

(RESEARCH ARTICLE)



## Assessment of the application of Good Manufacturing Practices (GMP) in some wheat mills in Sudan

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### Abstract

The present study was conducted during the period from April to December 2018. The objectives of this work were to assess the application of Good Manufacturing Practice (GMP) in nine wheat mills in Khartoum State and one wheat mills in Elobeid - North Kordofan State. Ready questionnaire prepared by Primus Lab Checklist (2013) was used and data were categorized according to GMP system. Concerning the first part of general GMP, the result revealed that two wheat mills in Khartoum state adopted the general GMP system whereas eight wheat mills were not adopted it. Regarding pest control requirements the mills scores ranged (48-87) out of 95 degree, for storage area and packaging material the score was (33-55) out of 55 degree, only one wheat mills in Khartoum state scored full degree. Concerning the operational practice requirement, all mills scores ranged (80-133) out of 144 degree and for the employee practice requirement they gained (9-45) out of 64 degree. In case of the equipment, the score was (32-50) for all mills and (40%) of wheat mills in Khartoum scored full degree whereas for the equipment cleaning requirement they acquired (26-60) and (20%) of them that belong to Khartoum had full degree, for general cleaning they recorded (32-73) out of 83 degree and for building and ground requirement they obtained (77-102) out of 106 degree. The total degree of Good Manufacture Practice (GMP) varied from 346 to 641 compared to 642 degree. The result showed that the mean total score of Good Manufacturing Practices in all expellers in this study was 693.3 points (69.33%) the highest score recorded 855 points (85.5%) in M8 and the lowest score obtained 555 points (55.5%) in M2, M6 and M10, respectively out of 1000 points. These findings indicated that the M8 plant was categorized as very good, while M9 was standard, but the rests of wheat mills studied in present investigation were categorized as unsatisfactory.

**Keywords:** Assessment; GMP; Wheat Mills; Sudan

### 1 Introduction

The term Good manufacturing practice (GMP) was introduced to regulate manufacturing and packaging operations in the food Industry (1). GMP is a system of connection of elements that join to fortify that food does not cause any harm to human health when consumed. The segment of the system includes programs, goals, objectives, policies, standards, control measures, roles, responsibilities, relationships, document control, record keeping and resources needed by food manufacturing industries (2). (3) defined Good Manufacturing Practices (GMP) as a segment of quality assurance, which guarantees that food products are uniformly manufactured and well controlled as per the quality standards suitable for their use as expected by the marketing authorization. GMP is often referred to as cGMP, with the 'c' indicating 'current' or the modern technology and systems that are needed or are being implemented (4). It is an essential element in GMP systems as it prevents misinterpretation in other standards (5). For example, GMP requirements of one or two decades ago are almost certainly unacceptable by today's higher standards. GMP is a term that is well known globally for the

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effective control and proper management of manufacturing and quality control testing of foods, pharmaceutical products and medical devices. GMP covers various matters, including facilities design, documentation, production, quality control, product delivery and validation (4).

Most GMP requirements give flexibility for individual manufacturers to decide for themselves what the best ways are to meet the necessary controls. Hence, a conclusion can be made that GMP is an 'open ended' requirement and not rigid. The primary objective of GMP is that quality should be implemented into a product and GMP is not to be used only as a way of assessing the finished product quality. With GMP compliance and implementation, the guarantee is that the finished product not only meets the consumer expectation, but the same safety and control measures are being enforced each time a product is made throughout the entire production process. GMP provides benefits in the sense that it reduces the operating cost of rework, customer rejects, complaints, and that it increases efficiencies and customer's acceptance of products. Due to the various benefits of GMP, it is crucial for the establishment to implement GMP guidelines without compromising. Unfortunately, there is a lack of information on GMP implementation amongst manufacturers and other quality systems such as Hazard Analysis Critical Control Point (HACCP) and International Organization for Standardization mainly on the flours and others food industry (ISO) (6), so the general objective of this study was to assess the application of Good Manufacturing Practice (GMP) in wheat mills in Khartoum and North Kordofan (Elobeid) States, and also to evaluate the limit implementation of GMP system in wheat mills in Khartoum and North Kordofan States.

