$  was  $62.36 \pm 32.7$  against 25 prescribed by the EP. It is noteworthy that in the routine, the PN bags were filled after an initial double flushing of the whole assembled systems. Therefore, these bags were always conform.

### EUROPEAN PHARMACOPEIAS' STANDARDS

	Number of particles $\geq 10\mu\text{m}$ authorized	Number of particles $\geq 25\mu\text{m}$ authorized
Infusion solution with a volume greater than 100ml	25	3



### FINISHED PRODUCTS

Analyzed elements	Number of units	Mean Number of particles $\geq 10\mu\text{m}$	Mean Number of particles $\geq 25\mu\text{m}$
Normal Bags	9	7	0
Control Bags	39	8	0

### MATERIALS

Analyzed elements	Number of units	Mean Number of particles $\geq 10\mu\text{m}$	Mean Number of particles $\geq 25\mu\text{m}$
Baxa with connection to bottle of water	6	4	0
Baxa without connection to ingredients	6	6	0
Bag EVA 250ml	3	8	0
Bag EVA 1000ml	3	1	0
Bag EVA 2000ml	3	3	0
Bag EVA 3000ml	3	10	0
Pipe V connected to 1 bottle of water	3	4	0
Pipe D connected to 1 bottle of water	3	8	0
Pipe V	10	1	0
Pipe D	9	3	0
Port adaptor	10	0	0

### INGREDIENTS

Analyzed elements	Number of units	Mean Number of particles $\geq 10\mu\text{m}$	Mean Number of particles $\geq 25\mu\text{m}$
Vaminolact <sup>®</sup>	3	2	0
Aminosteril hepa <sup>®</sup>	3	3	0
Tracutil <sup>®</sup>	3	8	0
Heparin	3	6	0
Sodium acetate	3	7	0
Sulphate Magnesium	3	2	0
Calcium sandoz <sup>®</sup>	3	16	1
Sodium chloride	3	4	0
Potassium chloride	3	2	0
Phosphate APT	3	3	0
Distilled water 2L	3	0	0
Distilled water 1L	3	1	0

### CONCLUSIONS

Each individual part of the system shows a particulate load within the limits, however, the assembled pump at the beginning of a session releases an important quantity of particles. It is therefore obligatory that they are removed during the initial flushing operations. This will guarantee the conformity of the PN. These results confirm the adequacy of the routine procedures of PN bags production.



### FLUSHING VOLUME

Analyzed elements	Number of units	Mean Number of particles $\geq 10\mu\text{m}$	Mean Number of particles $\geq 25\mu\text{m}$
Flushing volume	9	62	1

### REFERENCES

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