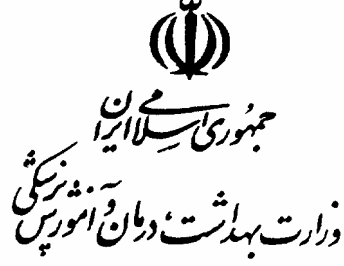


Code of document:GMP/F-002



Self assessment checklist for GMP in Food & Beverage manufacturers

**Ministry of Health & Medical Education
Food and Cosmetic Control Affairs
October 2007**

GMP Self-assessment Report

1. Name and address of the site:

Name:	
Address:	
Date of visit:	Date of last visit (if the site has been visited before by MOH):
Scope of assessment:	
Name of assessors:	
Name and kind of products(Flow diagram of identified products must be attached):	
Number of branches with their addresses:	
List of countries that products are exported (documents must be attached if the products export to ENAJA countries):	
Type of packaging:	
Certificates & approval(copy of valid certifications must be attached): ISO9000 series ISO14000 ISO17025 HACCP system ISO22000:2005 IFS BRC CFS(Free sale) FDA Others	

2. Facility, including:

- Description of its size and nature of construction
- Number of staff
- Amount and type of products made
- The company's quality policy

3. The manufacturing facility:

- Floor plan, nature of construction, (i.e. type of building, is it open or closed construction, type of walls), air quality and type of air filtration system if relevant.
- Method of cleaning relevant to the type of product, pest control program (if relevant).
- Details of any other manufacturing activity carried out on site.
- Good quality photographs can be used to illustrate features, where appropriate.

4. Storage facilities:

- Brief description of the storage facility.
- Procedures and facilities for quarantining incoming materials (both raw materials and finished product) until approved for release.
- Procedures for quarantining and disposal of reject material.
- QA procedures for releasing both raw materials and finished product from storage and quarantine.

5. Sanitation:

- Description of cleaning and general hygiene procedures.
- Evidence of documented cleaning procedures, e.g. a copy of an SOP for cleaning.

6. Personnel issues:

- Qualifications/experience of production manager and QC manager
- Staff training needs and what is done to address them.
- Personal hygiene and protective clothing needs relative to needs of the product and what is done to address them.

7. Process water:

- Quality required and steps taken to ensure that water quality meets those requirements.
- If the required standard is water drawn from the domestic water supply, then that should be stated in the specification for process water.
- Type of testing required if relevant, how often, evidence that it is done.
-

8. Equipment:

- Type of equipment used.
- What steps are taken to ensure that it is correctly installed, regularly calibrated, maintained and adequately cleaned?
- Details of cleaning procedures and checks carried out on cleaning procedures to ensure that they are adequate if different products are made in the same equipment.
- Details of procedures for making sure there is no cross contamination from other parts of the facility.

9. Specifications:

- Confirmation that written specifications for raw materials, intermediates and finished products as well as packaging materials exist (these should be consistent with registration specifications).
- Examples of specifications should be provided (e.g. for representative raw materials and final product).

10. Production procedures:

- Procedures for checking that raw materials meet specifications.
- Details of the production procedure; packaging and labeling procedures.
- Description of in-process quality checks (e.g. for unwanted micro-organisms such as wild yeasts, moulds and bacteria) and quality tests on the finished product.
- Documented release procedures to ensure that finished product is not released until results of all required tests are available and have been checked against release specifications.
- Description of batch records kept which cover the process from starting materials to finished products.
- If different products are made in the same equipment, procedures for ensuring there is no cross-contamination from the previous product of the product being made.
- Documented procedures for implementing PMS program

11. Quality control procedures:

- Evidence of quality control function that is related to production and marketing.
- Evidence that it is being implemented correctly.
- Documented change control procedures.
- Ability to conduct required quality control checks.

12. Brief description of recall procedures, complaints handling procedures and self-inspection procedures.

13. Documentation - all procedures must be documented and signed by the quality control manager.

Name & signature of Quality manager:

Name & signature of managing director:

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 1 of 12
---	---	---

Name of manufacture:

Address:

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Surrounding yard of plant	1-Determining of Plant surrounding and yard			
	2-Cleaning of plant yard and surrounding area			
	3-Enclosing uncleanable areas in plant's' yard so as to be acceptable			
	4-Considering appropriate plant distance to pollutant centers , complied with health ministry procedure			
	5-Regular collection and removing waste materials and rubbish			
	6-Paving the internal routes of plant with suitable consistent matters in order to prevention of dust			
Structural facilities	1-Providing facilities and sufficient and separated space for storage of raw materials			
	2-Providing facilities and sufficient space for storage of inedible matters and disinfectants and pesticides			
	3-Providing facilities and sufficient separated area for packaging material			
	4-Providing appropriate dressing room for workers before entering to production area			
	5-Providing facilities and sufficient area for laboratory			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 2 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Structural facilities	6-Separating microbiological part, culture room and chemistry part appropriately in laboratory			
	7-Sufficient space for keeping equipments related to maintenance of machinery tools			
	8-Providing appropriate raw materials receiving area with sufficient space for delivery and storage			
	9-Providing separated and sufficient space for storing finished product			
	10-Providing sufficient and separated space for collection and removing of wastes			
	11-Providing sufficient space in case of needing waste water collection system			
	12-In case of using non potable water, providing facilities and sufficient space for filtration and disinfection			
	13-Facilities and sufficient space for wash rooms			
	14-Providing appropriate production area for processing			
Designing of plant	1-Appropriate design the structure of plant in order to connect processing unit and receiving area and warehouse so that process of working easily done and preventing contamination			
	2-Separation the clean and unclean parts in appropriate manner			
	3-Providing suitable spaces for machinery, equipments and movement of personnel's			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 3 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Doors	1-Proper width with firm materials (excepting wood)			
	2-Ability to clean easily			
	3-Automatic closing of doors			
	4-Complete closing the doors in order to prevent ingress of insects and rodents (pests)			
	5-Necessary actions and amendments for doors of production area that open to external environment such as wind curtain, striped curtain or dual step doors			
Windows	1-Adequate size with firm materials (excepting wood)			
	2-Appropriate slope (gradient) for windows toward inside			
	3-Ability to clean easily			
	4-Using a suitable screen for windows			
	5-Complete closing open-able windows for preventing of entrance dusts and probable pollution			
	6-Using unbreakable glasses in case of necessity			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 4 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Floor	1-Floor must covered with suitable materials so that to be firm and impermeable, smooth and cleanable and disinfect able			
	2-Suitable gradient in floor opposing to processing area toward the sinks			
	3-Specifying the passage ways, equipment's space, clean and unclean parts on the floor (photo is needed)			
Wall	1-Suitable materials, firmed and stable, smooth, impermeable without any crack and split			
	2-Easy cleaning, washing and disinfecting			
	3-Suitable coloring of walls (as possible as bright color)			
	4-Conjunction point of floor to wall and wall to wall must be rounded			
Ceiling	1-Using of suitable ceiling in production area where the product exposed to environment			
	2-Suitable, stable, smooth and cleanable ceiling (photo is needed)			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 5 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Drains and sink	1-Suitable designing of drains to prevent from accumulation of water in production area			
	2-Adquate gradient and size of drains (sinks) and easy cleanable (photo is needed)			
	3-Appropriate gradient of drains opposing to working area			
	4-Suitable protection of outlets and inlets of drains to prevent of entering rodents			
	5-Proper materials for coverage of drains, they must be fit, separate able and clean able			
Light	1-Adequate and suitable light			
	2-Adequate light in important parts of producing area (in case of need)			
	3-Suitable and non glass coverage of bulbs			
	4-Ability to clean easily			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 6 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	No	Notice
Ventilation	1-Installing hood and strong ventilator, appropriate for production capacity in production section when processing cause dusts or condense in to water vapor			
	2-Having screen or wire mesh with suitable and cleanable material for ventilator or trap door			
	3-Suitable actions should be done to provide clean air in processing area because of product sensitivity and to prevent from spreading pollution from environment, for example creating positive pressure with installing air maker			
Waste water filtration	1-Providing effective waste water filtration system			
	2-Collection and remove plant's waste water in case of not having filtration system (document are attached)			
	3-Considering the standards of concerned countries for waste water filtration system			
Filtration of water	1-Installing filtration devices such as chlorinator, separator, RO or UV in case of using non potable water			
	2-Application the specifications of using water with microbial & chemical specifications of potable water (documents are attached)			
	3-Having the plan of pipelines with color or mark, and numbering the potable water pipes from non potable waters for recognition			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 7 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Washing rooms	1-Observe appropriate intervals between washing rooms and production area for prevention of pollution			
	2-Having fluid soap, disposable towel, nail brusher and disinfectant for hands			
	3-Opening and closing the taps without involving of hand			
	4-Installing suitable ventilator with screen and flush tank in toilettes			
	5-Numbers of washing rooms must be proportionate with number of producing personnel			
Health of personnel	1-Responsible someone for personal health			
	2-Having valid health examination card for workers (personnel) and performing repeated examination for ill workers after recovery			
	3-Using suitable and clean hat and cloth, boot or special shoe and mask by workers(photo is needed)			
	4-Using different clothes by personnel in different parts of production, storage, laboratory for easy recognition			
	5-Applying and record necessary tests for controlling the hygiene of nails, throat and nose health for personnel of production area			
	6-Committing the personnel for non using ornaments such as watch, ring and etc in production parts			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 8 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Storage / Cold storage / Heating ware house	1-Suitable materials on floor and wall of warehouse so that to be resistible, cleanable and without any hole or crack			
	2-Designing the ceiling of warehouse, using suitable matters to prevent from gathering dusts and nesting of birds and rodents			
	3-Clean down the ceiling of warehouse			
	4-Using suitable pallets, firmed, resistant and cleanable			
	5-The plan for putting the traps in warehouse			
	6-Consideration FIFO conditions in warehouse			
	7-Considering suitable intervals between the walls of warehouse from pallets about 20 cm			
	8-Marking the quarantine parts, acceptable product, (distinction), returned products in order to recognize them			
	9-proper width and complete closing the entrance door of warehouse and exit the products			
	10-Using suitable platform with ceiling for loading from warehouse			
	11-Using non fossil fuel transporting vehicles in warehouse			
	12-Regarding suitable conditions and standards for arrangement of products and commodity in storage (photo is needed)			
	13- Divide the warehouse depending on the plant condition and products, suitably			
	14-Having the thermometer, hygrometer in warehouse in case that product should be kept in special conditions			
	15- Installing the alerting device in order to declaring uncontrollable conditions for heating or cold warehouses			

