

SGS GMP Inspection is applicable for food manufacturing companies to ensure that effective governance is established and continually improved in manufacturing of safe, legal and quality food. GMP Inspection shall be conducted based on the agreed scope. It is a process and product conformance based audit, focusing on significant aspects, risks, and objectives required by the SGS GMP Inspection Checklist. Methods of assessment included interviews, observations, and review of documentations. The audit structure is to be conducted on an unannounced basis or be scheduled as an announced audit in accordance with a proposed audit plan. There shall be at least one batch or one production line running for the food product within the scope of the audit to facilitate more relevant onsite inspection and documentation verification.

The Auditor/ Inspector will spend minimum 80% of the time onsite to verify GMP compliance. The onsite verification will cover the core areas such as production, filling, packing, storage, facilities for raw material, semi-finished & final product(s), laboratory, processes, and other supporting areas. Documentation verification shall also be conducted as supporting to onsite inspection. Inspection results and agreed finding summary will be provided in the closing meeting of inspection. Full report with inspection grade and score will be provided upon completion of the internal file review process.

Certificate of completion will be issued for grades A, B & C. No certificate will be issued for grade D for failed inspection.

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Grade	Abbreviation	% Deduction	Description
Satisfactory	S	0%	The condition/practice observed fully meets the standards or requirements.
Minor	m	1%	A clause does not fully meet requirement, but is unlikely to result in a direct customer/consumer health risk or major non-compliance to product specification.
Major	M	10%	A substantial failure to meet the requirements. The condition observed is likely to have a negative impact on the safety of food products or leads to a breakdown of food safety practice if not effectively controlled.
Critical	C	50%	Failure to comply with regulatory requirements, a process step that has caused a significant customer/consumer health risk and/or where product is contaminated. Contact McDonald's immediately and stop product shipment.
Not Applicable	N/A	0%	Not applicable

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Score	Percentage	Description
A	100-95%	Meets or Exceeds Requirements: Significant results are achieved through a sound systematic approach that is fully responsive to GMP inspection expectations with emphasis on continuous improvement.
B	94%-85%	Generally Meets Requirements: Meets most of the requirements through a sound systematic approach that is fully responsive to GMP inspection expectations with emphasis on continuous improvement. However, there are some areas for improvement.
C	84%-70%	Partially Meets Requirements: Meets the minimum requirements for GMP inspection expectations. There are significant areas for improvement.
F	Below 70%	Fail to Meet Requirements: <ul style="list-style-type: none"> Does not meet minimum GMP inspection's requirements. If any critical/non negotiable finding is identified by the auditor

The information in the GMP Inspection Checklist for Food Manufacturing is intended as general information of good manufacturing practice, food safety practice in food manufacturing and common regulatory requirements. It shall not be regarded as legal advice. This checklist is not intended to address all applicable regulatory and statutory requirements. Compliance to this checklist shall not be interpreted as compliance to all applicable regulatory and statutory requirements.

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3)	Content, workflow and responsibilities defined in the documentation is clear and sufficient for facilitating safe food production.		
4)	The procedure, work instruction and specification shall include the control and parameters critical to food safety, quality and legality.		
5)	Current version of work instructions, formula, specification and supporting documentation is used.		
6)	Obsolete documentation is identified, removed and managed adequately to prevent unintended use.		
7)	Production records are complete and verified by authorised personnel.		
8)	Production and supporting records retention are complied with local regulation or customer requirements.		
9)	Corrective action procedure shall be documented to include the following elements: <ul style="list-style-type: none"> Responsibility and authority involved in reviewing the non-conformities and finalizing the decision of corrective action Flowchart/sequence of addressing the corrective action Nature of process and equipment failure Description of corrective action Root cause investigation Verification of corrective action taken Recordkeeping 		
10)	Control of non-conforming procedure shall be documented to include the following elements: <ul style="list-style-type: none"> Responsibility and authority involved in reviewing the non-conforming material or product and finalizing the decision of disposition Methods of handling: segregation, identification, labelling, storage and recording Methods of disposition: rework, disposal, down grade to non-food and others Recordkeeping 		
11)	Proper segregation and identification of non-conforming material or WIP items onsite.		
12)	Evidence of timely corrective action to address non-conforming WIP or finished product onsite.		
13)	Corrective action taken is verified by authorised personnel.		
14)	Non-conforming material or WIP is approved by authorised personnel.		
15)	Traceability and recall procedure are documented. Mock recall shall be minimum annually. Records shall be maintained.		
16)	Conduct live traceability onsite to verify traceability process for 100% recovery within 3 hours.		
17)	When change occurred in production, i.e.: equipment setting, formulation, processing method and packaging material, the following control shall be taken into consideration to ensure that change does not endanger product safety, quality and legality. <ul style="list-style-type: none"> Re-conduct hazard analysis Re validate the product data Re-establish processing and product characteristics Specify the reason for amendment 		
18)	Any production change is recorded, dated and approved by authorised personnel.		
19)	Loose items such as production tool, maintenance tool, stationery and other items are adequately stored such		

