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பொதுசனக் கருத்துரைக்கான கட்டளை வரைவு  
DRAFT STANDARD FOR PUBLIC COMMENT

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අදහස් එවිය යුතු අවසාන දිනය  
அபிப்பிராயங்களை தெரிவிப்பதற்கான இறுதித்திகதி  
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Draft Sri Lanka Standard  
REQUIREMENTS FOR GOOD MANUFACTURING PRACTICES  
(DSLS ..... : .....)

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இவ்வரைவு இலங்கைக் கட்டளையெனக் கருதப்படவோ அன்றிப் பிரயோகிக்கப்படவோ கூடாது  
This draft should not be regarded or used as a Sri Lanka Standard.

අදහස් එවිය යුත්තේ : ශ්‍රී ලංකා ප්‍රමිති ආයතනය, 17, වික්ටෝරියා පෙදෙස, ඇල්විටිගල මාවත, කොළඹ 08.

Comments to be sent to: SRI LANKA STANDARDS INSTITUTION, 17, VICTORIA PLACE,  
ELVITIGALA MAWATHA, COLOMBO 08.

නැඳින්වීම

මෙම ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත , ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සකසන ලදුව, සියලුම උදෙසාම අංශ වලට තාක්ෂණික විවේචනය සඳහා යටත් ලැබේ.

අදාළ අංශ භාර කමිටු මාර්ගයෙන් ආයතනයේ මහා මණ්ඩල වෙත ඉදිරිපත් කිරීමට පෙර , ලැබෙන සියලුම විවේචන ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සලකා බලා අවශ්‍ය වෙනස් කෙටුම්පත සංශෝධනය කරනු ලැබේ.

මෙම කෙටුම්පතට අදාළ යෝජනා හා විවේචන නියමිත දිනට පෙර ලැබෙන්නට සැලැස්වුවහොත් අභය කොට සලකනු, තවද, මෙම කෙටුම්පත පිළිගත හැකි බැව් හැඟෙන අය ඒ බව දන්වන්නේ නම් එය ආයතනයට උපකාරී වනු ඇත.

මේ පිළිබඳව එවන සියලුම ලිපි පහත සඳහන් ලිපිනයට එවිය යුතුය.

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17, වික්ටෝරියා පෙදෙස,  
ඇල්විටිගල මාවත,  
කොළඹ 08.

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Introduction

This Draft Sri Lanka Standard has been prepared by the Sri Lanka Standards Institution and is now being circulated for technical comments to all interested parties.

All comments received will be considered by the SLSI and the draft if necessary, before submission to the Council of the Institution through the relevant Divisional Committee for final approval.

The Institution would appreciate any views on this draft which should be sent before the specified date. It would also be helpful if those who find the draft generally acceptable could kindly notify us accordingly.

All Communications should be addressed to:

The Director General  
Sri Lanka Standards Institution,  
17, Victoria Place,  
Elvitigala Mawatha,  
Colombo 08.

DSLS:

**DRAFT SRI LANKA STANDARD  
REQUIREMENTS FOR GOOD MANUFACTURING PRACTICES**

**DSLS:**

**Gr.**

For Public Comments

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**Colombo 08**  
**Sri Lanka**

## DRAFT SRI LANKA STANDARD REQUIREMENTS FOR GOOD MANUFACTURING PRACTICES

### FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committees on Food Products, Textile & Garments, Leather & Leather products, Paper, Board & Packaging, Nano Technology, Chemical & Polymer Technology, Ayurveda, Agriculture Sector and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on .....

Good Manufacturing Practices (GMP) consist of processes, procedures and documentation that ensures manufacturing products, such as food, agricultural products, cosmetics, coir, pharmaceutical, ayurveda, chemical & chemical based products and services such as catering are consistently produced/ offered and controlled according to set standards. GMP helps ensure the proper design, monitoring, and control of the manufacturing processes, facilities and services provided. Organizations that adhere to this standard help to assure the identity, strength, and quality of their products.

Implementing GMP reduces losses and waste, avoid seizures, fines, legal actions and recalls. Overall, it protects both organization and consumer from quality and safety issues. It helps to increase consumer confidence.

### 1 SCOPE

This standard prescribes the requirements for Good Manufacturing Practices for manufacturing and/or related service providing organizations.

