



## Research Article

# Assessment of the extent implementing the Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Point System (HACCP) in Sudan sugar industry factories

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## Abstract

The present study was conducted in Sudan Sugar industry factories (Kenana, White Nile, Assalaya, Sennar, Guneid, and New Halfa) during the production season of 2017. The study aimed to evaluate the existing Assessment of the extent of implementing the Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Point System (HACCP) by Sudanese sugar factories with reference to FSMS of the ISO 22000: 2005. The data were collected using ISO 22000 checklist and direct interviews. Likert Five-Point Scale was used in scoring the checklist statement and the arithmetic mean was obtained. The result showed that the Good Manufacturing Practices were varied between major deficiencies in White Nile, Assalaya, Sennar, and New Halfa due to score less than (3.6 points) and non-compliance in Kenana and Guneid due to score less than (2.6 points); the Sanitation Standard Operation Procedures (SSOP) assessed as major deficiencies in (Assalaya and Sennar) and minor deficiencies in (White Nile and New Halfa) due to score less than (5points). Moreover, the Hazard Analysis and Critical Control Points System revealed that it was varied between non-compliance in (Kenana, White Nile, and Guneid) and not applicable in (Assalaya, Sennar and New Halfa) due to score less than (1.8 points). Interestingly, the Sudanese sugar industries take all quality control characteristics from cane production to sugar production carefully, but unfortunately don't care about any food safety systems. Lack of top management commitment and involvement and lack of government support represent the main constraints and Barriers of implementing food safety systems in Sudanese sugar companies. The study recommendations that the Sudanese Sugar Industry needs to establish proper quality assurance laboratories to help in monitoring the quality and safety of raw materials and end productions.

## Introduction

Food manufacturing and producing industries should follow and adopt Good Manufacturing Practices (GMPs) [1] to make sure that all products are manufactured in a safe and healthy environment, which ensures the safety and quality of their products to fulfill the requirement of standards regulations [2-6]. GMPs are regulations given to ensure effective hazard-free overall practices to ensure product quality, safety, and standards (PQSS) [1,4,5]. GMPs must follow various practices of product

testing, manufacturing, storage, handling, and distribution. GMPs should fulfill the standards of Safety, Integrity, Purity, Quality, and Composition (SISPOC) [1,5]. The practices of Hazard Analysis and Critical Control Points (HACCP) and GMP programs give confidence and faith to consumers that proper testing consistency and safety and quality checks have been maintained throughout manufacturing, packaging, and distribution of products [5]. GMP is a risk assessment trial and it is currently adopted by industries to ensure the PQSS [1,6-8]. GMP has science and technology-based rules, regulations



and standards. It also has an integrated systems approach for quality, facilities and equipment, materials, production, packaging, labeling, and laboratory control. It keeps proper records for proposed amendments regarding validation and cross-contamination [3,4,9].

HACCP is well recognized in the food industry as an effective approach to establishing good production, sanitation, and manufacturing practices that produce safe foods [4,10]. HACCP is a system of process control used by the industry to prevent hazards to the food supply and as a tool in the control, reduction, and prevention of pathogens in food. HACCP make GMP complete. It is very important and need to be strictly observed by any food industry. First of all HACCP program was developed in the 1960s for NASA to ensure the safety of food products that were to be used by the astronauts in the space program [1,4,5,8].

### Why GMP / HACCP is required?

GMP or HACCP establishes minimum GMP for methods to be used and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a food or drug to assure that the food or drug is: safe, has the appropriate identity, purity, and strength, meets quality and purity characteristics [4,8]. Food safety and quality control are essential in ensuring that food aid supplies are safe, of good quality, and available in adequate amounts, in time, at affordable prices to ensure an acceptable nutritional and health status for all population groups [5]. HACCP, GMP, ISO, WHO [2], and Codex Alimentarius are major food safety and quality systems [5,11]. GMP is a system to ensure that products meet food PQSS and legal requirements. HACCP can be part of GMP and is a systematic program to assure food safety [4,7,12]. GMP provides a high-level assurance that food items, drugs, or medicines are manufactured in a way that ensures their safety, efficacy, and quality and also gives marketing authority with stability [1,5,6,8,13]. So this trial was aimed to evaluate the existing Assessment of the extent of implementing the Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Point System (HACCP) by Sudanese sugar factories with reference to FSMS of the ISO 22000: 2005.

