1. OBJECTIVE

This guideline has been prepared to provide guidance about storage and distribution of investigational products to be used in clinical trials under suitable conditions.

2. DEFINITIONS

Definition in the Good Clinical Practice Guideline and in the relevant legislation shall apply.

3. QUALITY SYSTEM AND ASSURANCE

3.1. The institution or organization performing storage operations should establish a quality system.

3.2. A quality system ensuring that the quality of the investigational products stored at the warehouse is maintained throughout the shelf-life should be in place.

3.3. The quality assurance system should ensure that at least the following are met with respect to the investigational products:

3.3.1. The investigational products are used in an approved clinical trial in accordance with the relevant legislation,

3.3.2. The investigational products are permitted for import in accordance with the relevant legislation,

3.3.3. Storage conditions including the shipment processes are continuously under control and are suitable,

3.3.4. The investigational products shall not be subjected to contamination or cross-contamination with the other products,

3.3.5. An effective emergency action plan is in place,

3.3.6. A system ensuring monitoring to easily identify defective products is in place.

3.4. Written, approved standard operating procedures for all processes and procedures that may affect the quality and distribution operations of the products such as goods acceptance and control, storage pest control, shipment, destruction, recording, actions to be taken for returned goods, precaution systems against natural disasters should be established.

4. PERSONNEL

4.1. Organization chart of the warehouse should be prepared indicating the key personnel as well.

4.2 The person to be assigned as storehouse supervisor at warehouse should graduated from Faculty of Pharmacy and should have executive competence to practice his/her profession in Turkey.

4.3 The person to be appointed to be responsible for the implementation of quality systems in the warehouse must be employed as a responsible person for quality assurance in his/her capacity as an authorized person who has the knowledge or experience about the product or products.

4.4. All employees should have received training concordant with the duty assigned to them, and records of such trainings should be maintained. Such trainings should be repeated at suitable intervals indicated in the standard operating procedures.

4.5 Job descriptions indicating the tasks and responsibilities of all employees should me made clearly and documented.

4.6. All the personnel processing the investigational products in the warehouse should be subjected to periodic health control and their records should be maintained. Persons with infectious diseases or open wounds shall not be appointed to tasks that require a direct contact with the investigational products.

4.6. The warehouse employees should wear suitable protective or working clothes on or instead of their usual clothes.

5. BUILDINGS/FACILITIES AND TOOLS/EQUIPMENT

5.1. The building and equipment should be suitable and adequate to ensure that the investigational products are properly stored and distributed.

5.2. Necessary measures should be taken against fire and natural disasters and adequate number of fire-extinguishing tubes and powder should be available.

5.3. Floors, walls and ceilings of the storage area should be water-resistant, easily-cleanable and of durable material.

5.4. The circumstances stipulated for the storage of the investigational products under suitable conditions should be monitored with appropriate instruments and devices and all relevant records should be kept accordingly.

5.5. The storage area should have an administrative division, goods acceptance and shipment division, storage division, refused goods division, quarantine division as main parts and other necessary divisions

5.6. The storage area should be designed to have enough space to allow easy acceptance and shipment processes and ensure the storage and distribution of all investigational products in the warehouse under suitable and safe manner and conditions.

5.7. The area for receiving and shipping of the goods should be separated from the areas where the investigational products are stored.

5.8. The investigational products should be protected from bad weather conditions during loading and unloading processes.

5.9. All instruments and equipment in the warehouse should be in operable conditions.

5.10. All monitoring instruments in the warehouse should be regularly calibrated and the relevant records should be kept.

6. ACCEPTANCE

6.1. Acceptance area should be separated from storage area.

6.2. Acceptance area should be designed to protect the investigational products from bad weather conditions during unloading process.

6.3. During acceptance, whether the investigational products have been damaged, the received goods are the same with the ordered goods and the shelf life should be checked and the relevant records should be kept.