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	<p>personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives</p> <ul style="list-style-type: none"> • Permissibility of personal items, such as smoking materials and medicines, in designated areas only • Prohibition of the use of nail polish, false nails and false eyelashes • Prohibition of carrying of writing implements behind the ears • Maintenance of personal lockers so that they are kept free from rubbish and soiled clothing • Prohibition of storage of product contact tools and equipment in personal lockers 		
	D2: Personnel Hygiene Facilities and Toilets		
1)	Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.		
2)	<p>Establishments shall:</p> <ul style="list-style-type: none"> • Provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash basins, supply of hot and cold or temperature controlled water (32°C-45°C) and soap and/or sanitizer) • Have sinks designated for hand washing, whose taps should not be hand operated, separate from sinks for food use and equipment cleaning stations • Provide an adequate number of toilets of appropriate hygienic design, each with hand washing, drying and, where required, sanitizing facilities • Have employee hygiene facilities that do not open directly onto production, packing or storage areas; • Have adequate changing facilities for personnel • Removal of high risk clothing is in specially designated area only • Have changing facilities sited to enable food handling personnel to move to the production area in such a way that risk to the cleanliness of their work wear is minimized 		
	D3: Staff Canteens and Designated Eating Areas		
1)	Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross contamination of production areas is minimized.		
2)	Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods. Storage conditions and storage, cooking and holding temperatures, and time limitations, shall be specified.		
3)	Employees' own food shall be stored and consumed in designated areas only.		
	D4: Work Wear and Protective Clothing		
1)	Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).		
2)	Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.		
3)	<p>Work wear shall comply with the followings:</p> <ul style="list-style-type: none"> • Work wear shall not have buttons • Work wear shall not have outside pockets above waist level • Zips or press stud fastenings are acceptable 		

4)	Work wear shall be laundered to standards and at intervals suitable for the intended use of the garments.		
5)	Low risk, high care and high risk protective clothing and maintenance clothing must be washed separately.		
6)	Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.		
7)	Hair, beards and moustaches shall be protected (i.e. completely enclosed) by restraints unless hazard analysis indicates otherwise.		
8)	Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves should be avoided where possible.		
9)	Shoes for use in processing areas shall be fully enclosed and made from non absorbent materials.		
10)	Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.		
D5: Health Status			
1)	Subject to legal restrictions in the country of operation, employees shall undergo a medical examination prior to employment in food contact operations (including site catering), unless documented hazard or medical assessment indicates otherwise.		
2)	Typhoid vaccination is provided to all food handlers.		
3)	Typhoid vaccination record is kept for reference. Valid or active vaccination must be in place for all food handlers if it is required by local law.		
4)	Additional medicals shall be carried out at intervals defined by the organization, subject to legal requirement in the country of operation.		
D6: Illness and Injuries			
1)	Where permitted by law, employees shall be required to report the following conditions to management for possible exclusion from food handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.		
2)	People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food or materials which come into contact with food.		
3)	In food handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately. Dressings should be brightly coloured and metal detectable where appropriate.		
D7: Training & Education			
1)	Training program was documented for all food handlers and staff working in the food premises.		
2)	Training and education records for all personnel are maintained.		
3)	Training effectiveness evaluation is established and recorded.		
4)	Evidence of improvement action is recorded to meet the required competency.		
5)	Minimum training for food handlers depending on local regulation: Ministry of Health Approved Food Handler Course (Malaysia), HACCP, CCP, GMP, food defence, GMP and allergen training and supporting training required to ensure meeting required competency in the production process.		
6)	Annual refresher training minimum on all food safety courses such as HACCP, CCP, GMP, food defence, GMP, allergen training and supporting training required to ensure meeting required competency in the		

