Transport of cytostatic drugs and patient-specific preparations containing CMR substances

The transport of CMR drugs and patient-specific preparations containing CMR substances must be carried out in accordance with country-specific legal regulations.

What types of transport do we distinguish:

1. Transport of cytostatic drugs from the manufacturer (company) to the user (pharmacy) – hospital, community pharmacy, or manufacturing plant

2. Transport within the pharmacy from goods receipt via storage to the cleanroom (manufacturing)

3. Transport from the pharmacy within the building to the user – internal transport

4. Transport from the pharmacy to the user – external transport

1. Transport of Cytostatic Drugs from the Manufacturer (Company) to the User (Pharmacy) – Hospital, Community Pharmacy, Manufacturing Plant

1.1 Cytostatic drugs or CMR drugs should not be shipped together with other medications in the same shipping carton (mixed carton) – Reason: If a vial containing solid or liquid breaks, the entire contents of the carton can be contaminated.

1.2 All shipping cartons containing CMR drugs should be marked with the "Yellow Hand" label.

1.3 The area in the pharmacy where these cartons are unpacked should be clearly marked and easy to clean.

1.4 When unpacking cartons containing CMR drugs, gloves and, if possible, a protective gown should always be worn.

2. Transport within the pharmacy from goods receipt through storage to the cleanroom (manufacturing)

2.1. The internal transport and storage of these CMR-containing products could, for example, be carried out in plastic boxes that are labeled with the product name and lined with an absorbent cytostatic drug mat for easier cleaning/decontamination. Cleaning and decontamination should be performed according to the SOP "Cleaning and Decontamination". Transport from storage to the manufacturing area should be carried out according to the SOP "Entry Procedure" and/or after validation of the entry of, among other things, CMR-containing medicinal products.

Labeling Example 1: Cytostatics – Gemcitabine for storage box

Labeling Example 2: Cytostatics – RKD according to RKC for stainless steel boxes/trays for entry into the cleanroom (RKD = cleanroom class D or C)

2.2. CMR substances should not be stored above eye level (occupational safety).

3. Transport from the pharmacy within the building to the user – internal transport

3.1. Shipment of patient-specific preparations in a suitable transport box (description of the box will follow separately).

The shipping box label should include the "Yellow Hand" symbol, the recipient's/user's address and telephone number, and further procedural instructions regarding what to do in case of an accident and who to notify. Additionally, transport should be separated according to room temperature (15–25°C) or refrigerated storage (2–8°C). For short transport distances and immediate use, separate temperature-based shipping may be unnecessary (depending on national legal requirements or internal regulations).

3.2. Personnel assigned to transport must be appropriately trained. They should receive training at least once a year (theoretical and practical – country-specific) on the SOPs "Transport of CMR Drugs" and "Handling of the Spill Kit."

4. Transport from Production to User – External Transport

4.1. Ship patient-specific preparations in appropriate shipping boxes, separated according to room temperature (15–25°C) and refrigerated storage (2–8°C). Include a data logger to monitor the temperature, if possible. This serves as proof of proper temperature control during transport.

4.2. The personnel assigned to transport must be trained as described in section 3.2.

4.3. See also 3.1.

5. Description of a Transport Box

The transport box must be sturdy, shatterproof, leakproof, easy to clean and disinfect, clearly labeled, and comply with the legal requirements of the respective countries. Cooling packs should be available separately. Transport boxes validated with a corresponding packing scheme are available on the market (easier for the shipper). Otherwise, separate transport validation must be carried out.

The boxes should also ideally have a provision for a temperature logger.

Appendix: Photos