## Materials and methods

### The study area

Sudan (longitudes 22°–38° East and latitudes 4°–22° North) has numerous natural resources and potentials that can provide abundant inputs for industrial production. Most important of these are the agricultural elements and products that can ensure raw materials for many foodstuff industries, including sugar refining. Moreover, there are vast arable lands (about two hundred million feddans) and many assisting factors, such as the appropriate climate, fertile soil, labor, and reasonable infrastructures that provide greater potential for growing sugar cane, which is the mainstay of the sugar industry in Sudan. The sugar industry of Sudan started with the establishment of the Guneid Sugar Factory in the Gazira province in 1962. There are

now five sugar factories in the country, four of these factories are state-owned: The Guneid Factory, the New Halfa Factory, the Sennar Factory, and the Assalaya Factory. The fifth one, The Kenana Factory, is a joint venture with Sudanese, Arab, and other capital, formed in 1975. Kenana Sugar Factory is one of the biggest integrated sugar refineries placed under one administrative body in the world. Its total annual production has reached 300,000 tons of white sugar. This factory is a perfect example of successful joint venture projects in Sudan. It produces a variety of products: white sugar, sugar cubes, sugar syrup, and molasses. The Factory produces briquettes and animal fodder from the remnants of sugar cane [14–23].

This study was conducted in sugar industry factories in Sudan (New Halfa, Guneid, Assalaya, Sennar, Kenana, and White Nile). Numerical scores were given to sanitary observation on 5 classes of complementary conditions: 5- full compliance, 4- minor deficiency, 3- major deficiency, 2- non-compliance, and 1- not applicable. These classifications were developed accordingly to the issued standards criteria.

### Data collection

The data collection was done through an observation checklist and direct interviews with top management and senior managers in the production line. Six visits were carried out to sugar factories to evaluate the existing situation of food safety management system (ISO 22000) and their prerequisites programmers in the Sudanese Sugar industries based on the standard issued by the International Standardization Organization (ISO 22000:2005) and evaluation of each factory performance was documented.

### Assessment of good manufacturing practices and hazard analysis and critical control points system

**Audit checklist:** This assessment was carried out by using the Audit Checklist as prepared by Total Quality Certification Services International TOCSI, 2012). The scoring system was used to evaluate the implementation of the Food Safety Management System as follows in Tables 1–3 according to Likert Five-Point Scales.

Section (1) Assessment of Good Manufacturing Practices (GMP) in Sudanese sugar industries

Section (2) Assessment of Standard Sanitation Operations Procedure (SSOP) in Sudanese sugar industries

Section (3) Assessment of Hazard Analysis and Critical Control Points System in Sudanese sugar industries

**Table 1:** Scoring system for questions of Food Safety Management System.

Possible answer				
Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
Possible Points for the question				
Score = 5	Score = 4	Score = 3	Score = 2	Score = 1
Sorrel Brown, 2010				



**Table 2:** Compliance for questions in Food Safety Management System.

Answer	Criteria used
Total Compliance Or Strongly Agree	To meet the question and/or compliance criteria in full.
Minor Deficiency Or Agree	To have minor deficiencies against the question and/or compliance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or compliance criteria. To have covered most of the question compliance criteria, but not all.
Major Deficiency or Neither agree or disagree	To have major deficiencies against the question and/or compliance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or compliance criteria. To have single or isolated severe deficiencies against the question and/or compliance criteria. To have covered some of the question compliance criteria, but not most of it.
Non-compliance or Disagree	To have not met the question and/or compliance criteria requirements at all. Having systematic deficiencies against the question and/or compliance criteria (severe or Non-severe issue).
Not applicable Or Strongly Disagree	The requirement described in the question is not applicable for the operation being Audited. A justification should be provided in the auditor's comments. Be aware that there Are some questions that do not allow answering Non-applicable.

**Table 3:** Audit scoring summary criteria in case of mean and percentage.

How to explain meaning of arithmetic mean and percentage			
How to explain meaning of arithmetic mean		How to explain meaning of percentage %	
Numerical	Views	Numerical	Views
$M < 1.8$	Not applicable Or Strongly Disagree	$P < 36\%$	Not applicable Or Strongly Disagree
$1.8 \leq M < 2.6$	Non-compliance Or Disagree	$36\% \leq M < 52\%$	Non-compliance Or Disagree
$2.6 \leq M < 3.4$	Major Deficiency Or Neither agree or disagree	$52\% \leq M < 68\%$	Major Deficiency Or Neither agree or disagree
$3.4 \leq M < 4.2$	Minor Deficiency Or Agree	$68\% \leq M < 84\%$	Minor Deficiency Or Agree
$4.2 \leq M \leq 5$	Total Compliance Or Strongly Agree	$84\% \leq M \leq 100\%$	Total Compliance Or Strongly Agree

Sorrel Brown, 2010.

### Statistical analysis

The quantitative collected data was entered and analyzed by using Statistical Packing for Social Sciences (SPSS) version 16. To obtain descriptive statistics of percentages and arithmetic mean through using Likert Five-Point Scales (2010).

