

LINK NATURAL ACHIEVES GMP STATUS

By Janitha Mendis*

What is GMP?

Good manufacturing practice (GMP) is a guideline which ensures that the manufacturing process is unfailingly conducted and controlled to the standard operating procedures(SOP)/quality standards as appropriate to their intended use. The set of guidelines have an effect on production, development, production related services and testing.

"Good manufacturing practice is a guideline which ensures that the manufacturing process is unfailingly conducted and controlled to the standard operating procedures (SOP)/quality standards as appropriate to their intended use."

It also includes concerns on Personnel, Sanitation and Hygiene, Buildings and Facilities, Equipment, Production and Process control and Records and Reports.

GMP along with Standard Operating Procedures (SOP) is a prerequisite to the development of Hazard Analysis & Critical Control points (HACCP)

GMP – What it means to Link Natural

Getting closer to its vision of becoming a world class manufacturer and supplier of Ayurvedic pharmaceuticals and herbal care products, Link Natural was recently able to establish a Good Manufacturing Practices system in its factory and precincts. The certification was given on 3rd April 2013. GMP has a significant impact on the entire production process, and can be used as a management control tool.

There is no doubt that achieving GMP has been a profitable investment and it has become the production enriching avenue at Link Natural.

Personnel

In establishing and maintaining GMP standards at Link Natural, totally reliance has been placed upon the people who are directly involved with the process. In order

to minimize the potential contamination associated with all personnel, it is mandatory that employees wear the uniforms, overalls and factory shoes provided by the company, when entering a work station.

All personnel are instructed to have trimmed nails, sans finger nail polish and false finger nails. Chewing betel is strictly forbidden, with lipstick being another taboo.

As per the Link Natural jewelry policy, all jewelry must be removed before entering a production section. The Production supervisor maintains a Personal Hygiene Record Sheet where daily conditions are recorded and updated monthly. Link Natural employees undergo annual health checks and eye examinations prior or during the employment as appropriate. Employees are also given sufficient training on GMP as per the training schedule. Visitors or untrained personnel will not be taken to the manufacturing high risk areas, as a rule, but if the necessity arises, they are provided with prescribed clothing.

Equipment and utensils

Equipment and utensils are located in such a way as to minimize the risk of errors, avoid contamination and ensure sanitation.

"Surfaces in direct contact with products and equipment have been made with corrosion – resistance, non – absorbent, impervious material, and non-toxic substances as appropriate to the products used."

Surfaces in direct contact with products are made of corrosion – resistance, non – absorbent, impervious material, and non-toxic substances as appropriate to the products used. Fixed pipe lines, gas lines electrical conduits etc. are labeled in compliance with BSI standards, indicating its content and direction of flow. Preventive maintenance schedules are put in place to reduce the risk of breakdown which might cause contamination. A Calibration program for equipment is also effectively conducted twice a year by internal and outside calibration service providers.

* Assistant Manager, Manufacturing standards & Quality Systems, Link Natural

Buildings and facilities

Contamination can be significantly reduced through properly designed, well located, and organized buildings and facilities. A well designed ventilation system is in place mainly in the Sudantha, Samahan and essential oil plants to minimize the potential for contamination of products through dirt, sweat and vapour. A properly designed dust collection system is also in place to remove dust emissions in the grinding section in order to reduce the impact on cross contamination of raw materials at a significant level. Humidity has been controlled at an appropriate level in the production areas. Link Natural production floors are marked as personnel flow, material flow and finished goods flow and ceilings are so fitted in all manufacturing work station in order to ensure the safety of the products.

Link Natural operates an efficient waste management system along with an aerobic water treatment plant, incineration process, composting, recycling and reuse. The premises are always free of trash and debris due to proper ground cleaning program. Pest control is regulated through an outside Pest control agency.

Production and process control

Link Natural process manual relating to the ISO 9001 describes the procedures for all the processes from the receiving of raw material to the distribution of final products. In order to maintain a greater product quality and safety assurance, a HACCP plan has been developed for each of the manufacturing processes and there are 12 CCPs in the processes according to HACCP decision tree criteria. Finished products are handled and stored in such a way as to prevent the contamination, packaging damages etc. Instructions have been given to the stores keeper relating to storage procedure and inspections. Link Natural has introduced modern management control concept named "Performance Wheel" in each section in the factory focusing on the continuous improvement of quality. Link Natural Key Performance Index will evaluate the process monthly so as to make a snap shot about the process, through three main criteria such as Cost, Quality and Delivery.

Sanitary operations, facilities and control

Link Natural sanitary management system has a significant effect on ensuring that the product is free from contamination of micro-organism and foreign debris.

Food graded cleaning liquids and powders are given for cleaning activities in production areas. Cleaning is done according to the given cleaning schedule and instructions. Water taken to the factory premises from the

municipal supply, portable water suppliers and natural well water is tested twice a year by outside laboratory service providers. Hand washing facilities have been established at the number of entry points including foot operated taps, food graded washing liquid and hand dryer/tissues. "Machine/Equipment Cleaning Tag" will ensure details of the cleaning processes carried out.

Quality control

Link Natural R&D/QA Department is responsible for holding or the release of the product depending on the final quality test report. All raw materials and packaging materials are checked (using standards sampling methods) by the QA officers and depending on the results it can be accepted, rejected or re-worked. All the products undergo through in-process, online and final product testing.

Product recall

The Product recall procedure of Link Natural consists of identification of defective product, recalling the product (includes recall strategy), monitoring the effectiveness, termination of product recall and post recall reporting.

As always, Link Natural strives to deliver quality products to its customers, and achieving GNP status will no doubt be a main player in this.

