

Requirements on storage of pharmaceutical products

The storage condition of wholesalers of pharmaceutical products must be in compliance with the following requirements:

1. Storage facilities must comply with the Laws of Hong Kong.
2. Storage facilities of pharmaceutical products must be room or rooms designated for storage of pharmaceutical products, which shall be locked with an adequate lock. The storage area of the storerooms should not be less than 100 square feet or should be proportionate to the scale of relevant business.
3. Precautions must be taken to prevent unauthorized persons from entering storeroom.
4. Storeroom should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely products in quarantine, and released, rejected, returned or recalled products.
5. Storeroom should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature and humidity limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.
6. Storeroom should be clean, and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storeroom. There should also be written programme for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of pharmaceutical products. There should be appropriate procedures for the clean up of any spillage to ensure complete removal of any risk of contamination.
7. Receiving and dispatch area should protect products from the weather. Receiving area should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.
8. Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security.
9. Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled, or returned products. The products and area concerned should be appropriately identified.
10. Radioactive materials, dangerous drugs, psychotropic substances, and cytotoxic drugs should be stored in dedicated areas that are subject to appropriate additional safety and security measures.
11. Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
12. A system should be in place to ensure that pharmaceutical products due to expiry first are sold and/or distributed first. Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

13. Rejected pharmaceutical products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is taken on their fate.
14. Broken or damaged items should be stored separately from usable stock and disposed properly.
15. Storeroom should be provided with adequate lighting to enable all operations to be carried out accurately and safely.
16. Storage conditions for pharmaceutical products should be in compliance with the instructions on the label, which are based on the results of stability testing.
17. Recorded temperature and humidity monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year. Temperature and humidity mapping should show uniformity of the temperature and humidity across the storage facility. It is recommended that temperature and humidity monitors be located in areas that are most likely to show fluctuations.
18. Equipment used for monitoring of storage conditions should be calibrated and maintained at defined intervals. Relevant records should be kept and available for inspection by Department of Health.
19. Any non-compliance of storage condition detected should be reported to Department of Health.
20. Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.
21. All significant stock discrepancies should be investigated to check that there have been no advertent mix-ups, incorrect issue and/or misappropriation of pharmaceutical products.
22. Any breakage of security, or any unexplainable stock discrepancy should be reported to Department of Health.
23. All facilities for the storage of poisons and pharmaceutical products should be licensed or approved and have proper security control.

Pharmacy & Poisons (Wholesale Licences) Committee
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