Quality control confirmation: Name and signature:	Date of confirmation :
---	-------------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 9 of 12
---	---	---

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Tables and equipments	1-Suitable materials for surfaces in contact with food so as to be smooth and shiny (preferably to be stainless steel)			
	2-Suitable designing of surfaces in contact with food stuffs so that to be easily cleanable			
	3-Proper material of trays, tanks, transferring pips and other using utensils in contact with food materials, so that to be resistible, with out any crack and split, washable and disinfect able			
Receiving of raw materials	1-Receiving plat form must be isolated, limited with ceiling and prevent the transferring pollution to production area			
	2-Suitable place for receiving of raw materials in case of receiving raw materials simultaneously with large quantity			
Production and processing area	1-Separating different parts of production area with suitable doors or strip curtains			
	2-Washing room must equipped with liquid soap, disposable towel, taps without involvement of hand for opening and closing and pedaled dust or trash bin in entrance of production area			
	3-Suitable connection of producing equipments so that avoid void space			
	4Do not keeping spare items (such as maintenance devices, raw material containers and etc) in the production area during processing			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 10 of 12
---	---	--

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Production and processing area	5-Consideration of hygienic conditions and absence of particle and corrosion on external surfaces and whole body of reservoirs and different tanks			
	6- Collect trashes and wastes in pedaled bins and dispose them in proper time			
	7- Installing the efficient and suitable system for attracting insects in acceptable place or regarding appropriate interval from processing products.			
	8-Consideration of hygienic conditions and coloring different metal surfaces (which don't contact with food material) of equipments and machinery			
	9-Using suitable non glass covers for shades and windows of production section in case of necessity			
	10-Surround processing equipments to prevent possible transmission of contamination during processing			
	11-Installing warning and hygienic signs in production section			
Cleaning & disinfection	1-Designing a regulate program for washing, disinfecting, and cleaning for each parts (documents must be attached)			
	2-Install taps for washing and cleaning operations or install air pump in different parts of production area for cleaning			
	3-Necessary facilities for collecting of hoses when aren't used			
	4-Installing the washing tools on wall and suitable place (sweeper, brushes...)			
	5-Proper space for washing and disinfecting equipments and utensils			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 11 of 12
---	---	--

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
	6-Considering facilities for hot and cold water, under pressure vapor and air (in case of necessity) for cleansing and washing			
	7-Installing visible permanent cleaning and washing time table			
Pest control	1-Applying a control program for insects and pests (documents are attached)			
	2-Complete performance of program by plant responsible person			
	3-Putting proper traps in warehouse for preventing, ingress of insects and rodents			
Repair and maintenance	1-Apply a regular program for maintenance and repair with necessary efficacy (documents are attached)			
	2-Recording the maintenance and repair reports			
	3-Numbering (coding) all of equipments machinery, and laboratory devices			
	4-Presence of procedures related to maintenance for all of above cases			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------

Ministry of Health & Medical Education Food and Cosmetic Control Affairs	Self assessment checklist for GMP In Food & Beverage manufacturers	Code of document:GMP/F-002 Date of Issue: 10/2007 Review: 00 Review date:00 Page 12 of 12
---	---	--

Auditing Site	Auditing Case	Results		
		Yes	NO	Notice
Control & testing	1-Presence of inspection and testing facilities in the plant			
	2-Experts and specialized personnel for performing physical microbial and chemical tests			
	3-Expert and specialized personnel's for inspecting of processing and laboratory operations			
	4-Approval of laboratory by authorities			
	5-Using international and national standards in laboratory			
	6-Regulating and registration of implementing procedures (procedures are attached)			
	7-Presence of program for calibration of laboratory devices (documents are attached)			
	8-Presence of conditions for sampling and repetition of tests			

Quality control confirmation: Name and signature:	Date of confirmation :
--	------------------------