6.4. The products which require special storage conditions should be immediately identified during acceptance and stored in accordance with the written standard operating procedures and the relevant legislation.

7. STORAGE

7.1. The investigational product should be stored under conditions suitable for its quality.

7.2. Temperature and humidity amount of the storage area should be monitored and recorded electronically 7 days/24 hours in a manner that the data cannot be changed, and the data should be reviewed regularly. In these systems, there should be a system which gives alarm when temperatures and humidity amounts are out of the expected values, and intervention systems should be developed in a manner to protect the quality of the storage products.

7.3. Temperature distribution map should be generated for the storage area.

7.4. Storage areas should be clean and free from pests. Adequate and effective methods should be implemented to prevent breaks, spillage, contamination with microorganisms and cross-contamination.

7.5. Persons other than those in charge and who are authorized should not be allowed to enter the storage areas. Entries and exits should be recorded.

7.6. Investigational products of which the shelf life is expired should be immediately separated from the available stock, necessary measures should be taken and their distribution should not be done in any way.

7.7. Necessary measures should be taken for the investigational products which should be stored under cold chain conditions.
7.8. There should be a quarantine area.
7.9. Places where narcotic, psychotropic products, products containing live microorganisms and toxic products should be as a separate section and locked up.
7.10. Instruments or systems that can run on alternative energy resources should be held in reserve against power outage.

8. SHIPMENT

8.1. The products that are shipped should be secured, and protected from unacceptable levels of heat, cold, light, moisture or other undesired affects or damages.
8.2. During the shipment of the products subject to cold chain, necessary measures should absolutely be taken to ensure the products are stored within the specified temperature ranges.

9. RECORDS

9.1. An emergency plan should be determined in writing. Any practices should be recorded and records should be kept.
9.2. Any return or rejection processes should be recorded.
9.3. Records should be kept in a manner to monitor all activities and events during each process.
9.4. The records should be legible, clear and easily accessible when necessary.
9.5. Records kept on computer system should be secured through a backup system and systems should be validated.
9.6. A self-inspection (auto-control) system should be established, regularly performed and its records should be kept for control of compliance with the relevant legislation.
9.7. Training records should be kept and regularly performed.
9.8. Destruction processes should be performed in accordance with the relevant legislation and destruction records should be kept.

10. APPLICATION AND APPROVAL

10.1. The permission required for the institutions and organizations intending to be in service for the purpose of storage and distribution of investigational products under appropriate conditions to be used in clinical trials is given by the Turkey Pharmaceuticals and Medical Devices Agency
10.2. Institutions or organizations intending to take a permission should apply to the Turkey Pharmaceuticals and Medical Devices Agency with the application form published on the website of Turkey Pharmaceuticals and Medical Devices Agency.
10.3. Audit for institutions or organizations whose application is approved should be performed within 45 days at the latest.

11. OTHER PROVISIONS

11.1 This Guideline does not cover labeling activities for investigational products and the required permissions should be obtained in accordance with the relevant legislation if such activities to be performed.
11.2 After the permission is given by the Turkey Pharmaceuticals and Medical Devices Agency, audit should be performed at least once a year.

12. SUPERSEDED REGULATIONS

"The Guideline on Storage and Distribution of Investigational Products Used in Clinical Trials" entered into force upon the Authority Consent dated 23.08.2011 and numbered 7481 has been superseded.

13. PROVISIONAL CLAUSE

Provisional Clause 1: Institutions or organizations which took approval and performed storage activities before the entry into force of this guideline, must bring their activities into conformity with this guideline within 6 (six) months starting from the date when this guideline was entered into force. Since existent approvals of such institutions and organizations will be considered invalid at the end of 3 months, such institutions and organizations should apply again to the Turkey Pharmaceuticals and Medical Devices before the expiration of this period in order to operate in storage and distribution activities.

14. EFFECTIVE DATE

This Guideline comes into effect on the date of approval.