Guidelines on Good Storage & Distribution Practices of **Food Supplement Products** in Lebanon

Edition 1 – 2017

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The Quality Assurance of Pharmaceutical Products program is the Ministry of Public Health quality unit summing up all activities and responsibilities required to ensure that the drug that reaches the patient has preserved its safety and integrity. This guideline among other guidelines issued by our program arose in part out of months of hard work. By that time, a great number of people has contributed in assorted ways to this project realization and deserve special mention. I convey my gratitude to all members of the Food Supplement Committee in my humble acknowledgment. A special mention goes to Mrs. Christelle Fransawi. Her truly scientist and management intuition has exceptionally inspired and enriched this project.

Dr. Rita Karam

Table of Contents

Introduction

A Food supplement is defined under European Union legislation as foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders.

Therefore, as they are designed to supply nutrients, micronutrients and other physiologically active substances, their adequate distribution and storage is a crucial activity to maintain their quality and integrity and to protect consumers from potential health risks and to ensure that they are not provided with misleading information.

This document is intended to provide guidelines for the promotion of best practices in the storage and distribution of food supplements. Furthermore, it sets out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits food supplement products into the marketplace via the distribution chain.

The Lebanese Ministry of Public Health stresses the importance of adhering to this guideline by all parties involved in any aspect of the storage and distribution of food supplement products, as relevant to the particular role that they play, from the premises of the manufacturer of the product to the person dispensing or providing food supplement products directly to a consumer or his agent.

Glossary

The definitions provided below apply to the words and sentences used on these guidelines:

Auditing
An independent and objective activity designed to add value and improve an organization's operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes. [1]

Batch
A defined quantity of food supplement products processed in a single process or series of processes so that it is expected to be homogeneous. [1]

Batch number
A distinctive combination of numbers and/or letters used to uniquely identify a batch, for example, on the labels, its batch records and corresponding certificates of analysis. [1]

Counterfeit product
A food supplement product deliberately and fraudulently mislabeled, with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging. [1]

Contract
Business agreement for the performance of work at a specified price. [1]

Expiry date
The date given on the individual container (usually on the label) of a food supplement product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture. [1]

First Expiry/First Out (FEFO)
A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used. [1] [4]

Good Distribution Practices (GDP)
That part of quality assurance that ensures that the quality of food supplement product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded food supplement products. [1]

Good Storage Practices (GSP)
That part of quality assurance that ensures that the quality of food supplement products is maintained by means of adequate control throughout the storage thereof. [1]

Food supplement
Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. [2]

Product recall
A process for withdrawing or removing a food supplement product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency. [1] [4]

Quality system
An appropriate infrastructure encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. [1]

Standard operating procedure (SOP)
An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). [1]

Quality
The degree to which a set of inherent characteristics fulfills requirements. [3]

Continuous improvement
The recurring activity to increase the ability to fulfill requirements. [3]

Corrective actions
Action to eliminate the cause of a detected nonconformity or other undesirable situation. [3]

Preventive actions
Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. [3]

Plan Do Check Act

The methodology known as "Plan-Do-Check-Act" can be applied to all organization's operations. It can be briefly described as follows:

- Plan: establish the objectives of the system and the resources needed to deliver results in accordance with customers' requirements and the warehouse's policies and identify and address risks and opportunities.

- Do: implement what was planned.

- Check: monitor and measure operations and the resulting products and services against policies, objectives, planned activities and requirements and report the results.

- Act: take actions to continually improve process performance, as necessary. [3]

1. Organization and management

1.1 There shall be an adequate organizational structure for each entity, defined with the aid of an organizational chart that clearly identifies responsibilities, authorities and interrelationships of all personnel. [1]

1.2 Duties and responsibilities shall be clearly defined through documented job descriptions and understood by the concerned individuals, who shall be trained on their respective duties and responsibilities and who shall be aware of the relevance and importance of their activities and how they contribute to the achievement of the warehouse quality objectives and policy. [1] [3]

1.3 A designated competent person shall be appointed within the warehouse, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained. He shall be accountable on reporting to top management on the performance of the quality management system and any need for improvement and ensuring the promotion of awareness of customer requirements throughout the warehouse. [1] [3]

1.4 The organization shall design, construct and maintain buildings in a manner appropriate to the nature of the operations. Buildings shall be of durable construction which presents no hazard to the product. [4]

