

## **APPROVAL STANDARDS**

### **ATCM APPROVAL SCHEME FOR SUPPLIERS OF HERBAL MEDICINE AND ACUPUNCTURE PRODUCTS**

**(Established in January 2015)**

#### **Contents:**

1. Introduction
2. Glossary
3. Personnel
4. Premises and facilities
5. Storage requirements
6. Returned goods
7. Dispatch and transport
8. Product recall

Bibliography

## **1. Introduction**

In order to ensure the quality and safety of herbal medicine and acupuncture supplied by the wholesale businesses in the UK or elsewhere, the Association of Traditional Chinese Medicine and Acupuncture UK (ATCM) establish this Approval Scheme with its standards given herewith, as a guide for suppliers of acupuncture and herbal medicine products. Suppliers who meet these standards and approved by this scheme will be recognised by the ATCM to be designated ATCM Approved Suppliers. Wherever possible, members of ATCM are requested to obtain these products used in their own practice from the approved suppliers only.

The Scheme and its standards are established in the view that ATCM members and the public can have greater confidence in the supply chain of acupuncture and herbal medicine products and the products purchased by ATCM members are ensured to meet the required quality standards.

## **2. Glossary**

The definitions given below of some of the terms used in this document take into account the terminology of current regulations and recommendations.

### ***Acupuncture product***

Products used in and for acupuncture practice, including mainly acupuncture needles of all kinds and all sizes, as well as products that are used in and for other acupuncture related therapies such as moxibustion sticks and cones, cupping sets, massage oil, etc.

### ***Contamination***

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, or intermediate or finished product during production, sampling, packaging or repackaging, storage or transport.

### ***Cross-contamination***

Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

### ***Expiry date***

The date given on the individual container (usually on the label) of an acupuncture or herbal product up to and including 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. Expiry date sometimes is indicated as “Best Before” in the labelling.

### ***Herbal products***

Products made from herbal materials for the purpose of diagnosing, treating or preventing diseases, or maintaining good health state of people. Herbal products are mostly based on the herbal formulation from different traditional medical systems, with traditional Chinese medicine (TCM) being predominant form of traditional medicine practiced in the UK. Herbal products can be in various dose forms such as powders, granules, pills, tablets, capsules, oral liquids, ointment, lotion, cream, or plaster, etc. In this document, loose raw herbs are also deemed as herbal products.

### ***Labelling***

The action involving the selection of the correct label, with the required information, followed by line clearance and application of the label.

### ***Manufacture***

All operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products, and the related controls.

### ***Material***

A general term used to denote starting materials, reagents, solvents, process aids, intermediates, packaging materials and labelling materials.

### ***Packaging material***

Any material, including printed material, employed in the packaging of an acupuncture or herbal medicine product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

### ***Production***

All operations involved in the preparation of an acupuncture and herbal product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.

***Retest date***

The date when a material should be re-examined to ensure that it is still suitable for use.

***Storage***

The storing of acupuncture and herbal medicine products and materials up to their point of use.

***Supplier***

A person or a business providing acupuncture and herbal medicine products and materials on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where possible, suppliers should be authorized by a competent authority.

### **3. Personnel**

3.1 At each storage site there should be an adequate number of qualified personnel to achieve quality assurance objectives, with well-defined job descriptions, training and objectives so that they can competently perform the tasks required, and performance and training reviewed annually and documented.

3.2 All personnel should receive proper training in relation to good storage practice, regulations, procedures and safety.

3.3 All members of staff should be trained in, and observe high levels of, personal hygiene and sanitation.

3.4 In particular, a company is expected to include a person dealing with Quality Assurance issues, who should demonstrate suitable training for the job and should be able to demonstrate an ability to produce standards of manufacture on all products sold by the company. The company is also expected to provide an on-going programme for updating information relating to the latest QA requirements.

3.5 Personnel employed in storage areas should wear suitable protective or working garments appropriate for the activities they perform.

#### **4. Premises and facilities**

##### ***Storage areas***

- 4.1 Precautions must be taken to prevent unauthorized persons from entering storage areas.
- 4.2 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, namely starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned or recalled products.
- 4.3 Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, checked, monitored and recorded. Materials and 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.
- 4.4 Storage areas 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 storage areas. There should also be a written programme for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of the materials and products. There should be appropriate procedures for the cleaning up of any spillage to ensure complete removal of any risk of contamination.
- 4.5 Receiving and dispatch bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials and products to be cleaned, if necessary, before storage.
- 4.6 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. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.
- 4.7 There should normally be a separate sampling area for starting materials in a controlled environment. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.
- 4.8 Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned materials or products. The materials or products, and areas concerned should be appropriately identified.
- 4.9 Highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and pharmaceutical products, as well as substances presenting special risks of abuse, fire or explosion, (e.g. combustible liquids and solids and pressurized gases) should be stored in a dedicated area that is subject to appropriate additional safety and security measures.
- 4.10 Materials and products should be handled and distributed according to GMP as defined in this document.
- 4.11 Materials and products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
- 4.12 Materials and products should be stored in conditions which assure that their quality is maintained, and stock should be appropriately rotated. The “first expired/first out” (FEFO) principle should be followed.
- 4.13 Rejected materials and products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is taken on their fate.