## 2 Material and methods

### 2.1 Study area

This study was conducted in nine wheat mills in Khartoum State and one wheat mills in Elobeid-North Kordofan State.

### 2.2 Sampling technique

Ten wheat mills (nine wheat mills were chosen from the total number of wheat mills in Khartoum and one wheat mill in Elobeid>

### 2.3 Methodology of the research

The primary data were collected using a questionnaire contacting checklist as prepared by (7) (appendix 1). Secondary data were collected using books, reports, journals and previous studies.

**Table 1** Scoring system for questions in section (1) and section (2) in GMP

Possible answer	Possible points for the question			
	15 points	10 points	5 points	3 points
Total compliance	15 points	10 points	5 points	3 points
Minor deficiency	10 points	7 points	3 points	2 points
Major deficiency	5 points	3 points	1 points	1 points
Non-compliance	0 points	0 points	0 points	0 points
Not applicable	0 points	0 points	0 points	0 points

**Table 2** Audit scoring summary

Criteria	Percentage / category
Superior	95-100%
Excellent	90-94%
Very Good	85-89%
Standard	80-84%
Unsatisfactory	Less than 80%

Source: (7).

**Table 3** Compliance for questions in GMP option

Answer	Criteria used
Total Compliance	To meet the question and/or compliance criteria in full.
Minor Deficiency	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	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	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 issues).
Not Applicable	The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there were some questions that do not allow answering non-applicable.

Source: (7).

## 2.4 Data analysis

The results were analyzed by descriptive statistical in tables and percentages

## 3 Results and discussion

**Table 4** Total score of GMPR of some wheat mills in Khartoum and North Kordofan States

Requirements	Scores	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10
General GMP	45	27	15	23	27	35	15	35	45	45	16
Pest control	95	60	48	79	55	58	55	71	87	85	49
Storage area and packaging materials	55	44	33	47	50	42	43	47	55	52	49
Operational Practices	144	130	100	117	113	110	91	131	133	131	80
Employee Practices	64	16	11	31	23	22	13	38	43	45	9
Equipment	50	50	45	50	45	50	32	45	50	45	47
Equipment Cleaning	60	52	26	57	55	53	39	57	60	60	37
General Cleaning	83	55	42	58	52	41	35	73	72	60	31
Building and Grounds	106	98	86	102	91	89	77	94	96	102	78
Total scores	642	532	406	564	511	500	400	591	641	625	396

As shown in (4) the first part of the GMP, the result revealed that the general GMP was applicable in two wheat mills but in eight wheat mills not applicable, Also the pest control requirements score (48-87) from 95 degree, there are M8 and M9 scored minor deficiency but M3 and M7 scored major deficiency, while M1, M4, M5 and M6 noncompliance; and M2, M10 not applicable this is one of the weak point scored, in cases of the storage area and packaging materials score (33-52) from 55 degree, there were M8, M9 and M4 scored minor deficiency, but M1, M2, M3, M5, M6, M7 and M10 scored major deficiency; and only M2 noncompliance. Additionally the operational practices scored (80-130) from 144 degree, there were M1, M7, M8, and M9 scored minor deficiency, M2 to M6 scored major deficiency; and only M10 as noncompliance. the employee Practices scored (9-45) from 64 degree, There are M8 and M9 scored minor deficiency and only M7 scored major deficiency, but M3, M4 and M5 noncompliance; while M1, M2, M6, M7 and M10 not applicable

this is of the weak point scored. Also the equipment scored (32-50) from 50 degree, there are all scored full compliance and only M6 scored minor deficiency. in cases of equipment cleaning scored (26-60) from 60 degree, there were M8 and M9 scored full compliance but M1, M3, M4, M5 and M7 scored minor deficiency, while M6 and M10 scored major deficiency and only M2 noncompliance. Additionally the general cleaning score (31-73) from 83 degree, there are M7 and M8 scored minor deficiency, but M1, M3, M4 and M9 scored major deficiency; while M2, M5, M6 and M10 noncompliance. The building and grounds score (78-102) from 106 degree, there were M3 and M9 scored minor deficiency, but M1, to M5 and M7, M9 scored major deficiency; while M6 and M10 noncompliance.

