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GMP/GDP Requirements for Different Storage Areas

by Thomas Peither

General requirements

Adequate size and lighting of all areas where medicinal products, starting materials and packaging materials are stored is essential for the proper performance of operations. Access to storage areas must be clearly regulated and protected.

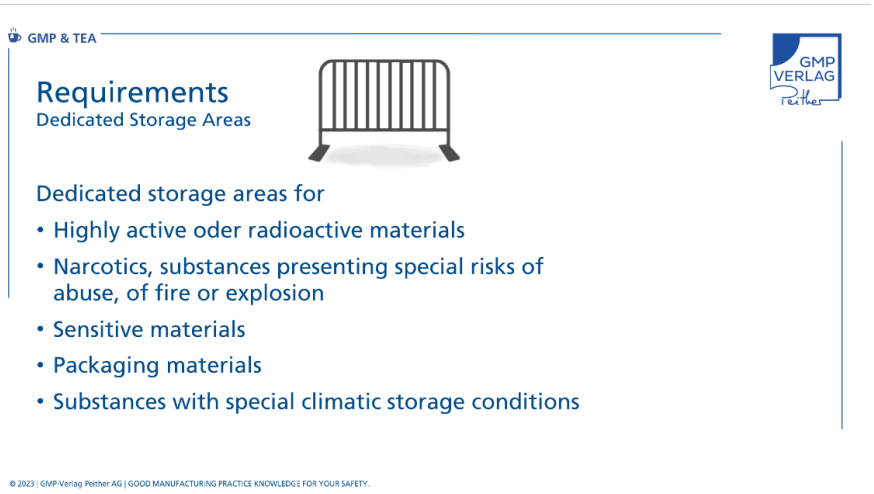
Both EU GMP and EU GDP guidelines emphasise the importance of storage protected from the weather. Goods should therefore always be received inside the warehouse. Only in exceptional cases is it acceptable to do this outside under a canopy.

In addition, the receiving and shipping areas should be separated. If space is limited, additional organisational measures may be necessary, such as separating delivery and collection or at least separating the areas with mobile partitions or barriers.

Dedicated storage areas

Rejected, blocked and returned commercial material must be marked "blocked" and stored in a separate blocked storage area accessible only to authorised personnel.

Dedicated storage areas are also required for highly potent substances. According to the WHO-GSDP (Good Storage and Distribution Practices for Medicinal Products) guideline, this also applies to radioactive materials, narcotics, substances with a risk of misuse or with a risk of fire or explosion, hazardous materials or sensitive substances.

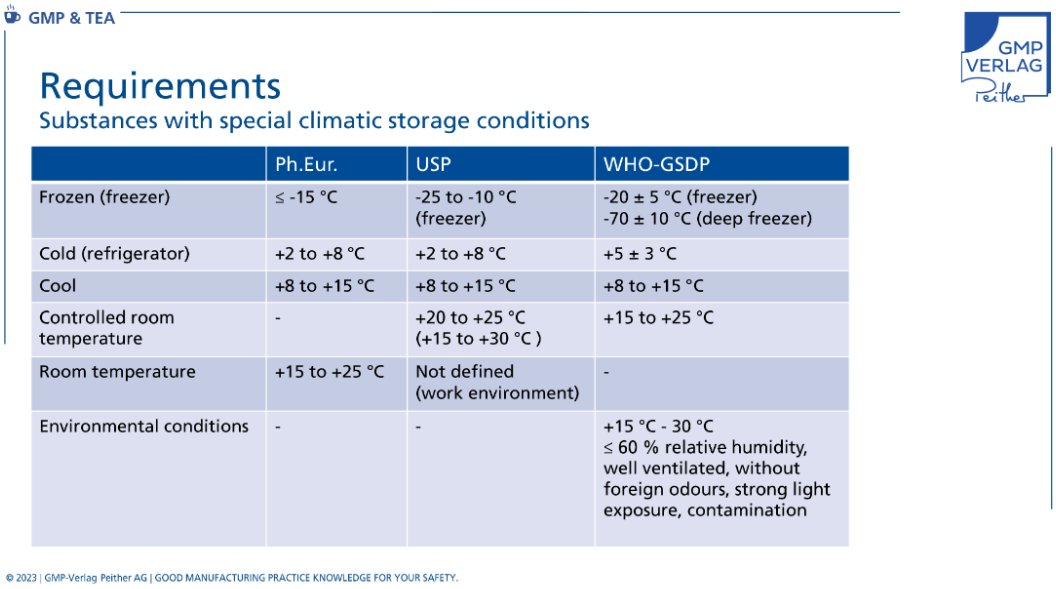


Special requirements for the storage of critical materials are defined, among others, in national regulation on narcotics and the hazardous substances. Printed packaging material is also considered critical from a GMP point of view; special climate-controlled intermediate storage may be required for conditioning for the packaging process.

Dedicated storage is required for substances with deviating climatic storage conditions. Often, this requires special cold storage facilities or storage areas with special specifications for relative humidity. Basic specifications for this can be found in the EU GMP guidelines as well as in the GDP guidelines and in 21 CFR 211.

Storage instructions based on stability data shall be considered as target values for storage conditions in order to be able to adopt, for example, expiry dates. The storage temperature specifications stated on the packaging of the finished product shall be selected in accordance with the EMA Guideline on Declaration of Storage Conditions. Relevant pharmacopoeias and the WHO-GSDP provide storage instructions for specific temperature ranges.

But be careful! Terms such as "deep-frozen" or "room temperature" can mean different temperatures depending on the source. The following comparison of the terms and requirements in the various regulations can be helpful here.


GMP & TEA

Requirements

Substances with special climatic storage conditions

	Ph.Eur.	USP	WHO-GSDP
Frozen (freezer)	≤ -15 °C	-25 to -10 °C (freezer)	-20 ± 5 °C (freezer) -70 ± 10 °C (deep freezer)
Cold (refrigerator)	+2 to +8 °C	+2 to +8 °C	+5 ± 3 °C
Cool	+8 to +15 °C	+8 to +15 °C	+8 to +15 °C
Controlled room temperature	-	+20 to +25 °C (+15 to +30 °C)	+15 to +25 °C
Room temperature	+15 to +25 °C	Not defined (work environment)	-
Environmental conditions	-	-	+15 °C - 30 °C ≤ 60 % relative humidity, well ventilated, without foreign odours, strong light exposure, contamination

This article is a shortened and translated excerpt from the 32nd episode of our GMP & TEA webcast .

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