4.14 Broken or damaged items should be withdrawn from usable stock and separated.

4.15 Storage areas should provide adequate lighting to enable all operations to be carried out accurately and safely.

***Storage conditions***

4.16 Storage conditions for acupuncture and herbal products and materials should be in compliance with the labelling, which is based on the results of stability testing. Normal storage conditions are deemed as storage in dry, well-ventilated premises at temperatures of 5–25°C or, depending on climatic conditions, up to 30°C. Extraneous odours, other indications of contamination, and intense light must be excluded.

***Monitoring of storage conditions***

4.17 Recorded temperature 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 material or product plus 1 year, or as required by national legislation. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

4.18 Equipment used for monitoring should also be calibrated at defined intervals.

## **5. Storage requirements**

### ***Documentation: written instructions and records***

5.1 Written instructions and records should be available which document all activities in the storage areas including the handling of expired stock. These should adequately describe the storage procedures and define the route of materials and products and information through the organization in the event of a product recall being required.

5.2 Permanent information, written or electronic, should exist for each stored material or product indicating recommended storage conditions, any precautions to be observed and retest dates. Professional requirements and current national regulations concerning labels and containers should be respected at all times.

5.3 Records should be kept for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date. Where national regulations prescribe that records must be retained for a certain period, this must be observed. (Otherwise such records should be retained for a period equal to the shelf-life of the incoming materials and products, where applicable, plus 1 year).

5.4 Comprehensive records should be maintained showing all receipts and issues of materials or acupuncture and herbal medicine products according to a specified system, e.g. by batch number.

### ***Labelling and containers***

5.5 All materials and products should be stored in containers which do not adversely affect the quality of the materials or products concerned, and which offer adequate protection from external influences. In some circumstances, this could include bacterial contamination.

5.6 All containers should be clearly labelled with at least the name of the material, the batch number, the expiry date or retest date, the specified storage conditions and reference to the pharmacopoeia, where applicable. Unauthorized abbreviations, names or codes should not be used.

### ***Receipt of incoming materials and products***

5.7 On receipt, each incoming delivery should be checked against the relevant purchase order and each container physically verified, e.g. by the label description, batch number, type of material or product and quantity.

5.8 The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier's batch number should the delivery comprise more than one batch.

5.9 Each container should be carefully inspected for possible contamination, tampering and damage, and any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.

5.10 When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling instructions. Containers from which samples have been taken should be labelled accordingly.

5.11 Following sampling, the goods should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

5.12 Materials and products should remain in quarantine until an authorized release or rejection is obtained.

5.13 Measures should be taken to ensure that rejected materials and products cannot be used. They should be stored separately from other materials and products while awaiting destruction or return to the supplier.



***Stock rotation and control***

5.14 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.

5.15 All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue.

5.16 In manufacturing facilities, partly used containers of materials and products should be securely reclosed and resealed to prevent spoilage and/or contamination during subsequent storage. Materials and products from containers which have been opened or partly used should be used up before those in unopened containers.

5.17 Damaged containers should not be issued unless the quality of the material has been shown to be unaffected. Where possible, this should be brought to the attention of the person responsible for quality control. Any action taken should be documented.

***Control of obsolete and outdated materials and products***

5.18 All stocks should be checked regularly for obsolete and outdated materials and products. All due precautions should be observed to prevent the issue of outdated materials and products.

## **6. Returned goods**

6.1 Returned goods, including recalled goods, should be handled in accordance with approved procedures and records should be maintained.

6.2 All returned goods should be placed in quarantine and returned to saleable stock only after this has been approved by a nominated, responsible person following a satisfactory quality re-evaluation.

6.3 Any stock reissued should be so identified and recorded in stock records. Materials and products returned from patients should not be taken back as stock, but should be destroyed.

## **7. Dispatch and transport**

7.1 Materials and products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained.

7.2 Special care should be exercised when using dry ice in cold chains. In addition observing to safety precautions, it must be ensured that the materials or product does not come in into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing.

7.3 Where appropriate, the use of devices to monitor conditions such as temperature during transportation is recommended. Monitoring records should be available for review.

7.4 The dispatch and transport of materials and products should be carried out only after receipt of a delivery order. The receipt of the delivery order and the dispatch of the goods must be documented.

7.5 Dispatch procedures should be established and documented, taking into account the nature of the materials and products concerned and any special precautions that might be required.

7.6 The outside container should offer adequate protection from all external influences and should be indelibly and clearly labelled.

7.7 Records for dispatch should be retained, stating at least:

- the date of dispatch;
- the customer's name and address;
- the product description, e.g. name, dosage form and strength (if appropriate), batch number and quantify;
- the transport and storage conditions.

7.8 All records should be readily accessible and available on request.

## 8. Product recall

8.1 There should be a procedure to recall from the market, promptly and effectively, acupuncture and herbal medicine products and materials known or suspected to be defective.

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