### Results and discussions

#### Evaluation of Good Manufacturing Practices (GMP) in the Sudanese Sugar industry with reference to FSMS of the ISO 22000: 2005

Table 4 shows that the General Arithmetic means of Good Manufacturing Practices were 2.23 and 2.27 reported in factory Kenana and factory Guneid respectively this mean is corresponding the Non-compliance according to FSMS requirements of the ISO 22000: 2005. While the arithmetic

means of the factories White Nile, Assalaya, Sennar, and New Halfa were 3.14, 2.77, 2.73, and 2.64 respectively as a result, the corresponding major deficiencies when compared to FSMS requirements of the ISO 22000: 2005. Gaps and weak points in Good Manufacturing Practices system in all investigated Sudanese sugar industries represented in not have designated person responsible for the food safety program, The operation has not pest control program, there is no designated area for employees to leave aprons, sleeves, and gloves when on break and before using toilets and there are no designated areas for smoking, eating, chewing and drinking. All requirements mentioned above obtained scores not applicable in the six factories under study. Some requirements obtained score non-compliance in all sugar industries like Employees observed not remove smocks, aprons, sleeves, and gloves when on break and before using the toilets and when going home at the end of their shift and Wall, floor and ceiling are it were not easy to clean.

#### The requirement of the Sanitation Standard Operation Procedures (SSOP) in Sudanese sugar industries with reference to FSMS of the ISO 22000: 2005

Table 5 shows that the General Arithmetic means of Sanitation Standard Operation Procedures were 3.75 and 3.50 reported in factory White Nile and factory New Halfa respectively this mean is corresponding the minor deficiencies according to FSMS requirements of the ISO 22000: 2005. While the arithmetic means of the factories Assalaya and Sennar were 2.63 for each as a result of the corresponding major deficiencies when compared to FSMS requirements of the ISO 22000: 2005. The arithmetic means of the factories Kenana and Guneid were 2.25 and 2.38 respectively, as a result of the corresponding Non-compliance according to FSMS requirements of the ISO 22000: 2005.

#### The requirement the elements of Hazard Analysis and Critical Control Points System (HACCPs) in Sudanese sugar industries with reference to FSMS of the ISO 22000: 2005

Table 6 shows that the General Arithmetic means of Hazard Analysis and Critical Control Points System were 2.00 for factories Kenana, White Nile, and Guneid this mean is corresponding the Non-compliance according to FSMS requirements of the ISO 22000: 2005. While the arithmetic means of the factories Assalaya, Sennar, and New Halfa was 1.00 as a result the corresponding not applicable when compared to FSMS requirements of the ISO 22000: 2005. It was concluded that the non-compliance scored in the three factories (Kenana, White Nile, and Assalaya) resulted from all food safety hazards that are reasonably expected to occur in the sugar process line were not identified and recorded. Through the observation, the biological hazard analysis was conducted in three industries mentioned above (Kenana, White Nile, and Assalaya). The rest of the factories did not carry out any hazard analysis in the sugar process line (physical, chemical, and biological). It resulted in all these factories scoring not applicable concerning to (HACCP).

**Table 4:** The requirement of the Good Manufacturing Practices (GMP) in Sudanese sugar industries with reference to FSMS of the ISO 22000: 2005:

Operations to prevent contamination	Factories					
	Kenana	White Nile	Assalaya	Sennar	Guneid	New Halfa
designated person responsible for the food safety program	1	1	1	1	1	1
All so all chemicals (pesticides, sanitizers, detergent, lubricants, etc.) were not stored securely, safely, and were not labeled correctly	3	4	4	4	2	3
the signs supporting GMP posts were not existed in all expellers	2	3	4	2	2	2
The operation have a pest control program	1	1	1	1	1	1
All storage areas clean, especially the racking structures, ceilings, floor areas by the wall and other hard to reach areas	2	4	4	3	2	4
Materials (commodities, packaging, ingredients, work in progress etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)	3	4	4	4	3	4
Rejected or on hold materials clearly identified and separated from other materials?	2	3	3	3	3	3
Materials (commodities, packaging, ingredients, processing aids, work in progress rotated using FIFO policy	2	3	3	3	3	3
The process flow, facility layout, employee control, utensil, internal vehicle use etc., ensure that finished (processed) products are not contaminated by raw products	3	4	3	3	3	3
All employees wearing outer garments suitable for the operation ( smocks, aprons, sleeves and gloves)	2	4	3	3	3	3
there a designated area for employees to leave aprons, sleeves and gloves when on break and before using toilets	1	1	1	1	1	1
smoking, eating, chewing and drinking confined to designated areas	1	1	1	1	1	1
Employees remove smocks, aprons, sleeves and gloves when on break and before using the toilets and when going home at the end of their shift	2	2	2	2	2	2
External & internal of the premises are clean	2	4	3	3	3	3
Wall, floor and ceiling are easy to clean	2	2	2	2	2	2
Restroom facilities have adequate Ventilation	2	3	3	3	3	3
Draining system is well designed around and within the plant	3	4	3	3	3	3
Sewage and waste water in the premises are clean	2	4	3	3	2	4
Ground does not allow contamination	3	4	3	4	3	4
Building allows enough lighting, ventilation and movement	2	4	3	4	2	3
The maintenance shop organized –i.e. equipment and spares stored in a neat and tidy fashion?	3	4	4	4	3	3
Toilet facilities and hand-washing station clean	3	4	3	3	2	2
General Arithmetic means	2.23	3.14	2.77	2.73	2.27	2.64
Verbal	Non-compliance	Major deficiencies	Major deficiencies	Major deficiencies	Non-compliance	Major deficiencies