1.5 The organization shall give consideration to potential sources of contamination from the local environment. [4]

2. Personnel

2.1 The warehouse shall determine the necessary competence of personnel involved in the storage and distribution activities, doing work that affects the performance and effectiveness of the quality management system. [1] [3]

2.2 All personnel involved in the storage and distribution activities shall be competent on the basis of appropriate education, training, skills and experience in the requirements of good distribution and storage practices of food supplement products, as applicable. The warehouse shall provide necessary training to achieve needed competency. [1] [3]

2.3 The warehouse shall assess personnel performance in line with their job descriptions and shall take appropriate measures, detecting and providing necessary training needs to achieve needed competency. [1] [3]

2.4 Personnel training shall be based on written standard operating procedures (SOPs). They shall receive initial and continuing training relevant to their tasks, in accordance with a written training program and they shall be assessed as applicable to evaluate the effectiveness of the actions taken. Appropriate records shall be maintained, including details of subjects covered and participants trained. [1] [3]

2.5 Delivered trainings shall cover the topic of good storage and distribution practices, as well as aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. [1] [3]

2.6 Appropriate procedures relating to personnel hygiene and safety, relevant to the activities to be carried out, shall be established and observed. Such procedures shall cover health and safety, hygiene and clothing of personnel. [1]

2.7 Codes of practice and punitive procedures shall be in place to prevent and address situations where persons involved in the distribution of food supplement products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product. [1]

3. Quality system

3.1 There shall be a documented quality policy describing the overall intentions and requirements of the warehouse regarding quality, and including a commitment to comply with those requirements and continually improve the effectiveness of the quality system, as formally expressed and authorized by management. This policy shall be communicated and understood by all personnel. [1] [3]

3.2 The warehouse shall conduct a hazard analysis to assess potential hazards to the quality and integrity of food supplement products. The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised periodically to address new hazards identified during the hazard analysis. [1]

3.3 Top management shall review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall take into consideration:

a. The status of actions from previous management review meetings;
b. Changes in external and internal issues that are relevant to the quality management system;
c. Information on the performance and effectiveness of the quality management system including trends in:
   - Customer satisfaction and feedback from relevant interested parties
   - Non conformities and corrective actions
   - Warehouse performance and conformity of products and services
   - Audit results
   - The performance of external providers
d. The adequacy of resources;
e. The effectiveness of actions taken to address risks and opportunities;
f. Opportunities for improvement. [3]

3.4 Records from management review shall be retained. The outputs of the management review shall include decisions and actions related to opportunities for improvement, any need for changes to the quality management system and resource needs. [3]

3.5 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or

international guidelines) by external bodies are recommended. Such certification shall not, however, be seen as a substitute for compliance with these guidelines. [1]

Traceability of food supplement products

3.6 The warehouse shall foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. There shall be procedures in place to ensure traceability of products received and distributed in order to facilitate product recall. [1]

3.7 The warehouse shall identify all parties involved in the supply chain, depending on the product's type and national policies and legislations. [1]

3.8 Measures shall be in place to ensure that food supplement products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling or supplying the product to the consumer or to the agent. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability. [1]

4. Premises, warehousing and storage

4.1 The warehouse shall ensure that storage areas are easily accessible for load assembly as required, that aisles and assembly areas are planned so that unimpeded movement is possible to and from all parts of the warehouse; to facilitate proper stock rotation, particularly important in relation to short-life and date-marked food supplement products; and to obtain maximum utilization of available space. [5]

4.2 Storage areas shall be designed or adapted to ensure appropriate and good storage conditions. In particular, they shall be clean and dry and maintained within acceptable temperature limits. Food supplement products shall be stored off the floor and suitably spaced to permit cleaning and inspection. [1] [5]

4.3 Storage areas should be regularly inspected for cleanliness and good housekeeping, and to identify lots of products which have exceeded their shelf-life or, in the case of date-marked products, leave insufficient time for retail display. These inspections should be formally documented, including any corrective action taken if necessary. [5]

4.4 Pallets shall be kept in a good state of cleanliness and repair. They should be checked periodically for structural integrity. Where appropriate, corner boards should be positioned at the corner of each stack, both to make the corner 'stand out' visually, and to protect the product from accidental impact damage by high lift and powered pallet trucks. Pallets should be placed in prescribed places and be so spaced as to allow proper ventilation. [5]

4.5 Storage areas shall be provided with adequate lighting as high as possible above the product; the smaller the angle of light source from ground level, the smaller is the shadow made by the stack. Lights should be protected by shatterproof covers where appropriate. [1] [5]

