Cytostatic Wipe sample set
PharmaMonitor

Safety at work

Set for wipe sampling and cytostatic - analysis of surfaces

In cooperation with the Institute for Energy and Environmental Technology e.V.
Cytostatic wipe sample set
PharmaMonitor

The company: BERNER International GmbH, DE-Elmshorn

✓ For over 25 years the specialists in work and drug safety for pharmaceutical and biotechnological application areas

✓ Complete PPE (Personal protective equipment) of the highest category 3

✓ Cytostatic safety cabinet and microbiological substances

✓ Proven quality management system in accordance with DIN EN ISO 9001:2008

✓ Associated with many national and international organisations
Daily handling of cytostatic agents

- Pharmacies
  (Hospital and dispensing chemists)
- Doctors’ practices
- Hospitals
- Pharmaceutical industry
- Day care centres
- Nursing homes
- Veterinary practices
- Veterinary clinics
- Drug delivery companies
Examples of unintentional release of cytostatic substances

- Substances can be transmitted via contaminated gloves, protective clothing, shoes, trolley wheels or containers, etc.
- Contaminated packaging (e.g. at the reception inspection due to soiled vials, …)
- Interruption in air flow in safety cabinets
- Release of gaseous components during production and from the exhaust air downstream of the safety cabinet (due to defective filters)
- Incorrect handling of residues and waste
- Accidents during transport, preparation or application
- Application errors
Health and safety at work legislation

In Europe: EC directives 89/391/EEC, 89/656/EEC and 89/686/EEC:

→ When handling CMR drugs or microorganisms, the employer is required to carry out a risk assessment

→ Cytotoxic substances are often colourless and contaminations are thus only slightly or not all visible to the user. Also, they are CMR substances (carcinogenic, mutagenic, toxic to reproduction)

→ As part of a german Monitoring-effect-study for wipe samples in pharmacies (MEWIP-Study 2007/2008) 1.269 samples were examined. In 61% of all samples cytostatic substances were detected.

→ The German employers liability association for health and welfare services therefore recommends regular monitoring to identify and stop any weaknesses in the workflow.
Benefits from regular wipe sample analysis

➔ Improved protection for your personnel

➔ Document optimum working practice
(e.g. for your customers, adhering to health & safety guidelines, accreditation/certification,…)

➔ Uncover weak points

➔ Monitor potential improvements of operational processes

➔ Simple procedure, can be performed by your own personnel

➔ Cost-effective, as it is possible selective identification of single cytostatic substances
The product

→ The wipe sample set contains all necessary utensils, to be able to carry out the wipe sampling on site (including all forms and other auxiliary tools).

→ The cooled samples are sent to the Institute for Energy and Environmental Technology (IUTA e.V.) using a courier.

→ The samples are then examined for a single substance (out of 25) or a group of cytostatic substances. A list of the substances which can be analysed is enclosed in the parcel.

→ The customer will be directly informed of the detailed investigation results by the institute. The data will not be passed to third parties.
Detectable substances

- **Detectable substances in the single analysis:**
  5-Fluorouracil, 6-Mercaptopurine, Acemetacine, Azathioprine, Busulfane, Capecitabine, Carboplatin, Carmustine, Chlorambucil, Cisplatin, Clomiphene, Cyclophosphamide, Cytarabine, Etoposide, Flutamide, Gemcitabine, Ifosfamide, Methotrexate, Mitomycin, Oxaliplatin, Tamoxifen, Thalidomide, total-platinum

*Also available in the single analysis after consultation:*
Docetaxel and Paclitaxel.

- **Traceable substances using multi-methods:**
  - **Multimethod 1:** 5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabin, Etoposide, Methotrexate, Paclitaxel, Docetaxel.
  - **Multimethod 2:** 5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabin, Etoposide, Methotrexate, Paclitaxel, Docetaxel, total platinum.
  - **Multimethod 3:** 5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabin, Etoposide, Methotrexate, Paclitaxel, Docetaxel and Cisplatin, Carboplatin, Oxaliplatin and total platinum.
  - **Platinum analysis:** Cisplatin, Carboplatin, Oxaliplatin and total platinum.

- **Additional substances available on request.**
The results

- Analysis of wipes in a special laboratory
- Use of the latest gas chromatographs
- Detailed analysis of single substances
- The results of the analysis will be sent to you
- If required: Expert support to solve any problems
A selection of BERNER products:
You can contact us by:

Tel: +49 / (0) 41 21 / 43 56 – 0
Fax: +49 / (0) 41 21 / 43 56 - 20
Info@berner-international.de
www.berner-international.eu