OPTIMIZATION OF THE STERILE COMPOUNDING PREPARATION : EXAMPLE OF A FILLING COMPOUNDER AND ITS QUALIFICATION

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Introduction

The pharmacy prepare and dispense to the pediatric wards syringes composed of water- and fat-soluble vitamins.

⇨ 60 units per batch weekly

⇨ Bulk solution manually prepared

⇨ Filled into syringes with the Repeater® (Baxter) peristaltic pump

Several issues :

- Increased musculoskeletal disorders risks
- Time consuming work

An improvement of productivity and work environment is required.

⇨ A new compounder device was purchased to prepare the bulk solution and to fill in the syringes : SLB Mibmix® (Hemedis/SLB).

Objective: To qualify the new device and to valid the new process

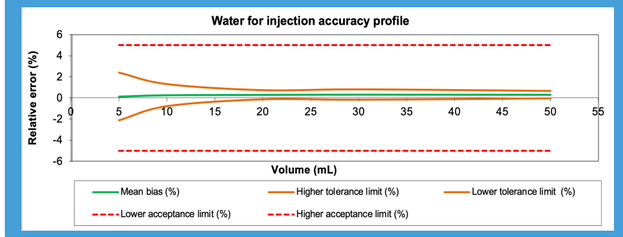
Material and method

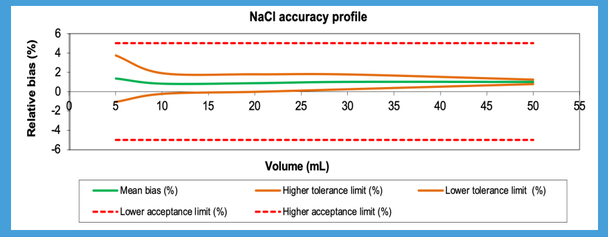
French Good Manufacturing Practices were followed :

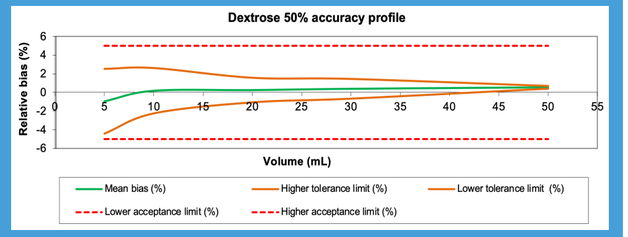
Installation qualification	Manufacturer	
Operational qualification	Volumetric accuracy and reliability	3 filling speeds, 5 volumes, 5 times each, on Water for injection, Saline solution, D50%, Clinoleic ®
	Repeatability	
	Media fill tests 	Visual control of microbial growth every 24h for two weeks : the first week at 20-25°C, the other week at 30-35°C
Performance qualification	Real life batch	

Results

Operational qualification	Volumetric accuracy and reliability	No volumetric difference Volumes calculated accurate
	Repeatability	
	Media fill tests	No contamination
Performance qualification	**4 minutes** for a 30 syringes batch No time difference was found on small volumes, between the slowest and the fastest speed. On larger volumes however, twice the time was needed between the slowest and highest speed.	







Conclusion

SLB Mibmix® C1 seems to be a good option for our current parenteral nutrition activity. It permits to be more efficient and is less traumatic. This device allows the fully automatization of the process.