4.6 The warehouse shall ensure that premises and storage areas undergo regularly a pest control program or must ensure that pest control activities are subcontracted to a specialized entity followed up regularly. [1]

4.7 Precautions must be taken to prevent unauthorized persons from entering storage areas and precautions. A suitable curtain should be provided at all entrances and exits in order to maintain the internal conditions of the warehouse at an appropriate level for the product therein. [1] [5]

4.8 The warehouse shall establish a procedure to identify the potential for emergency situations (such as firefighting, flooding and other emergencies) and to respond to such emergency situations. This procedure shall be tested and reviewed periodically where practical. [6]

4.9 Receiving and dispatch bays shall protect food supplement products from the weather. Receiving areas shall be designed and equipped to allow incoming containers of food supplement products to be cleaned, if necessary, before storage. [1]

4.10 All stored items should be marked with their identification to ensure that traceability is maintained. Products which have been recalled or returned or identified damaged shall be marked and physically segregated, preferably in an entirely separate storage facility. [5]

4.11 A system shall be in place to ensure that the food supplement products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). [1]

Storage conditions and stock control

4.12 Storage conditions for food supplement products shall be in compliance with the recommendations of the manufacturer. [1]

4.13 Records of temperature and humidity monitoring data shall be available for review. There shall be defined intervals for checking temperature. [1]

4.14 The equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained. Temperature mapping shall show uniformity of the temperature across the storage facility. [1]

4.15 Periodic stock reconciliation shall be performed. Stock discrepancies shall be investigated in accordance with a specified procedure. [1]

5. Vehicles and equipment

5.1 There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. [1]

5.2 All vehicles should be free from rodents, birds and insects or contamination from them; free from odors, nails, splinters, oil and grease, accumulations of dirt and debris, and should be in good repair, without holes, cracks or crevices that could provide entrances or harborage for pests. [1] [5]

5.3 Prior to loading, it is advisable that the vehicle interior (including walls, floor and ceiling) be inspected for general cleanliness, freedom from moisture foreign materials which could cause product contamination or damage to the packages. [1] [5]

5.4 A procedure should be set up to deal with consequences of accidents and damage occurring when food supplement products are in storage or distribution. [1] [5]

5.5 Security precautions should include means of deterring and preventing any tampering with goods in storage and distribution. [1] [5]

5.6 Fork lift and other trucks used within the warehouse should normally be battery driven or otherwise equipped to prevent fume or fuel contamination. [1] [5]

6. Shipment containers

6.1 The warehouse shall ensure that imported food supplement products are stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination. [1]

6.2 Written procedures shall be available for the handling of damaged and/or broken shipment containers. [1]

7. Documentation

7.1 The warehouse shall establish appropriate documented procedures and instructions related to all storage and distribution of food supplement products. [1] [5]

7.2 The title, nature and purpose of each document shall be clearly stated. The contents of documents shall be clear and unambiguous. Documents shall be laid out in an orderly fashion and be easy to check. Where a document has been revised, systems should be operated to prevent inadvertent use of superseded documents. [1] [5]

7.3 All documents shall be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and shall not be changed without the necessary authorization. [1] [5]

7.4 Procedures shall be established and maintained for the editing, review, approval, use of and control of changes to all documents relating to the distribution and storage activities. Procedures must be in place for both internally generated documents and those from external sources. [1] [5]

7.5 All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation. [1]

7.6 The warehouse shall ensure appropriate backup systems for electronic documents and records. The server room shall also be appropriated maintained to prevent any data loss. [1]

8. Complaints

8.1 There shall be a written procedure in place for the handling of complaints. [1] [5]

8.2 All complaints shall be reviewed according to written procedures describing the action to be taken, including the need to consider a recall where appropriate. Consideration shall be given to whether other batches of the product shall also be checked. [1] [5]

8.3 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint. Complaints reports should be regularly analyzed, summarized and reviewed. Results of the investigation of the complaint, shall be shared with all the relevant parties. [1] [5]

9. Recalls

9.1 The warehouse shall put in place written withdrawal and recall procedures, and these should be capable of being put into operation at short notice, at any time, inside or outside working hours. These procedures shall be checked regularly and updated as necessary. **[1] [5]**

9.2 The withdrawal and recall procedures should be shown to be practicable and operable within a reasonable time by carrying out suitable testing of the procedure. **[1] [5]**

