

## **The Quality System of Martin Bauer Spa (Italy)**

Martin Bauer Spa (Italy) manufactures herbal, fruit and medicinal teas (coarse cut and fine cut), as well as herbal source materials for pharmaceuticals, food and cosmetics (e.g. herbal powder).

The dried raw herbal materials are cultivated. Some under controlled conditions or they grow and are being collected in the wild.

The raw herbal materials that are grown under controlled conditions are cultivated and processed in accordance with the guidelines for good agricultural practice (GAP).

When the goods are being received at our stock a visual inspection on any infestation, mould, contamination, feeding traces or other conspicuous indications (e.g. unusual smell), as well as wet spots and damage to the packaging materials or to the herbal raw materials themselves is obligatory.

Damaged or contaminated goods are rejected and are initially put into quarantine. Goods that comply with the requirements for quality are put into storage in special purpose-built halls (with computerised stock management). These buildings have natural ventilation and are equipped with automatic fast-closing doors to prevent birds, rodents and insects from getting inside.

The incoming raw herbal materials first of all are being inspected organoleptic by the drawer of the samples and the purchaser. A sample (according to sampling plan MB, at least GMP = root N+1) of the material is being analysed at the laboratory according to defined specification and following released through the direction of control. The complexity of the analysis depends on the classification of the raw herbal material as ungraded quality (not graded as food or pharmaceutical - lowest level), food quality or as raw material for pharmaceuticals. The specification is based on the Codex Herbarum guidelines: Foodstuff specifications for herbal infusion products, the stipulations of the European Pharmacopoeia or the pharmacopoeias of other EU member states. Inspection and testing instructions are also prescribed for specific products in addition to this. Inspections and tests are performed and documented regularly, but not on every batch and every quality, with respect to the following quality parameters:

- Identification
- physical and chemical test
- microbiological quality
- mycotoxins
- residual pesticides
- heavy metals
- radioactivity



- infestation
- visible signs or other indications of deterioration

The microbiology is only being analysed upon agreement with the customer, resp. if explicit a product conform to a special requirement, such as EHIA, Ph.Eur. 4a or Ph.Eur. 4b is being ordered.

Herbal materials naturally have a higher levels of micro-organisms than those found in most other foodstuffs.

Sampling plays a crucial part in the precision of the determination of the levels of microbial contamination, which are very heterogeneously distributed in a lot, in particular in a lot of food products with a large particle size such as whole herbal drug.

The heat from boiling water kills a large number of the micro-organisms present in the dry herbs thereby ensuring that the hot beverage is perfectly safe for consumption.

In other application is highly recommended a reduction of the number of micro-organism by post-processing treatments.

The aflatoxin content must be within the tolerances laid down in the Directive on the maximum admissible mycotoxin load dated 2nd June 1999 and/or the Directive covering the prohibition on the use of aflatoxin dated 19th July 2000.

The test for residual pesticides is carried out on food and pharmaceutical qualities according to a plan for randomized tests, which is being updated annually or additionally upon need due to new cognitions. It is being assessed regarding critical products. Ungraded qualities are only being analysed upon agreement with the customer. The test for residual pesticides is being carried out on the raw material (incoming goods inspection) as a general rule. The maximum quantities of residual pesticides are laid down in the requirements of the EC regulations covering maximum residual substances and/ or the stipulations of the European Pharmacopoeia (see the list in data sheet).

The heavy metal content is restricted in accordance with the relevant product specification inserted in data sheet and are being analysed upon agreement in intervals or on every batch.

Cleaning and purification instructions have been drawn up in writing for all rooms and production facilities. The cleaning and purification measures are documented.

Infestation monitoring and assessment measures have been implemented, with bait that is weighed continuously and sticky pheromone traps, checking the number of caught insects at regular intervals. Written instructions have been drawn up for these activities and all monitoring measures are documented.



Where there are signs of pest attack in the warehouse, the infested zone is localised and the causes are investigated. Infested and potentially jeopardised goods are treated with carbon dioxide according to the prescribed special method.

Various particularly critical products receive an additional treatment as a precautionary measure prior to shipping, to ensure that the products are free of any as yet undiscernibly pest attack on delivery.

Herbal raw materials of ungraded qualities may contain foreign components, such as bits of wood, metal wire or nails, seeds, sand or grass etc. It is possible to filter out these unwanted components by means of suitable cleaning and screening processes, such as metal separation (removing metal parts by means of inductance measurement and magnets), sieving and pneumatic sifting processes and special separating techniques with vibrating inclines. For a good result mostly a milling is necessary.

Production equipment and facilities are cleaned with vacuum cleaners, brooms, brushes and compressed air. Dust extraction systems are installed throughout the entire production area.

Representative samples are taken after every stage in the production process and these are inspected for conformity with the product specification by Quality Control. The products are accepted or rejected according to the results of these inspections. The inspection results and subsequent analyses are documented.

Most of the quality control work is performed by internal Quality Control, accredited of Health Italian Minister pharmaceutical laboratory.

Disposable packaging materials are generally used to dispatch the manufactured goods. These take the form of paper sacks or containers made of plastic, such as lined plastic bags and Big Bags made of polypropylene and polyethylene respectively. If these Big Bags are to be used again, they are vacuumed and beaten clean. They subsequently undergo a disinfestation treatment to prevent the next filling being jeopardised by any pests or parasites left in the bag. The bags or sacks are loaded onto pallets for transportation and these pallets are also disinfested in the same manner at regular intervals.

The warehouse, production and quality control personnel are qualified in accordance with the requirements of their respective jobs and attend regular training courses. These courses deal with such subjects as personal hygiene (cleanliness of working apparel and at the workplace, washing hands, conduct in the event of injury or infectious disease, works hygiene agreement) and other critical aspects that can exert a negative influence on product quality.

The production area is equipped with an adequate number of sanitary installations and social facilities to guarantee the necessary standard of production and personal hygiene.



Purchasing, storage, production, quality control, development, sales and shipping are integral elements of the Martin Bauer quality management system in accordance with described in the Martin Bauer Quality Manual.

The quality management system also includes an HACCP concept - whereby critical control points are identified and monitored within the framework of internal studies - the stipulations of the Food Hygiene Directive and the requirements of the drugs legislation for pharmaceutical companies (GMP – see attached certificate).

The effectiveness of the quality management system (see organization chart) ensures that active quality assurance is practised to guarantee a consistently appropriate standard of product quality in an aim to achieve customer satisfaction.