### 2 REFERENCES

ISO 9000 Quality management systems - Fundamentals and vocabulary

### 3 DEFINITIONS

For the purpose of this Standard, the following definitions shall apply:

**3.1 competence:** GMP is most effective when all employees understand and apply the skills, training, education and experience needed to perform their roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

**3.2 corrective action:** action to eliminate the cause of a nonconformity and to prevent recurrence

### NOTE

1. *There can be more than one cause for a nonconformity*

2. *Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.*

**3.3 objective:** result to be achieved

#### NOTES

- 1 *An objective can be strategic, tactical, or operational.*
- 2 *Objectives can relate to different disciplines (such as financial, health and safety, and environmental objectives) and can apply at different levels.*
- 3 *An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).*

**3.4 policy:** intentions and direction of an organization as formally expressed by its top management.

**3.5 infrastructure:** system of facilities, equipment and services needed for the operation of an organization

**3.6 internal audit:** a systematic, independent documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. They are conducted by the organization itself. Independence can be demonstrated by the freedom from responsibility for the activity being audited.

**3.7 management review:** a regular evaluation of the performance of management systems based on their purpose and goal, as well as whether they are producing desirable results aligned with the organization's needs.

**3.8 non-conformity:** non-fulfilment of a requirement.

**3.9 product:** output of an organization that can be produced without any transaction taking place between the organization and the customer.

**3.10 service:** output of an organization with at least one activity necessarily performed between the organization and the customer.

**3.11 traceability:** ability to trace the history, application or location of an object

#### NOTE

1. When considering a product or a service, traceability can relate to the origin of materials and parts the processing history the distribution and location of the product or service after delivery.
2. In the field of metrology, the definition in ISO/IEC Guide 99 is the accepted definition.

**3.12 work environment:** set of conditions under which work is performed.

#### NOTE

1. *Conditions can include physical, social, psychological and environmental factors (such as temperature, lighting, recognition schemes, occupational stress, ergonomics and atmospheric composition).*

## **4 REQUIREMENTS**

### **4.1 General**

Relevant code of practice(s) (see Appendix A), product specifications and regulatory requirements shall be followed as applicable.

### **4.2 Management Responsibility**

Top management shall demonstrate leadership and commitment with respect to Good Manufacturing Practices (GMP) by:

- a) taking accountability for the effectiveness of GMP;
- b) ensuring that the GMP policy and the GMP objectives are established for GMP;
- c) ensuring that the resources needed for GMP are available;
- d) communicating the importance of effective GMP management and of conforming to the GMP requirements;
- e) ensuring that GMP achieves its intended result;
- f) engaging, directing and supporting persons to contribute to the effectiveness of GMP;
- g) promoting improvement.

### **4.3 GMP Policy**

The organization's management shall define a policy with regard to GMP of the organization.

The GMP policy shall:

- a) be documented and maintained;
- b) be communicated, understood and applied within the organization.

### **4.4 Organizational roles, responsibilities and authorities**

Top management shall ensure that the roles, responsibilities and authorities for relevant personnel within the scope of GMP are assigned, documented and communicated at all levels in the organization.

### **4.5 GMP objectives**

The organization shall establish objectives in order to maintain and continually improve GMP.

### **4.6 Support**

#### **4.6.1 Resources**

The organization shall determine and provide resources needed for implementation of GMP.

##### **4.6.1.1 People**

The organization shall ensure that persons necessary for the effective implementation of GMP are provided.

#### **4.6.1.2 Infrastructure**

The organization shall provide infrastructure necessary to achieve conformity with the requirements of GMP.

#### **4.6.1.3 Work environment**

The organization shall provide the work environment necessary to achieve conformity with the requirements of GMP.

#### **4.6.1.4 Facilities for workers**

The organization shall provide adequate facilities for workers. Such facilities should be suitably located and should not be used for other purposes.

#### **4.6.2 Competence**

The organization shall:

- a) ensure that employees responsible for the operation of key activities, are competent on the basis of appropriate education, training and/or experience;
- b) retain appropriate evidence of competence.

#### **4.6.3 Awareness**

The organization shall ensure that all relevant persons doing work under the organization's control shall be aware of:

- a) the GMP policy;
- b) the GMP objectives; and
- c) their roles and responsibilities.

#### **4.6.4 Communication**

The organization shall determine appropriate methods of internal and external communication relevant to GMP.

