

IN-PROCESS GRAVIMETRIC CONTROL VALIDATION OF ANTINEOPLASIC PREPARATIONS BY THE ACCURACY PROFILE AND TOTAL ERROR CALCULATION ANALYSIS

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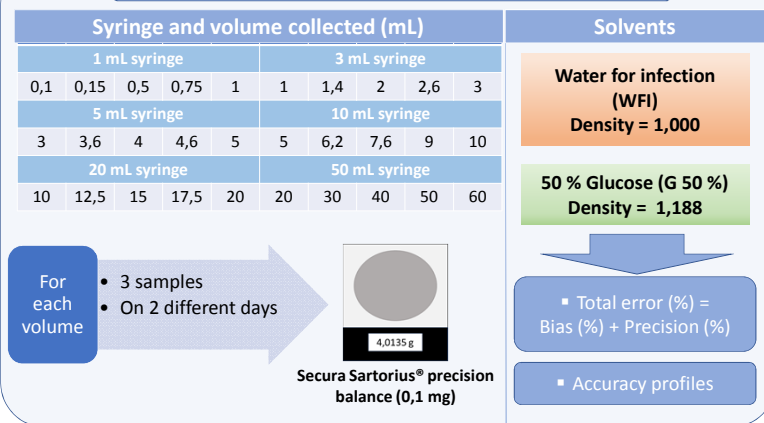
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Introduction

Approximately 15000 preparations are produced per year and under isolator in our chemotherapy reconstitution unit. In-process gravimetric control was retained for the double control of these preparations. The objective of this work is to qualify this method of analysis and determine the rate of controllable preparations with a margin of error of 10 % or 5 % depending on the volume taken.

Methods

In the isolator



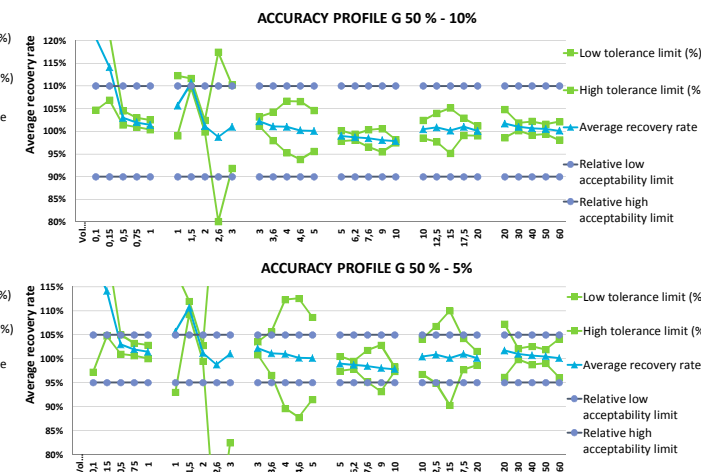
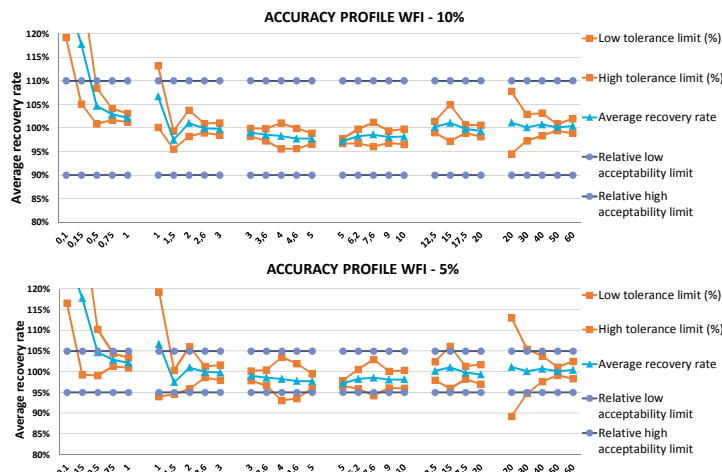
Results

WFI

Syringe	1 mL					3 mL				
	Volume (mL)	Bias (%)	Precision (%)	Total error (%)	...	Volume (mL)	Bias (%)	Precision (%)	Total error (%)	
Volume (mL)	0,10	0,15	0,50	0,75	1,00	1,0	1,5	2,0	2,6	3,0
Bias (%)	28,33%	17,78%	4,67%	2,89%	2,17%	6,67%	-2,56%	1,00%	-0,06%	-0,22%
Precision (%)	3,18%	3,27%	1,10%	0,53%	0,40%	0,94%	0,58%	0,52%	0,40%	0,39%
Total error (%)	31,51%	21,05%	5,77%	3,42%	2,57%	7,60%	-1,97%	1,52%	0,33%	0,16%

G 50 %

Syringe	1 mL					3 mL				
	Volume (mL)	Bias (%)	Precision (%)	Total error (%)	...	Volume (mL)	Bias (%)	Precision (%)	Total error (%)	
Volume (mL)	0,10	0,15	0,50	0,75	1,00	1,0	1,5	2,0	2,6	3,0
Bias (%)	20,65%	14,10%	2,97%	1,95%	1,43%	5,64%	10,63%	1,15%	-1,26%	1,01%
Precision (%)	4,03%	2,84%	0,67%	0,45%	0,48%	1,01%	0,36%	0,56%	2,49%	1,18%
Total error (%)	24,68%	16,94%	3,64%	2,39%	1,91%	6,65%	10,99%	1,71%	1,24%	2,19%



45 densities found

Solvent bags	Antineoplastic
<ul style="list-style-type: none"> Datamatrix present on all bags Not exploitable 	<ul style="list-style-type: none"> 35 secondary packaging 28 primary packaging 11 workable

Datamatrix code lookup

01034009570752001721120010249541

Presentation ID code: 010340095707520017
Expiration date (AA/MM): 2112
Batch number: 0010249541

Density and datamatrix codes research of 50 antineoplastic products used routinely

- Primary packaging
- Secondary packaging
- Solvent bag

Conclusion

This analytical method is reliable and accurate for 93% of our preparations outside clinical trials with an uncertainty of 10 %. This uncertainty can be reduced to 5% for 64% of them, which is more commonly accepted in clinical practice. Only volumes smaller than 3 mL will remain visually controlled. To this quantitative analysis will be associated a qualitative analysis of vials and solvent bags through a datamatrix code whose feasibility in time will have to be evaluated.