

Performance Qualification of a Syringe Filling Machine, Smartfiller®

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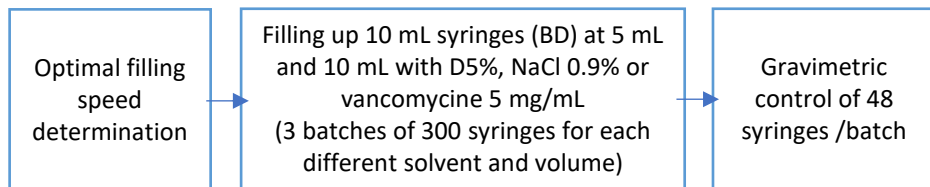
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Background

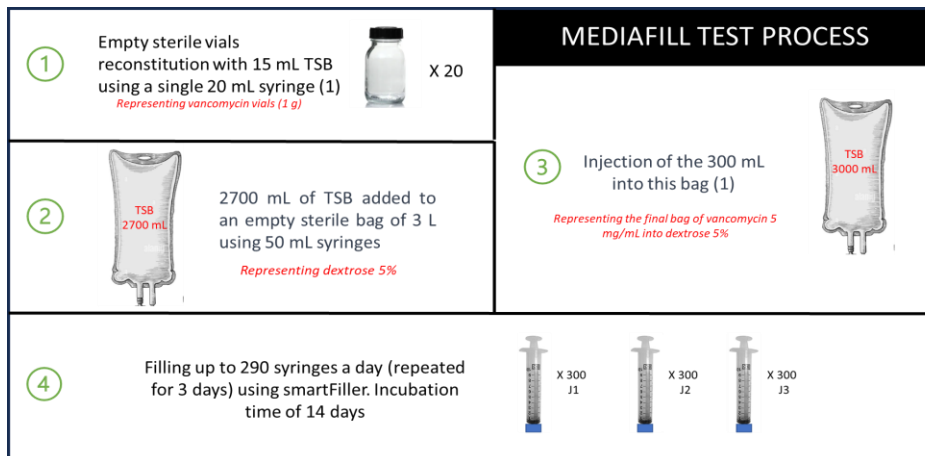
A Smartfiller® syringe filling machine (AddedPharma Nederland) has been set up in our unit to ensure centralized production of injectable medications (CIVAS - Centralized Intravenous Admixture Services), particularly vancomycin syringes for the neonatology department. The goal of this work was to carry out the performance qualification of Smartfiller® and assess its capability.

Methods

PERFORMANCE QUALIFICATION



MICROBIOLOGICAL QUALIFICATION



CAPABILITY ANALYSIS

Followed criteria : % of error (target : 100%) on the 720 syringes controlled by gravimetry during the performance qualification

Long term capability evaluation (for a tolerance of 2, 3, 4 and 5%) :

- Pp (dispersion of the process)
- Ppk Process Capability Index),
- Ppm (overall Process performance Index)
- Adjustment Yield (R%).

PERFORMANCE QUALIFICATION

Optimal filling speed of **7** selected

Results

Solvent	NaCl 0.9%		D5%		Vancomycine 5 mg/mL
V(mean) (3 batches, mL)	9.996	5.021	10.010	5.001	10.008
Standard deviation (3 batches, mL)	0.051	0.043	0.054	0.045	0.043
CV% RP	0.46	0.71	0.55	0.97	0.50
CV% FI	0.51	0.87	0.54	0.90	0.43

Expected results : Accuracy $\pm 2\%$; CV $\leq 2\%$ for repeatability (RP) ; CV $\leq 5\%$ for intermediate precision (FI)

Non-conformities (NC) identified :

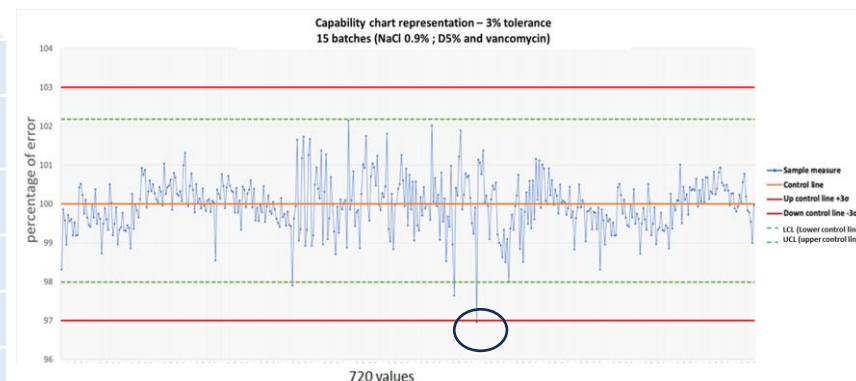
- 6 underfilled syringes (maximum error of 3.04%)
- 2 without caps
- 2 overfilled (maximum error of 2.14%)
- 8 unfilled.

MICROBIOLOGICAL QUALIFICATION
No microbiological growth was observed

CAPABILITY ANALYSIS

Target : $1.67 > x > 1.33$

Tolerance	2%	3%	4%	5%
Standard deviation(%)	0.696			
Mean (%)	100.110			
Pp	0.958	1.437	1.917	2.396
PpK	0.904	1.383	1.862	2.341
Ppm	0.946	1.419	1.892	2.364
R (%)	94.315	96.210	97.158	97.726



No deviation observed : only 1 syringe out of 720 was completely outside the tolerance range (97-103%).

Conclusion

The performance of the machine for filling 10 mL syringes meets the specifications for 98.33% of the prepared syringes. The observed NCs are minor and detectable by the implemented controls. The Smartfiller® machine can be used routinely to produce vancomycin CIVAS.