#### **4.6.5 GMP Documentation**

The structure of the GMP documentation shall include policies, objectives, procedures, work instructions, process flow diagram(s) & process control plan(s), as appropriate.

The organization shall identify and document the controls pertaining to the outsourced processes as appropriate.

The organization shall have a method for the control of documents and records relevant to GMP.

The organization shall identify the external documents and control their distribution to prevent the use of obsolete documents.

The organization shall identify and maintain necessary records relevant to GMP. Those shall be readily retrievable and be stored to prevent damage or loss.

## **4.7 Operational planning and control**

### **4.7.1 Establishment of the process flow diagram(s) & process control plan(s)**

The organization shall document process flow diagram(s) & process control plan(s). The process flow diagram(s) & process control plan(s) should have a sequence of activities. The process control plan(s) shall carry information with regard to activities, responsibilities, control parameters, frequency of sampling and testing and relevant documents and records, at the stages of incoming material control, in process control and release of the finished product(s) and/or service(s).

### **4.7.2 Storage facilities**

The organization shall:

- a) provide adequate storage facilities in order to preserve the product;
- b) dispose of any rejected material in a proper manner.

## **4.8 Identification and traceability**

The organization shall use suitable means to identify product(s) and service(s) where it is necessary to ensure the conformity. The organization shall control the unique identification of the products and services where traceability is a requirement, and shall retain the evidence of traceability.

## **4.9 Control of monitoring and measuring resources**

The monitoring and measuring equipment used shall be:

- a) calibrated or verified at specified intervals prior to use;
- b) identified to enable the calibration status to be determined;
- c) safeguarded from adjustments that would invalidate the measurement results;
- d) protected from damage and deterioration.

The results of calibration and/or verification shall be retained.

## **4.10 Emergency preparedness and response**

The organization shall respond to potential emergency situations, including:

- a) establishing planned activities for emergency situations, including the provision of first aid;
- b) providing training for emergency situations;

The organization shall maintain relevant documents and retain records.

## **4.11 Performance evaluation**

### **4.11.1 Internal audit**

The organization shall conduct internal audits at planned intervals to provide information on suitability and effective implementation of GMP.



#### **4.11.2 Management review**

The management shall review GMP at specified intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the GMP policy and the objectives stated by the organization as appropriate. Records of reviews shall be retained.

The management shall meet at appropriate intervals to discuss:

- a) GMP policy and objectives;
- b) internal and external audit reports;
- c) process and product nonconformities;
- d) adequacy of staff and machinery and/or equipment; and
- e) customer complaints on product(s) and/or service(s).

#### **4.12 Nonconformity and corrective action**

When a nonconformity occurs, including any arising from complaints, the organization shall:

- a) take action to control and correct it;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity,
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;

The organization shall retain records as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

For Public Comments

## APPENDIX A

## Code of Practices – Food

Sl No.	Standard No.	Title of the Standard
1.	SLS 143	Code of practice for general principles of food hygiene
2.	SLS 208	Code of hygienic practice for the processing of lobsters and prawns
3.	SLS 209	Code of hygienic practice for the manufacture of fruit and vegetable products (processed)
4.	SLS 393 Part 1	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuffs -General rules for the preparation of the initial suspension and decimal dilutions
5.	SLS 393 Part 2	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuffs - Specific rules for the preparation of meat and meat products
6.	SLS 393 Part 3	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuffs - Specific rules for the preparation of fish and fishery products
7.	SLS 393 Part 4	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuff - Specific rules for the preparation of miscellaneous products
8.	SLS 393 Part 5	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuffs - Specific rules for the preparation of milk and milk products
9.	SLS 393 Part 6	Code of practice for preparation of test samples, initial suspension and decimal dilutions for microbiological examination of food and animal feeding stuffs - Specific rules for the preparation of samples taken at the primary production stage
10.	SLS 454	Code of practice for harvesting handling and packaging of betel leaves
11.	SLS 467 Part 1	Code of practice for labelling of prepackaged foods - general guidelines
12.	SLS 467 Part 2	Code of practice for labelling of prepackaged foods - guidelines on claims
13.	SLS 467 Part 3	Code of practice for labelling of prepackaged foods - date marking
14.	SLS 686	Code of practice for storage of paddy and rice
15.	SLS 871 Part 1	Code for use of plastic materials for food contact applications - general guidelines for manufacture
16.	SLS 871 Part 2	Code for use of plastic materials for food contact applications - polyvinyl chloride (PVC)
17.	SLS 871 Part 5	Code for use of plastic materials for food contact applications - polyethylene phthalate (PET)
18.	SLS 871 Part 6	Code for use of plastic materials for food contact applications - polystyrene (PS)