**Table 5:** The requirement of the Sanitation Standard Operation Procedures (SSOP) in Sudanese sugar industries with reference to FSMS of the ISO 22000: 2005.

Sanitation Practices	Factories					
	Kenana	White Nile	Assalaya	Sennar	Guneid	New Halfa
Written sanitation standard operating procedures for cleaning and disinfectants	4	4	4	4	4	4
There is a check sheet for workers to verify all that have been processed	2	3	2	2	2	2
Cleaning and sanitation programs are done every day with records	2	4	3	3	2	3
Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?	2	4	2	2	2	4
Are there written cleaning procedures Sanitation Standard Operating Procedures) for the facility and all equipment?	2	4	3	3	3	3
Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?	2	4	3	3	2	3
Is there a routine program and written procedure to validate sanitation effectiveness?	2	3	2	2	2	3
Is there a log indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?	2	4	2	2	2	4
General Arithmetic means	2.25	3.75	2.63	2.63	2.38	3.50
Verbal	Non compliance	Minor deficiencies	Major deficiencies	Major deficiencies	Non compliance	Minor deficiencies





**Table 6:** The requirement of the elements of Hazard Analysis and Critical Control Points System (HACCP<sub>s</sub>) in Sudanese sugar industries with reference to FSMS of the ISO 22000: 2005.

Hazard analysis	Factories					
	Kenana	White Nile	Assalaya	Sennar	Guneid	New Halfa
Food safety team conducted a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and control measures is required.	2	2	1	1	2	1
All food safety hazards that are reasonably expected to occur in sugar process line were identified and recorded.	2	2	1	1	2	1
For each of the food safety hazards identified, the acceptable levels of the food safety hazard in the end product were determined.	2	2	1	1	2	1
hazard assessment conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels	2	2	1	1	2	1
Selection and assessment of control measures is capable to preventing, eliminating or reducing these food safety hazards to defined acceptable levels.	2	2	1	1	2	1
Monitoring systems were established for each CCP to demonstrate that the CCP is in control.	2	2	1	1	2	1
Corrective actions were taken when critical limits are exceeded shall be specified in the HACCP plan.	2	2	1	1	2	1
Verification process is essential for the successful implementation of the HACCP plan.	2	2	1	1	2	1
General Arithmetic means	2.00	2.00	1.00	1.00	2.00	1.00
Verbal	Non-compliance	Non-compliance	Not applicable	Not applicable	Non-compliance	Not applicable

## Conclusion

The elements of Good Manufacturing Practices were varied between major deficiencies and non-compliance. The recorded gaps and weak points, in the Good Manufacturing Practices system in sugar industries, were because there is no designated person responsible for the food safety program; the operation has not pest control program; there is no designated area for employees to leave aprons, sleeves, and gloves when on break and before using toilets; there are no designated areas for smoking, eating, chewing and drinking. Concerning the elements of Sanitation Standard Operation Procedures (SSOP) assessed as minor deficiencies and major deficiencies according to FSMS requirements of the ISO 22000: 2005. Assessment of the elements of Hazard Analysis and Critical Control Points System revealed that it was varied between non-compliance and not applicable when compared to FSMS requirements of the ISO 22000: 2005. The non-compliance scored in three factories because all food safety hazards that are reasonably expected to occur in the sugar process line were not identified and recorded. Sudanese sugar industries were adopted a quality management system at all levels of the production line but have not adopted any food safety systems.

## Recommendations

In order to control the food hazards, food establishments and government should put measures in place that improve the effects. In-job and in-class training should be conducted to the improve knowledge of employees and managers. Education and training are required for the effective management of HACCP practices. Resources such as human resources, money, equipment monitoring, and training aids should be obtainable for the successful management of food safety practices. Provision of laws and regulations is necessary to guide food safety products in the Sudanese Sugar Industries. Sudanese

Sugar Industry needs to establish some Food Safety systems like Good Agricultural Practices, Good Storage Practices, prerequisite programmers (GMP and SSOP) that represent minimum requirements to implement FSMS.

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