

ENVIRONMENTAL CONTAMINATION WITH CYTOTOXIC DRUGS IN A RECONSTITUTION UNIT



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OBJECTIVES

In spite of protective measures and equipments (spike, closed system, laminar airflow safety hood, isolator) the handing of cytotoxic drugs is referred to as an occupational to the contamination of the environment. Or the dermal absorption would be the main cytotoxic passage in the body (1).

It is necessary to assess and quantify the contamination to protect handlers, environment, patients and their families.

The present study evaluates surface contamination with a cytotoxic drug 5 fluorouracil (5FU) in a reconstitution unit of cytotoxic drugs.

MATERIAL AND METHODS

- Marker of contamination : 5 fluorouracil (5FU)
- **\$15** wipes samples of surfaces
 - > 12 in reconstitution unit of cytotoxic drugs
 - > 1 in box for dispensing of prepared cytototoxic drug
 - > 1 in container for transport of prepared cytotoxic drug
 - > 1 in kitchen staff
- Sending for dosage by HPLC
- Quantification limit (LOQ) = 0.02 μg
- ❖ Detectable amounts is reported in micrograms per square meter (µg/m²) of surface area sampled
- **❖** Contamination is considered important for an above 5-10 LOQ

Isolator room Computer desk pharmacist Monoclonal Cytotoxic drugs isolator antibodies Computer isolator desk handlers Dispensing Cytotoxic Infusion area drugs pass bags pass Inside isolator room through through 11 worktop Outside isolator room worktop 8 **Outside preparation room** Computer desk pharmacist

RESULTS AND DISCUSSION

- Only 3 samples were above the LOQ
- ❖ All other points of the UPA are below limit of quantification reflecting technical preparations mastered, good attitude agents, effective biocleaning

Kitchen staff	Container for transport	Dispensing area
3 x LOQ → Minor contamination	5 x LOQ → Minor contamination	705 x LOQ → Major contamination
 explained by a insufficient cleaning hand-borne contamination cross contamination (pollution?) 	 explained by a insufficient cleaning return preparations following a medical device or a quality defect handborne contamination by the patient environment 	leakage) unprotected

CORRECTIVE MEASURES:

- biocleaning more often risk areas
 - return of defective preparations in a tray
 - disinfecting door handles
 - reminder of hygiene rules

CONCLUSIONS

Of the 15 sampling points **only 3 were positive whose one significant**. This result demonstrates a mastery of working procedures and cleaning for some areas; for further efforts must be made to control contamination. Finally, beware of false negatives, these results should be confirmed. The lack of a standard for surface contamination by cytotoxic drugs us to strengthen and continuously improve our working procedures and cleaning for a lowest possible contamination.

In view of the results of new tests will be realized with more sampling points including the waste sas, the test will be carried out more frequently, urine of the manipulator will be collected to assess the cytotoxic contamination.