19.	SLS 872	Code of hygienic practice for dairy industries
20.	SLS 873 Part 1	Code of hygienic practice for canned foods - Low acid canned foods
21.	SLS 873 Part 2	Code of hygienic practice for canned foods - Acidified low acid canned foods
22.	SLS 902	Code of practice for canning of fish
23.	SLS 956	Code of hygienic practice for catering establishments
24.	SLS 965	Code of hygienic practice for biscuit manufacturing and bakery units
25.	SLS 972	Code of practice for packaging of lobsters and prawns for export
26.	SLS 974	Code of hygienic practice for fresh fish
27.	SLS 975	Code of hygienic practice for frozen fish
28.	SLS 996	Code of practice for qualification and certification of personnel for non-destructive testing
29.	SLS 1002	Code of practice for parboiling of paddy
30.	SLS 1003	Code of practice for processing of cashew nuts
31.	SLS 1004	Code of hygienic practice for molluscan shellfish
32.	SLS 1005	Code of hygienic practice for the products for aquaculture
33.	SLS 1017	Code of hygienic practice for salted fish
34.	SLS 1018	Code of hygienic practice for cephalopods
35.	SLS 1021	Code of hygienic practice for the collecting, processing and marketing of natural mineral waters
36.	SLS 1040 Part 1	Code of practice for harvesting and handling of fresh fruits and vegetables - Pineapples for exports
37.	SLS 1040 Part 2	Code of practice for harvesting and handling of fresh fruits and vegetables - Embul bannas for exports
38.	SLS 1040 Part 3	Code of practice for harvesting and handling of fresh fruits and vegetables - Rambutan
39.	SLS 1213	Code of practice for crabs
40.	SLS 1315 Part 1	Code of practice for tea industry - Good agricultural practices for the cultivation of tea
41.	SLS 1315 Part 2	Code of practice for tea industry - Good manufacturing practices for processing of black tea
42.	SLS 1327	Code of hygienic practice for spices and other dried aromatic plant
43.	SLS 1412 Part 1	Code of practice for fresh fruits and vegetables - Fresh fruits and vegetables (whole)
44.	SLS 1412 Part 2	Code of practice for fresh fruits and vegetables - Ready-to-eat fresh pre-cut fruits and vegetables
45.	SLS 1412 Part 3	Code of practice for fresh fruits and vegetables - Sprout production
46.	SLS 1564	Code of hygienic practice for Processing of meat

### Code of Practices - Non-food

Sl No.	Standard No.	Title of the Standard
1.	CS 159	Code of practice for seasoning of timber
2.	SLS 254	Code of practice for retreading pneumatic tyres
3.	SLS 322	Code of practice for cleaning of metals prior to electroplating

4.	SLS 323	Code of practice for packaging of natural rubber latex in drums
5.	SLS 367	Code of practice for harvesting and handling of anthuriums
6.	SLS 385	Code of practice for packaging of Standard Lanka Rubber
7.	SLS 408	Code of practice for laying of in-situ terrazzo finish
8.	SLS 410	Code of practice for the harvesting, handling and packaging of orchids
9.	SLS 450	Code of recommended practice for mechanical polishing of metals for electroplating
10.	SLS 482	Code of practice for hot-dip galvanizing of iron and steel
11.	SLS 544	Code of practice for handling and storage of bagged fertilizers
12.	SLS 631	Code of practice for Joints used in wooden furniture
13.	SLS 703 Part 1	Code of practice for electrical installations - Small residential buildings
14.	SLS 703 Part 2	Code of practice for electrical installations - Larger buildings including flats, commercial and office buildings
15.	SLS 703 Part 3	Code of practice for electrical installations - Industrial buildings
16.	SLS 745 Part 1	Code of practice for the design and construction of septic tanks and associated effluent disposal systems - Small systems disposing to ground
17.	SLS 745 Part 2	Code of practice for the design and construction of septic tanks and associated effluent disposal systems - Systems disposing to surface, systems for on-site effluent reuse and larger systems disposing to ground
18.	SLS 771	Code of practice for reception of television broadcasting
19.	SLS 876 Part 1	Code of practice for installation of asbestos-cement corrugated sheets and fixing accessories - Components and design considerations
20.	SLS 876 Part 2	Code of practice for installation of asbestos-cement corrugated sheets and fixing accessories - Installation and maintenance
21.	SLS 887	Code of practice for basic training and testing of manual metal arc welder
22.	SLS 925	Code of practice for target quality setting and controlling net contents of packaged goods
23.	SLS 973 Part 1	Code of practice fumigation of agricultural produce - General safety requirements
24.	SLS 973 Part 2	Code of practice fumigation of agricultural produce - Phosphine fumigation
25.	SLS 973 Part 3	Code of practice fumigation of agricultural produce - Methyl bromide
26.	SLS 996	Code of practice for qualification and certification of personnel for non-destructive testing
27.	SLS 1013	Code of practice for curing and preservation of hides and skins
28.	SLS 1014	Code of practice for flaying of hides and skins
29.	SLS 1170 Part 1	Code of practice on identification, grading and marking of imported construction timber - Grading, marking, and guidance on usage
30.	SLS 1170 Part 2	Code of practice on identification, grading and marking of imported construction timber - Nomenclature, identification, and general information