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	<ul style="list-style-type: none"> • Blenders • Homogenizers • Roasters • Other associated fittings 		
8)	Production changeover from allergen-containing products to non-allergen products or products that contain different allergens, verify to ensure that the system is thoroughly CIP cleaned and sanitized.		
9)	CIP system must be installed with strainers to prevent foreign material contamination of the spray balls or product contact surfaces. Evidence to show that spray balls to ensure they are in clean and good condition.		
10)	CIP operators are trained on the appropriate use of cleaning and sanitizing agents and proper operation of CIP equipment.		
11)	Verification of proper rinsing is completed and documented on a defined frequency.		
12)	CIP equipment is separated from active production lines (e.g. through the use of double seat valves, manually controlled links, blanks in pipe work or make-or-break connections with proxy switches as interlocks) to prevent cross-contamination. The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.		
13)	CIP systems are hygienically designed with no dead areas, limited interruptions to flow streams and allow good drainability.		
14)	Effectiveness of CIP cleaning is verified, validated and recorded.		
Section H: Pest Management			
H1: Pest Control Programme			
1)	The site has a documented pest control program.		
2)	All pest control activity must comply with legislative requirements.		
3)	Missing bait stations are recorded and investigated.		
4)	Effective pest control programme established to protect against birds, rodents, insects and other pests (e.g. appropriate barriers).		
5)	Evidence of frequent inspections and treatment of the site as a frequency based on the product risk assessment of based on the age, design and location of buildings and equipment.		
6)	External doors, windows or other openings are close fitting to prevent pest ingress.		
7)	Windows, doors and skylights that must be opened are screened to prevent pest entry both in production, storage area and in staff facilities.		
H2: Pest Control			
1)	<p>If external pest control service provider is engaged, the contract shall include the following details:</p> <ul style="list-style-type: none"> • Site name & address • Site contact person • Frequency of services • Scope of target pest and methods to be applied to control each of pest • Terms of the contract • Equipment and material storage specifications • List of approved chemicals, prior to use 		

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2)	Minimum monthly monitoring is carried out. Frequency of checking should be increased if the level of activity increases.		
3)	Exterior bait stations shall be tamper resistant and are positioned, anchored in place, locked, and labelled.		
4)	Bait station are placed at intervals of 15-30 m. Areas of high rodent detection should have more monitoring devices or as advised by the pest control service provider.		
5)	Exterior bait stations that use rodenticides are tamper resistant or locked with single-use cable ties, padlocks, bait station key or suitable devices.		
6)	All exterior bait station positioned, anchored in place, locked, and labelled.		
7)	Rodenticide/rodent bait shall be used shall be approved by appropriate governing authority. MSDS or equivalent shall be available.		
8)	Baits shall be securely fastened inside bait stations. It shall be maintained in good condition and to replace as appropriate to prevent deterioration.		
H8: Interior Rodent Monitoring Devices			
1)	Chemical baits of any form poisonous or non-poisonous shall not be used in the building interior.		
2)	Interior monitoring could include the following devices unless prohibited by regulation: <ul style="list-style-type: none"> • Glue boards • Mechanical traps • Extended trigger traps 		
3)	If there is any use of toxic or non-toxic treatments externally, it must comply with applicable regulatory requirements.		
4)	Based on the detailed site assessment, interior monitoring devices are placed in appropriate sensitive areas specific to the rodent species to ensure effective detection & monitoring: <ul style="list-style-type: none"> • Raw material store • Finished product warehouse • Staging areas for finished products • Both sides of doors that open to the exterior of the site. • Maintenance areas with exterior access • High traffic areas • Overhead areas for preventing roof rat activity • Areas with food sources such as canteen, food & beverage vending machines • Other areas with the potential for rodent access 		
5)	Monitoring devices are placed at intervals of 6-12 m along exterior walls, and are strategically placed in sensitive areas toward the interior of the site or as advised by the pest control service provider. Areas of high rodent detection should have more monitoring devices or as advised by the pest control service provider.		
6)	Interior monitoring devices are placed along perimeter walls. Spacing and number of traps are based on activity levels		
7)	Minimum weekly monitoring is carried out to ensure that all interior devices are adequately cleaned and inspected.		
8)	Facilities in countries that prohibit the use of mechanical traps may consider the use of alternative devices,		

