Table 3 Premises and Equipment Standards

3.1 Principle: Wholesale dealer must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.
3.2 Premises:
3.2.1 The premises should be designed or adapted to ensure that the required storage conditions are maintained. They should be suitably secure, structurally sound and of sufficient capacity to allow safe storage and handling of the medicinal products. Storage areas should be provided with adequate lighting and ventilation to enable all operations to be carried out accurately and safely.
3.2.2 Where premises are not directly operated by the wholesale dealer, a written contract should be in place. The contracted premises should comply with requirements of the national legislation.
3.2.3 Medicinal products should be stored in segregated areas which are clearly marked and have access restricted to authorised personnel. Any system replacing physical segregation, such as electronic segregation based on a computerised system, should provide equivalent security and should be validated.
3.2.4 Medicinal products pending a decision as to their disposition or medicinal products that have been removed from saleable stock should be segregated either physically or through an equivalent electronic system. The requirement for physical segregation and storage in a dedicated area should be assessed using a risk based approach. Falsified medicinal products, expired products, recalled products, rejected products and medicinal products not authorised for the internal market must always be physically segregated. The appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified.
3.2.5 Special attention should be paid to the storage of medicinal products with specific handling as specified in national legislation (e.g. storage of controlled drugs).
3.2.6 Radioactive materials and other hazardous medicinal products, as well as products presenting special safety risks of fire or explosion (e.g. medicinal gases, combustibles, flammable liquids and solids), should be stored in one or more dedicated areas subject to national legislation and appropriate security measures.

3.2.7 Receiving and dispatch bays should protect medicinal products from prevailing weather conditions. There should be adequate separation between the receipt and dispatch and storage areas. Procedures should be in place to maintain control of inbound and outbound goods. Reception areas where deliveries are examined following receipt should be designated and suitably equipped.

3.2.8 Unauthorised access to all areas of the authorised premises should be prevented. Prevention measures would usually include a monitored intruder alarm system and appropriate access control. Visitors should be accompanied by authorised personnel.

3.2.9 Premises and storage facilities should be clean and free from litter and dust. Cleaning programmes, instructions and records should be in place.

3.2.10 Premises should be designed and equipped so as to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme should be in place. Appropriate pest control records should be maintained.

3.2.11 Rest, wash and refreshment rooms for employees should be adequately separated from the storage areas. The presence of food, drink, smoking material or medicinal products for personal use should be prohibited in the storage areas.

3.3 Temperature and Environment Control:

3.3.1 Suitable equipment and procedures should be in place to check the environment where medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.

3.3.2 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. According to the size of premises which are at room temperature, an assessment of potential risks should be conducted and temperature monitors placed accordingly.

3.4 Equipment:

3.4.1 All equipment impacting on storage and distribution of medicinal products should be designed, located, maintained and cleaned to a standard which suits its intended purpose. Planned maintenance should be in place for key

equipment vital to the functionality of the operation.

3.4.2 Equipment used to control or to monitor the environment where the medicinal products are stored should be calibrated at defined intervals based on a risk and reliability assessment.

3.4.3 Calibration of equipment should be traceable to a national or international measurement standard. Appropriate alarm systems should be in place to provide alerts when there are excursions from predefined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality.

3.4.4 Equipment repair, maintenance and calibration operations should be carried out in such a way that the quality and integrity of the medicinal products is not compromised. Procedures should be in place to ensure the integrity of medicinal products is maintained in the event of equipment failure.

3.4.5 Adequate records of repair, maintenance and calibration activities for key equipment should be made and the results should be retained. Key equipment would include for example cold stores, monitored intruder alarm and access control systems, refrigerators, thermo hygrometers, or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain.

3.5 Computerised Systems:

3.5.1 Before a computerised system is brought into use, it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

3.5.2 A written, detailed description of the system or diagrams should be available. This should be kept up to date. The document should describe principles, objectives, security measures, system scope and main features, how the computerised system is used and the way it interacts with other systems.

3.5.3 Data should only be entered into the computerised system or amended by persons authorised to do so.

3.5.4 Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Backup data should be retained at least 5 years at a separate and secure location.

3.5.5 Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.

3.6 Qualification and Validation:

3.6.1	Wholesale dealers should identify what key equipment qualification and key process validation is necessary to ensure correct installation and operation. The scope and extent of such qualification and validation activities (such as storage, pick and pack processes, transportation) should be determined using a documented risk assessment approach.
3.6.2	Equipment and processes should be respectively qualified and validated before commencing use and after any significant changes (e.g. repair or maintenance).
3.6.3	Validation and qualification reports should be prepared summarising the results obtained and commenting on any observed deviations. Deviations from established procedures should be documented and further actions decided to correct deviations and avoid their reoccurrence. The principles of CAPA should be applied where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel.