STORAGE OF HAZARDOUS DRUGS 10

(See Section 5 in USP <800>.)

APIs of any type of HD and antineoplastic agents (with the potential entity-exemption of antineoplastics that need to be only counted or packaged) must be stored using the containment strategies and work practices defined in <800>. An entity's Assessment of Risk may exempt specific dosage forms of those agents listed in the NIOSH HD list tables for non-antineoplastics and reproductive hazards or those antineoplastics that need to be only counted or packaged if alternative containment strategies and/or work practices are identified and implemented.

10.1 What are the minimum storage requirements for the location of HD storage?

Hazardous drugs (HDs) must be stored in a room with fixed walls (not plastic curtains) that is separate from non-HD storage. The room must have a negative pressure between 0.01 to 0.03" wc, be vented to the outside, and have at least 12 air changes per hour (ACPH).

10.2 Am I required to store all HDs in a negative pressure room?

You must store any active pharmaceutical ingredients (APIs) of any HD in a negative pressure room. You must store any antineoplastic HD that has to be manipulated in a negative pressure room. The other agents and dosage forms are based on your Assessment of Risk. If you don't do an Assessment of Risk, all must be stored in a negative pressure room.

<800> allows you to perform an Assessment of Risk for

- antineoplastic agents that need to be only counted or packaged;
- non-antineoplastic agents; and
- reproductive hazards.

If your Assessment of Risk permits, you may not have to store those agents in a negative pressure room, but you have to identify how you mitigate the risks to personnel by identifying alternative containment strategies.

10.3 Where does <800> say that I have to keep two sets of inventory—one for nonsterile and one for sterile?

There is no requirement in <800> for two sets of inventory. You need to keep all HDs (unless entity-exempted in your Assessment of Risk) in negative pressure.

10.4 Are manufacturers required to clean the outer packaging of unit-dose/unit-of-use containers?

No, that is one of the reasons why HDs must be stored in negative pressure and separated from non-hazardous agents.

10.5 Why do HDs need to be stored in a negative room?

The negative room is used to contain the hazardous residue that may be on the outside of packages. There is no requirement by the U.S. Food and Drug Administration (FDA) or other regulators to ship packages that are free of HD residue. Because drugs need to be moved from storage to the compounding area, using a negative pressure storage area protects adjacent areas from the contamination.

10.6 Can I store HDs in the negative pressure buffer room?

Yes, you can store HDs in the negative pressure buffer room since the room exceeds the minimum requirements for storage as long as (1) you have adequate room for the storage and (2) the room maintains the required standards for certification. However, you cannot store any external containers (e.g., shipping containers, wholesaler totes) or corrugated cardboard in that area because it would introduce the potential for microbial contamination. You should store items intended only for sterile compounding in a negative pressure buffer room intended for sterile HD compounding.

10.7 Can HD and non-HD APIs be stored in the same negative pressure room if they are separated?

It depends what you do with your non-HD APIs. Is it used only for HD compounding? In that case, it could be acceptable. But if it's used for non-HD compounding, you would have to label any preparation with personal protective equipment (PPE) precautions. That is likely not an acceptable or practical way to handle this.

10.8 Do all my non-chemo agents need to be in a negative room?

All antineoplastic agents (with the potential exception of those final dosage forms that need to be only counted and/or packaged) and all APIs have to be in a negative pressure storage room. Storage of the non-antineoplastics and reproductive hazards on the National Institute for Occupational Safety and Health (NIOSH) list of HDs may not need to be stored in a negative pressure room if you conduct an Assessment of Risk and define alternative containment strategies and/or work practices.

10.9 If I use an injection for nonsterile compounding, where do I store it?

If it could be used for either nonsterile or sterile compounding, store it in the sterile compounding negative storage area, and develop a procedure to outline how it will be removed from that area and by whom. If it is used only for nonsterile compounding, it could be stored in the nonsterile compounding negative storage area.