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	<p>subject to regulatory requirements, on a case-by-case basis. Other devices which may be considered as per internal risk assessment if the use of mechanical trap is banned by country regulation. These alternative options include:</p> <ul style="list-style-type: none"> • Radio monitored trap (auto email or text alert) • Live catch traps • See-saw tubes • Carbon dioxide traps • Electrocutation traps • Others 		
	H9: Insect Light Traps		
1)	Insect light traps are installed in the designated area based on the detailed site assessment. Insect light traps are used to monitor flying insect activity at sensitive locations that are likely to allow access to the site.		
2)	Insect light tube shall be shatter-resistant. It shall be controlled in the glass and brittle plastic policy as appropriate. Insect light trap tubes are changed at least yearly or at the onset of active season.		
3)	Insect light traps are installed greater than 3 m from food contact surfaces, exposed products, packaging, food contact handling utensil, and raw materials in processing or storage areas.		
4)	Minimum weekly monitoring is carried out for warmer climate. Minimum monthly in colder climate. All service report and monitoring records shall be complete and maintained.		
5)	<p>The following conditions are checked and recorded:</p> <ul style="list-style-type: none"> • Glue board or collection devices • Condition of light tube to ensure no crack or breakage • Cleaning & repair the units 		
6)	The site records the types and quantities of insects found in the light traps, and uses the information to identify the type (e.g. flies, stored product insects, etc.) and quantity trapped (qualitatively or quantitatively) in order to eliminate the source of activity more effectively.		
	H10: Pheromone Monitoring Devices		
1)	Pheromone monitoring devices are installed in the designated area based on the detailed site assessment.		
2)	Pheromone monitoring devices are installed according to manufacturer's label requirements.		
3)	Pheromone monitoring devices are inspected and recorded on a planned interval.		
4)	The site records the types and quantities of insects found in the Pheromone traps, and uses the information to identify the type and quantity trapped (qualitatively or quantitatively) in order to eliminate the source of activity more effectively.		
	H11: Bird Control		
1)	Appropriate bird control shall be implemented as per detailed site assessment if required.		
2)	<p>Birds control method can include the following:</p> <ul style="list-style-type: none"> • Traps • Nets • Proper structural modifications • Other approved legal methods 		

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	documented.		
10)	If foot baths and sanitizers are not used for cross contamination control in a sensitive operation, a captive footwear program shall be practiced to prevent microbial contamination of product and processing areas.		
11)	Washroom and changing facilities are provided with functional exhaust fans that exhaust to the outdoors or do not open directly into production, packaging or raw material storage areas.		
12)	Adequate drainage flow in high risk area or laboratory to prevent back flow which may lead to cross contamination. There shall be a schematic map to show the direction of flow and location of any equipment fitted to prevent the back-flow of waste water which could lead to the risk of contamination of the high-risk/care area.		
13)	Drainage is designed and maintained to minimise risk of product contamination and does not compromise product safety.		
14)	Prevention includes the additional enclosure control in the high risk area such as filling, packing and sealing areas.		
15)	Control measure of dirt, dust and micro-organisms in filling and sealing areas to prevent product contamination.		
16)	Prevention to include action to avoid customer dissatisfaction incidence such as meat in vegetarian food and other potential concerns.		
I2: Chemical Control			
1)	The site has a documented procedures for the control of chemicals.		
2)	Procedures shall include the following elements, as applicable: <ul style="list-style-type: none"> • An approved list of chemicals • Material safety data sheets and specifications provided by the supplier • Support document, test certificate and confirmation that the chemicals are suitable for use in a food-processing area (i.e. Non toxin or food safe for food contact surfaces) • Avoid using strong-scented products • Identification and labelling of chemicals (including secondary container) • Designated storage with restricted access limited to authorised personnel • Use of chemicals by trained personnel only • Labelling of chemicals, MSDS shall be, where possible, in local language. Consideration may need to be given to the legislative requirements of specific countries.		
3)	Strong scented chemical including maintenance and building construction/renovation material shall be avoided to prevent the risk of taint contamination of products. It shall be addressed in the chemical control procedure.		
	All chemical shall be traceable to its production lots / batch number		
I3: Microbiological Control			
1)	Based on the onsite risk assessment, the site has a documented microbiological programme for the following area: <ul style="list-style-type: none"> • Raw materials • Packaging material 		



