

MEASUREMENT OF THE CHEMICAL CONTAMINATION BY A CYTOTOXICS FORMULATING MACHINE (CFM)

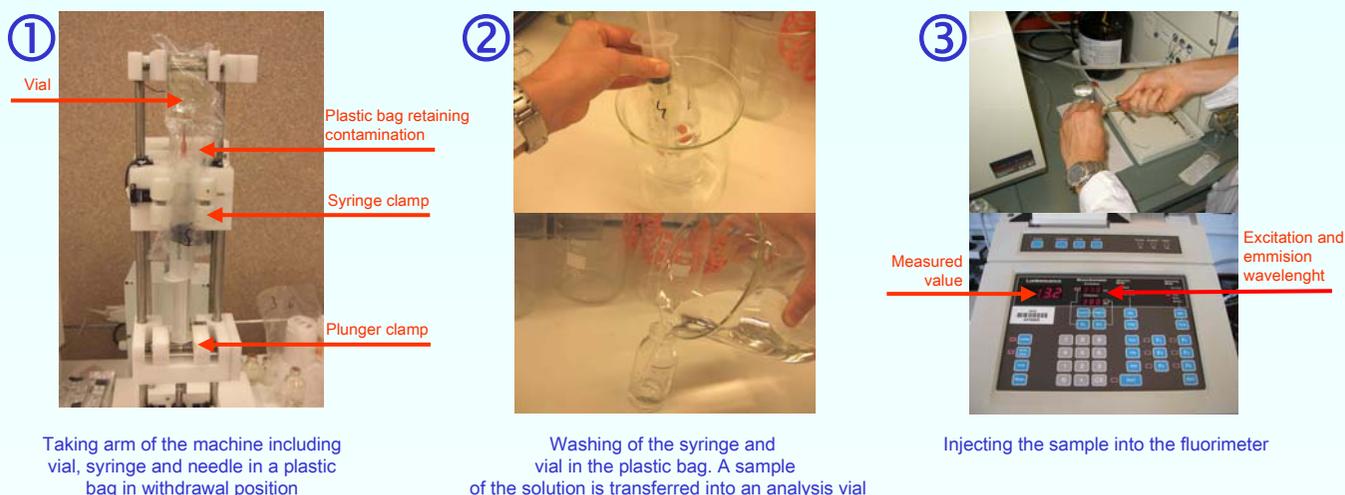
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Background

These last years, several automated methods were developed to produce cytotoxics. This evolution might improve the safety and reduce the need for technicians, but its impact on the chemical contamination is questionable. The objective of our study was to measure the amount of contamination occurring during fluid transfer with the CFM developed by Medical Dispensing Systems (Enschede, The Netherlands).

Methods

Using 10, 20, 50 ml vials of Quinine 2HCl solution 0.1M, transfers were performed by the machine. The volume of contamination was calculated, after a validated washing procedure of the sample, by a fluorimetric measurement method (Perkin Elmer LS 40, $\lambda_{ex}=330\text{nm}$, $\lambda_{em}=380\text{nm}$). Different parameters (vial volume, vial pressure, pumping speed, perforation speed, and needle size 16 G versus 19 G) were assessed regarding their relationship with contamination. CFM preparation was also compared to manual handling. On average 6 observations were made for each of the testing conditions.



Results

Vial volume and pumping speed did not influence contamination rates. Overpressure (+ 0.2 bar) caused a 3 time higher rate of contamination as normal and under (- 0.7 bar) pressures. Higher perforation speed decreased aerosol formation by a factor of 19. The larger size of needle produced more contamination than the smaller one (by a factor of 35). Automated preparation caused contamination rates in the same range as manual handling (1-3 μl).

Variation of perforation speed and needle size

Type of syringe	Contamination [μl] [Std. Deviation]			
	1 mm/s	2 mm/s	3 mm/s	4 mm/s
Green 16 G	25.77 [38.99]	3.91 [7.19]	1.09 [1.43]	1.13 [1.72]
Pink 19 G	0.22 [0.26]	0.31 [0.22]	0.16 [0.04]	0.23 [0.13]
Mean contamination	13.00	2.11	0.63	0.68

Comparison of manual and automated preparation

Method of preparation	Contamination [μl] [Std. Deviation]	
	Best conditions	Worst conditions
Machine	0.37 [0.72]	3.28 [6.14]
Manual	0.37 [0.45]	1.70 [3.38]
Best conditions:	Normal pressure, pink needle 19 G, perforation speed 4 mm/s (machine), pumping speed 3 mm/s (machine)	
Worst conditions:	Overpressure, green needle 16 G, perforation speed 1 mm/s (machine), pumping speed 3 mm/s (machine)	

Conclusion

Parameters impacting on chemical contamination are vial pressure, perforation speed and needle type. CFM preparation does not show to produce more contamination than human handling.

Conflict of interest : this work is supported by Medical Dispensing Systems, Enschede, The Netherlands.