

Manufacturer's Information

Wipe Sampling Set Pharma Monitor, Type 1, Art.-Nr. 4155

1. Read user guide carefully before commencing work!

2. Application, properties, different types and disposal

Area of application: Analysis - tool for wipe samples of a single or a group of cytostatic substances

Substances which can be analysed:

Multi-method 1: (5-Fluorouracil, Gemcitabine, Methotrexate, Ifosfamide, Cyclophosphamide, Etoposide, Docetaxel and Paclitaxel)

Multi-method 2: (5-Fluorouracil, Gemcitabine, Methotrexate, Ifosfamide, Cyclophosphamide, Etoposide, Docetaxel, Paclitaxel und Total platinum)

Multi-method 3: (5-Fluorouracil, Gemcitabine, Methotrexate, Ifosfamide, Cyclophosphamide, Etoposide, Docetaxel, Paclitaxel, Cisplatin, Carboplatin, Oxaliplatin and total platinum)

5-Fluorouracil, 6-Mercaptopurin, Acemetacine, Busulfane, Cabazitaxel, Capecitabine, Carboplatine, Carmustine, Cyclophosphamide, Cytarabine, Dacarbazin, Dexamethason, Etoposid, Flutamid, Gemcitabin, , Ifosfamide, Methotrexate, Sulfamethoxazol, total platinum, Treosulfane.

For **single substance analysis of Docetaxel and Paclitaxel** please use sampling set type 2!

Use: The functionality compared to other substances cannot be guaranteed!

Analysis of other substances only after consultation with the testing institute IUTA. – For **single use only!**

Contents:

The wipe sample set contains the following:

- 5x Sample containers, each with 3 folded wipes
(1 cloth for each wipe direction – also see instructions)
- 1x ca. 50 ml sampling solution (water, hydrochloric acid based)
- 5x Pipette
- 5x Pair of cytostatic protective gloves
- 5x Freezer packs (freeze before wipe sampling)
- 1x Adhesive tape for marking
- 1x Measuring tape
- 1x Permanent-marker pen for labelling the container
- 1x Polystyrene transport box
- Manufacturer's data and documentation for sending on to the test institute

Further optional materials (not included):

Protective gown, safety goggles, if necessary a digital camera for personal documentation of wipe sample surfaces

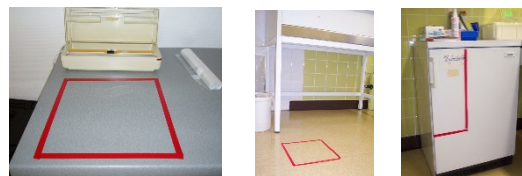


Area of application: The **Berner** cytostatic wipe sample set **PharmaMonitor** is used for sampling and analysis of surface contaminations when handling CMR-pharmaceuticals (e.g. cytostatics, virostatics). The analysis and display of potential contaminations reveals errors in the handling of cytostatic substances as well as subsequent cleaning procedures so that work instructions can be adjusted accordingly. Additionally, a validation of the cleaning procedures can be achieved with

wipe sampling. Suitable surfaces are marked in accordance with the instructions. The wipe samples are then sent, along with the required documentation, to our business partner, IUTA e.V. for analysis.



Examples of sampling locations:

Work surface inside and outside of preparation (size: e.g. 30 cm x 30 cm); storage areas; transport boxes and transport trolleys; floor in front of the safety cabinet; refrigerator door incl. handling; shrink wrap devices, etc. ; door handles; waste containers; cleaned surfaces after use of SpillKits, (e.g. for spilt cytostatics), etc.



Attention: the total area per wipe sampling point should not exceed 2.500 cm². Work instructions for carrying out wipe sampling: see 2. Document (Description wipe samples.)

3. Disposal:

Substance  	Origin			
	Human		Human	
	Risk potential			
	low	low	low	low
	AS 180101	AS 180108*	AS 180203	AS 180207*

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4. Enquiries regarding the results of the analysis:

Please send the wipe samples with the frozen ice packs within 48 hours to the IUTA. You will receive the results of the samples within 4 weeks via e-mail or post. In case of any queries in respect of the analysis, please get in direct touch with:



Institute for Energy and Environmental Technology e.V.

Dr. Türk, Bliersheimer Straße 60, 47229 Duisburg; Tel: 02065 / 418 - 190, E-Mail: analysis@pharma-monitor.de

5. Quality management system

The Berner quality management system is tested and certified in accordance with DIN EN ISO 9001:2015 by the TÜV Management Service GmbH.

6. Storage and transport requirements

Wipe sample set:

- Dark (protect from direct UV- and sunlight)
- Store in a cool (+5 to +40°C) and dry place.
- Freeze ice packs before transport

Samples:

- Transport only with frozen ice packs (max. 48h).
- If required the samples can be frozen (at -18°C) for up to 4 days.
- If necessary, please use additional dry ice packs to ensure a constant low temperature is maintained.

7. Date of manufacture: Digit 1-4: year, digit 5+6: month, code 39 readable

8. Expiry date: Digit 1-4: year, digit 5+6: month, code 39 readable

9. LOT – Number: Lot number, Code 39 readable

10. Copyright and industrial property rights

BERNER INTERNATIONAL GMBH shall not accept liability for any errors / damage arising from the improper use of the wipe sample sets. The contract partner for the customer is **Berner International GmbH**. The analysis part is sub-contracted to the Institute for Energy and Environmental Technology e.V. (IUTA). The wipe sample set may be subject to technical and production-related changes without prior notice. The German version of this manufacturer's information is binding.



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