

Apoteket

REGION

Preparation of medicinal products – Safe Handling

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Handling protection for personnel to cytotoxic drugs

- "Safe handling and preparation of cytotoxic drugs using gloves, protective cuffs, special gowning, mouth mask and glasses in a special vertical air laminar flow box do not give enhanced mutagenic activity in urine of personnel"

- » **B Kolmodin-Hedman, P Hartvig, M Sorsa, K Falck**
- » **Arch Toxicol 54: 25-33, 1983**

Handling protection for personnel to cytotoxic drugs

-low levels of cytotoxic drugs can be detected in and areas surrounding the hood. The contamination is still probably too low to cause any serious health effects

> **Dranisaries et al. J Oncol Pharm Practice
2005**

Who is interested in our work?

- Our personnel
- Our bosses
- The wards (patients, doctors and nurses)
- Our union leagues

Who is also interested

- Eudralex Vol. 4 annex 1.
- PIC/S guide to good practices for the preparation of medicinal products in healthcare establishments
- Local health authorities
- The working environment authorities

Typical cytostatic

- Starting with sterile products.
- Working mainly with closed systems.
- Short preparation time.
- Administration shortly after preparation.
- Preparation often intended for individual patients.

Typical cytostatic

- Shall be sterile when it is finished without endotoxins.
- Short shelf-life.
- No end product quality control tests
- We are working with likelihood that the product is sterile, because we can not wait for the test.

Focus in preparation of a medicinal product

- Man
- Machinery
- Methods
- Materials
- Milieu

Background: EU-GMP Vol. IV and PIC/S Guide to Good Practices for Preparation of Medicinal Products in Pharmacies

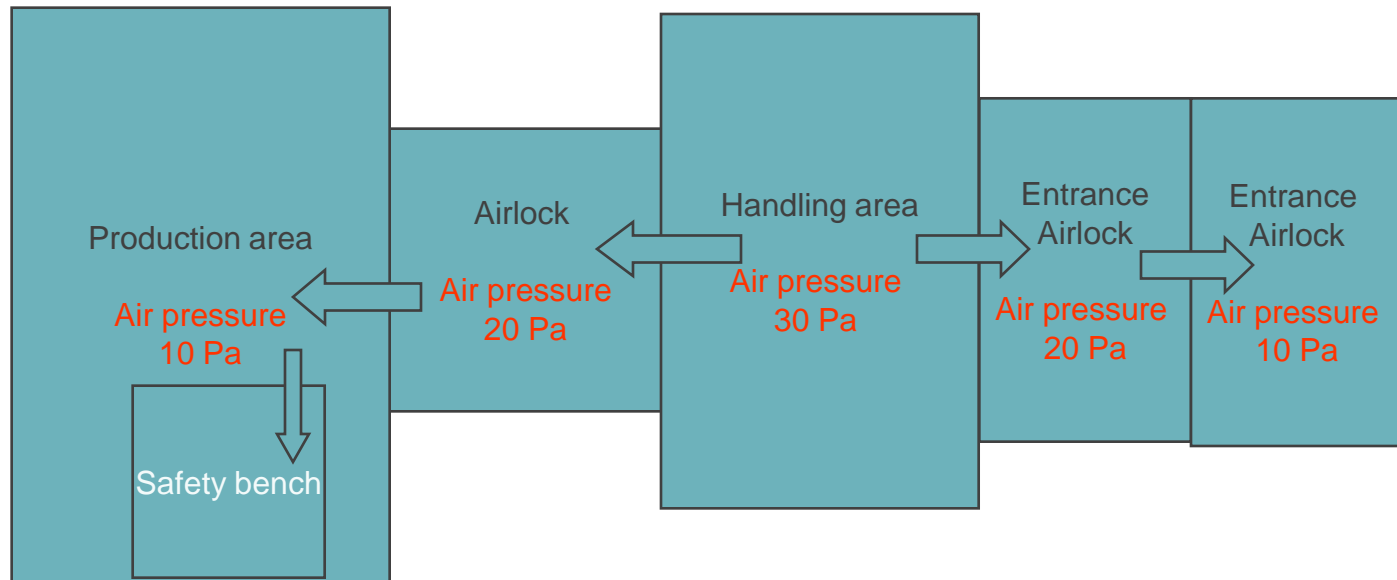
Safe Handling

- Design of preparation rooms
- Education of the staff
- Personnel protective equipment
- Working routines
- Contamination tests
- Industrial injuries

Design of preparation rooms

- Eudralex Vol.4 annex 1, and the PIC/S guide for preparation of medicinal products
 - Dedicated rooms for hazardous drugs
 - Classification of the rooms (class A/B or A/C)
- Air pressure directions in the production area
- Safety benches – vertical LAF

Design of preparation rooms



Education of the staff

- Training program
 - Practical (preparation methods)
 - Theoretical (GMP and contamination risk)
- Test after training
- Retraining every year

Personnel protective equipment

- Dress according to the GMP rules
- Wear an apron or gown buttoned in the back
 - Protecting sleeves
- Wear gloves – 2 pairs
- Head gear
- Beard mask
- Dedicated shoes or overshoes
- Respiratory mask
- Eye protection

Working routines

- Have a helper in the production room
- Gather all necessary items for the preparation before starting
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- Never over fill the bench
- Once seated at the bench – do not take "dirty" hands out
- When the product is finished – put it directly into a clean bag and seal

Working routines

Methods to avoid contamination of both product and surroundings

- Always work on a protecting pad
- Use closed systems
- Use under pressure technique
- Use protection equipment designed for preparation of hazardous drugs

Working routines



Contamination tests

- Wipe tests
- Technetium (^{99}TC) test
- Fluorescents test

Contamination tests

Wipe tests

- Selected places in the production area are wiped
- The swatches are tested for containment of cytotoxics
- The results are use for improvement of the working routines and cleaning methods
- A good method to show possible contamination at all places

Contamination tests

Technetium (^{99}TC) test

- A low concentration of ^{99}TC in NaCl is used for simulation of preparation
- Concentrations of ^{99}TC are measured at selected places (gloves, pad, apron)
- The results are used for improvement of working methods
- Shows the contamination risk at the specific preparation method

Contamination tests

Fluorescents test

- A vial containing fluorescein is used for simulation of preparation
- At selected places it is possible to prove contamination by using a UV-lamp
- The results are used for improvement of working methods
- Shows the contamination risk at the specific preparation method

Waste/litter/garbage/rubbish/trash/scrap

- Divide your waste in risk and non-risk disposals
- All waste products once entered the bench should be disposed of inside the bench
- Seal and wrap the container - taking the waste out of the bench
- Use containers as small as possible
- Once thrown – do not pick up again

Industrial injuries

- Benches and tables adjustable of highth
- Adjustable chairs
- Resting bars
- Rotation at work
- Limited hours of preparation work

- Important to make a training program
- Massage

European Standards for preparing cytotoxics.

QUAPOS

Quality Standard for the Pharmacy Oncology

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