31.	SLS 1170 Part 3	Code of practice on identification, grading and marking of imported construction timber - Properties
32.	SLS 1170 Part 4	Code of practice on identification, grading and marking of imported construction timber - Documentation for grading
33.	SLS 1196 Part 1	Code of practice for transport, storage and handling of LPG - General provisions
34.	SLS 1196 Part 2	Code of practice for transport, storage and handling of LPG - Design, installation and maintenance of bulk LPG storage at fixed installations
35.	SLS 1196 Part 3	Code of practice for transport, storage and handling of LPG - LPG piping system - design and installation
36.	SLS 1196 Part 4:	Code of practice for transport, storage and handling of LPG - Safe filling of LPG cylinders at filling plants
37.	SLS 1196 Part 5	Code of practice for transport, storage and handling of LPG - Storage of full and empty LPG cylinders and cartridges
38.	SLS 1196 Part 6	Code of practice for transport, storage and handling of LPG - Use of LPG in cylinders at residential premises
39.	SLS 1196 Part 7	Code of practice for transport, storage and handling of LPG - Transport of LPG in cylinders by road, rail or on water
40.	SLS 1196 Part 8	Code of practice for transport, storage and handling of LPG - Safe handling and transport of LPG in bulk by road
41.	SLS 1263	Code of practice for recycling of plastics
42.	SLS 1292 Part 1	Code of practice for design and construction of biogas systems - Domestic biogas systems
43.	SLS 1311	Code of practice for design and construction of micro hydropower systems
44.	SLS 1314	Code of practice for packaging of agro pesticides for retail market
45.	SLS 1337	Code of practice for refrigeration
46.	SLS 1348	Good manufacturing practices (GMP) for cleansing materials
47.	SLS 1378	Code of practice for application of thermoplastic road marking materials
48.	SLS 1415	Code of practice for storage of paper and board
49.	SLS 1416	Code of practice for packaging of paper and board
50.	SLS 1433	Code of practice for recycling of paper
51.	SLS 1441	Code of practice for manufacture of incense sticks
52.	SLS 1443	Code of practice for use of plastic containers for non-food products
53.	SLS 1444	Code of practice for manufacture of plastic containers
54.	SLS 1465	Code of practice for application of pesticides
55.	SLS 1487	Good manufacturing practice (GMP) for coir fibre pith substrate
56.	SLS 1522	Code of Practice for grid connected photovoltaic power systems – requirements for system documentation, installation, testing & commissioning
57.	SLS ISO 22716	Guidelines on Good manufacturing practices For cosmetics
58.	SLS ISO/IEC 27011	Information technology - security techniques - code of practice for information security controls based on ISO/IEC 27002 for telecommunications organizations

59.	SLS ISO/IEC 27017	Information technology - security techniques - code of practice for information security controls based on ISO/IEC 27002 for cloud services
60.	SLS ISO/IEC 27018	Information technology - security techniques - code of practice for protection of personally identifiable information (PII) in public clouds acting as pii processors
61.	SLS ISO/IEC 27050 Part 3	Information technology - electronic discovery – code of practice for electronic discovery

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For Public Comments