9.3 Recalled food supplement products shall be segregated and clearly labeled as recalled products. They shall be stored in a secure, segregated area pending appropriate action. **[1] [5]**

9.4 All concerned parties shall be informed promptly of any intention to recall the product. **[1] [5]**

9.5 All records shall be readily available to the designated person(s) responsible for recalls and shall contain sufficient information. **[1] [5]**

9.6 The progress of a recall process shall be recorded and a final report issued, which includes reconciliation between delivered and recovered quantities of products. **[1] [5]**

10. Returned products

10.1 The warehouse shall establish appropriate procedures for the management of returned products in a way to ensure they are appropriately identified, segregated and handled. [1]

10.2 Food supplement products that shall be disposed shall be manipulated in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment. [1]

10.3 Where applicable, records of all returned, rejected and/or destroyed food supplement products shall be kept for a predetermined period. [1]

11. Contract activities

11.1 Any activity relating to the distribution and storage of food supplement products which is delegated to another person or entity shall be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract. [1] [5]

11.2 The contract shall define the responsibilities of each party including observance of the principles of good distribution and storage practices. [1] [5]

11.3 All contract accepters shall comply with the requirements of these guidelines and shall be audited periodically. Proof of audits shall be maintained. [1] [5]

12. Internal quality audit

12.1 The warehouse shall conduct internal audits at planned intervals to determine whether the quality system conforms to planned arrangements, to the requirements of the Good Storage and Distribution Practices of Food Supplement Products guidelines and to the quality management system requirements established by the warehouse. Internal audits allow also ensuring the quality system is effectively implemented and maintained. [3]

12.2 Internal audits shall be planned taking into consideration the status and importance of the operations and areas to be inspected, as well as the results of previous audits. [3]

12.3 The internal audit criteria, scope, frequency and methods shall be determined. [3]

12.4 The selection of internal auditors and conduct of internal audits shall ensure objectivity and impartiality of the audit process. [3]

12.5 A documented procedure shall be established to define the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results. [3]

12.6 The results of all internal audits shall be recorded. Reports shall contain all observations made during the audit and, where applicable, proposals for corrective measures. There shall be an effective follow-up program. Management shall evaluate the internal audit report and the records of any corrective actions taken. [3]

13. Self-inspection

13.1 The warehouse shall conduct a self-assessment of its operations in order to monitor implementation and compliance with the principles of the good storage and distribution practices of food supplement products and if necessary to trigger corrective and preventive measures. **[1] [5]**

13.2 Self-assessments shall be conducted in an independent and detailed way by a designated competent person. **[1] [5]**

13.3 The results of the self-assessment shall be recorded on the latest version of the self-assessment sheets available on the Lebanese Ministry of Public Health website (www.moph.gov.lb). Sheets shall include all observations and relevant evidences detected during the assessment and where applicable, proposals for corrective measures shall be submitted. An effective follow up program shall be in place. **[1] [5]**

14. Measurement, analysis and improvement

14.1 The warehouse shall determine:

- What needs to be monitored and measured;
- The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- When the monitoring and measuring shall be performed;
- When the results from monitoring and measurement shall be analyzed and evaluated.

The warehouse shall evaluate the performance and the effectiveness of the quality management system and shall retain appropriate documented information as evidence of the results. **[3]**

14.2 The warehouse shall apply suitable methods for monitoring and where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the operations to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. **[3]**

15. Going Green

15.1 The warehouse shall adopt a systematic approach to environmental management by implementing environmental practices such as adopting the 3Rs practice, for Re-use, Reduce and Recycle. The warehouse shall also keep up with environmental news and green trends to identify areas of improvement. **[7]**

15.2 The warehouse shall ensure that persons doing work under the warehouse's control are aware of its environmental approaches in order to ensure the proper implementation of environmental practices and promote a cultural shift. **[7]**

15.3 The warehouse shall go digital where possible and save paper. **[7]**

15.4 The warehouse shall institute an energy saving, waste management and recycling program and shall promote awareness among its employees to ensure proper implementation. **[7]**

References

1. WHO good distribution practices for pharmaceutical products (WHO technical report series, No. 957, 2010)

2. Food supplements directive 2002/46/EC

3. ISO 9001:2015, quality management systems requirements

4. ISO 22002:2209, prerequisite programs on food safety

5. Quality guide for food supplements - Guidance for the manufacture of safe and consistent supplements across the EU

6. OHSAS 18001:2007, occupational health and safety management systems requirements

7. ISO 14001:2015, environmental management systems requirements