**Table 5** Good manufacturing practices requirements (GMPR) and food safety files requirements (FSFR) of some wheat mills in Khartoum and North Kordofan states

<b>GMPR Score and FSFR Total Score (out of 1000 points)</b>			
<b>Wheat mills</b>	<b>Points</b>	<b>Percentage %</b>	<b>Category</b>
M1	724	72.4	Unsatisfactory
M2	555	55.5	Unsatisfactory
M3	735	73.5	Unsatisfactory
M4	669	66.9	Unsatisfactory
M5	676	67.6	Unsatisfactory
M6	555	55.5	Unsatisfactory
M7	776	77.6	Unsatisfactory
M8	855	85.5	Very Good
M9	833	83.3	Standard
M10	555	55.5	Unsatisfactory

Category 80 unsatisfactory, category 80-84 standard, category 85-89 Very Good Category 90-94 excellent, category 95-100 superior.

**Table 6** Question response summary of Good Manufacturing Practices Requirements of Food safety files requirements of some wheat mills in Khartoum and North Kordofan States

<b>Conditions</b>								
<b>File</b>	<b>N of Q</b>	<b>T.S</b>	<b>Number of wheat mills</b>	<b>Full compliance %</b>	<b>Minor deficiency %</b>	<b>Major deficiency %</b>	<b>Noncompliance %</b>	<b>Not applicable%</b>
Chemicals Files	3	18	10	30	50	10	10	0
Pest Control Documentation	3	35	10	10	50	30	10	0
Operation Monitoring Records	6	54	10	60	40	0	0	0
Maintenance and Sanitation	9	65	10	40	50	10	0	0
Employee Documentation	4	26	10	0	40	50	10	0
Testing/Analyses Records	3	20	10	90	10	0	0	0
Temperature Controlled	4	30	10	50	30	20	0	0
<b>Total scores</b>	<b>32</b>	<b>248</b>	-	-	-	-	-	-

N of Q =number of questions. T.S= total scores

Table (5) showed that the mean total score of Good Manufacturing Practices in all expellers in this study was 693.3 points (69.33%) the highest score recorded 855 points (85.5%) in M8 and the lowest score obtained 555 points (55.5%) in M2, M6 and M10 respectively out of 1000 points. This result means that all wheat mills in Khartoum were unsatisfactory expect M8 and M9 were satisfactory.

As shown in (table 6) the chemicals files, there were 30% of wheat mills scored full compliance but 50% scored minor deficiency, but 10% scored major deficiency; and only 10% scored noncompliance. Also pest control documentation there was 10% of wheat mills scored full compliance but 50% scored minor deficiency, while 30% scored major deficiency; and only 10% scored major deficiency. In cases of the maintenance and sanitation, there were 40% of wheat mills scored full compliance, but 50% scored minor deficiency; and only 10% scored major deficiency. Additionally employee documentation, there were 40% of wheat mills scored minor deficiency, but 50% scored major deficiency; and only 10% noncompliance. The testing/analyses records, there were 90% of wheat mills scored full compliance, and only 10% scored minor deficiency. The temperature controlled, there were 50% of wheat mills scored full compliance, but 30% scored minor deficiency; while 20% scored major deficiency.

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#### 4 Conclusion

The study concluded that the only wheat mills number 8 and 9 were category satisfactory while all the rest wheat mills were category scored unsatisfactory.

The study found there are some gaps and weakness points in the elements of good manufacturing practices system application in Sudanese wheat mills.

In the same manner the questions regarding with food safety files requirements scored not applicable properly for all wheat mills.

More studies were needed know the (GMP) system in different food industries and plants to achieve high quality food products as recommended point of view.

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#### Compliance with ethical standards

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##### *Disclosure of conflict of interest*

The authors declared that no conflicts of interest for this article.

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