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	<ul style="list-style-type: none"> • Work in process • Finished product • Environment • Food contact surface and processing equipment • Others 		
2)	Microbiological test records shall be maintained. Records shall be retained as per record retention procedure.		
3)	Test samples are retained as per Microbial Control Program.		
4)	On site laboratory shall not be located in the production area. Adequate segregation shall be implemented to prevent the risk of product contamination.		
5)	Where samples are tested by in house microbiologist, the competency, training and proficiency test shall be adequately documented and recorded.		
6)	Where samples are tested by the third party laboratory, they shall be accredited to ISO/IEC 17025.		
7)	Proper hold and release are implemented as per documented release procedure. On hold shall be clearly identified with product details, test status with supporting test reports and documents. Product that fails the pathogen test must be withheld until receiving acceptable test results. Release of product or material shall be supported by acceptable test results, approval signatory and release documents.		
8)	Products that test positive for pathogens shall be appropriately reprocessed as per rework procedure or destroyed. Disposition and corrective action records shall be maintained. Re-processing records shall contain the product details and total quantity, batch number reworked and final test status to enable full traceability.		
I4: Management of Allergens			
1)	Documented allergen controls including specific allergen labelling process are established based on legislative requirement.		
2)	Procedures shall include the following requirements: <ul style="list-style-type: none"> • Allergen risk assessment. Safe handling of allergen during raw material receiving & storage, internal transfer and handling which include proper labelling and segregation • Prevention of cross contact or contamination during processing through production scheduling, control of rework, dedicated production lines, changeover procedures, cleaning & sanitation procedure, equipment and utensils management, product label reviews and control, personnel awareness training and education, verification of cleaning procedures for food contact equipment, approved supplier and monitoring system for ingredients and labels • Allergen validation test is conducted appropriately to ensure that the implementation is effective 		
3)	The site has the updated list of identified allergen onsite. The list shall include raw materials, processing aids, work in process and finished products and any new product development ingredients or products.		
4)	The procedure is revised when there are changes in the following: <ul style="list-style-type: none"> • Ingredients • Products • Processing aids • Ingredient suppliers • Processes 		

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	tight-fitting protective cover. They are adequately protected from foreign matters and airborne particles during the storage and handling process.		
	I10: Visual Inspection		
1)	If foreign material control device is not feasible to be used to detect, remove or prevent foreign materials from food material, then visual examination shall be conducted prior to process or dispatch the food products. Examples of these foods may include fruits, fresh produce, nuts, coconut and similar materials which are visually examined before use.		
2)	Records of visual inspection shall be maintained.		

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COMPANY NAME:		DATES OF AUDIT:		FOLLOW UP ACTIVITY DATE:	
COMPANY REPRESENTATIVE:		LEAD AUDITOR:		NUMBER OF NON-CONFORMITIES:	Minor- Major- Critical-

Final Score and Grade

GMP Requirements	Satisfactory	Minors	Majors	Critical	N/A	No. of Item Rated
Section A: Construction and Layout of Buildings						/
Section B: Layout of Premises and Workspace						/
Section C: Manufacturing & Operational Control						/
Section D: Personnel Practice & Training						/
Section E: Utilities						/
Section F: Equipment & Maintenance						/
Section G: Cleaning & Sanitation						/
Section H: Pest Management						/
Section I: Prevention of Cross Contamination						/
Total Number of Rating:						/

Final Score %:	
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Grade:	
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Categories	Minor	Major	Critical	Remark
Facility Operational and Personnel Practices				
Maintenance for Food Safety				
Cleaning Practices				
Integrated Pest Management				
Adequacy of Prerequisite and Food Safety Programs				
Total Number of Finding:				

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