FOOD, MEDICINE AND HEALTH CARE ADMINSTRATION AND CONTROL AUTHORITY OF ETHIOPIA (FMHACA)

SMALL SCALE MEDICINE ESTABLISHMENT DIRECTIVE

June 2014
Addis Ababa

Contents

PREAMBLE

WHEREAS, it is necessary to protect public health through regulation of small scale medicine manufacturers to operate in accordance with the required safety, quality and efficacy requirements of medicine products;

WHEREAS, regulatory provisions regarding the layout, design, location, construction, and maintenance of the premise; installation of equipments and utilities, personnel of small scale manufacturer are important factor in the resulting safety, quality and efficacy of products;

WHEREAS, it is found appropriate to take the necessary administrative measures on non-complying small scale manufacturers operating against the provision of this directive and other applicable laws;

NOW, THEREFORE, this directive is issued by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority in accordance with article 55(3) of the Food, Medicine and Healthcare Administration and Control Proclamation No. 661/2009.

PART ONE
GENERAL PROVISION

1. Short title

This directive may be cited as the "Small Scale Medicine Establishment Directive No. 339/2020

2. Definitions

Without prejudice to the definition provided under the Food, Medicine and Healthcare Proclamation No. 661/2009:

1) " manufacturer" means a manufacturer classified as small scale by the Authority and involved in processing or production of products for external use only, including sanitary items, cosmetics, antiseptic, and medical supplies and other related products using none sophisticated technology;
2) "sanitary item" means any preparation used in the maintenance of cleanliness of human, household, and includes pads, tampons, dentifrices, sweat-bands and detergents;
3) "active ingredient" means any substance or mixture of substances intended to be used in medicine manufacturing and that, when so used, enables to the finished product to achieve its intended purpose;
4) "authorized person" means the person recognized by the Authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the requirements of marketing authorization;
5) "bulk product" means any product that has completed all processing stages up to, but not including, final packaging;
6) "calibration" means the demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable

standard over an appropriate range of measurements. Limits for acceptance of the results of measuring shall be established;

7) "self-contained area" means an area which provides complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers, but does not necessarily imply two distinct and separate buildings;
8) "Person" means a physical person or juridical person.
9) "Authority" means the Ethiopian Food, Medicine and Health Care Administration and Control Authority;

3. Scope of Application

This Directive shall be applicable on small scale medicine establishments.

4. Objectives

The objectives of this directive shall be:

1) to ensure products manufactured in small scale medicine establishments are up to the required safety, quality, and as appropriate, efficacy requirements;
2) to set and define minimum requirements with respect to practices, premises, professionals and products of the small scale medicine establishments ; and
3) to ensure adherence to current Good Manufacturing Practice and Good Laboratory Practice.

5. Principles

1. Any person who wants to engage in small scale medicine establishments shall get Certificate of Competence from the Authority.
2. Certificate of competence to be issued in accordance with sub article (1) of this article shall be in compliance with this directive.

3. In case where manufacturer fails to continually observe applicable requirements after getting the Certificate of Competence, the Authority shall take appropriate administrative measures.

PART TWO
CERTIFICATE OF COMPETENCE

6. General

It shall be mandatory to get a certificate of competence issued by the Authority to engage in small scale medicine establishments.

7. Application to get certificate of competence

1) An applicant for a certificate of competence shall:

   a) complete an application form in accordance with ANNEX-I of this directive;
   b) fulfill the requirements provided in respect of premises, professionals and equipments; and
   c) pay the appropriate service fee;

2) The actual conduct of the site audit shall depend on the assessment of the outcome of the application profile and checklist completed by the applicant in Accordance with Annex-II of this directive.
3) The Authority shall evaluate and, as the case may be, recommend or decide after receiving duly filled application, premises inspection report and all other necessary documents from the inspectors.
4) The Authority may approve, reject or recommend corrections to the application by providing reason for its decision. Where the premises requirements have not been met, the applicant shall, as appropriate, be informed by official letter to address the deficiencies or the reason for rejection.
5) Applicants who are required to take corrective action shall carry out remedial measures before re-inspection of the premises. Re-inspection may be carried out by

the Authority free of charge. Whereas, inspection request beyond re-inspection shall be subject to addition charge.

8. Pre-approval inspection

1) The purpose of pre-approval inspection shall be to issue a manufacturing certificate of competence.
2) An inspection team shall be established by the Authority for the conduct of compliance check of requirements provided under this directive.
3) Once requirements are met to guarantee the issuance of certificate of competence, the Authority shall grant the same to the applicant.

9. Premise

1) General

a) The premise shall be located, designed, constructed, adapted and maintained to suit the operation to be carried out.
b) The layout, design and construction of premises shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt and in general any adverse effect on the quality of the product.
c) The premise shall have at least quality control room, production room, store (raw material, finished products and packaging materials), sample retention room or area, and, as appropriate, stability study room or area.
d) The premise shall provide separate rooms or areas for storing flammable substances, fuming and concentrated acids and bases, volatile amines and other chemicals related to business operation.
e) The premise shall have changing areas and toilets appropriate for the number of users.
f) Electrical supply, water supply, lighting, temperature, humidity and ventilation shall be appropriate such that they do not adversely affect, directly or indirectly, either the products during their manufacture and storage.

2) Premises location

a) Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products.
b) The premises shall be located away from sites or activities that emit obnoxious materials like fumes and contaminants; open sewerage, malting and brewery industries or other offensive trades having direct or indirect impact on the quality, safety or efficacy of medicine.
c) The premises shall be located in such a way that it shall have no direct link to any other building engaged in other business activity and/or belonging to other business entity.

3) Storage and weighing area

a) The premise where products and materials are stored shall be sited where the risk of contamination from the local environment, or from other nearby activities, is low. There shall be appropriate mapping design for the control of the room temperature and humidity.
b) The size or capacity of the working and storage areas shall permit the orderly and logical storage, flow of process and materials so as to minimize the risk of confusion between different stage products.
c) Premises for sampling and weighing of materials shall have the same cleanness as for the subsequent production area.

10. Production area

1) The total manufacturing and processing area of the product shall be designed to suit the intended purpose to achieve the applicable room temperature, humidity,

equipment accommodation, operators comfort and safety to permit easy cleaning and material movement.

2) The premise in production areas shall be, as appropriate, ventilated with facilities appropriate all to the products handled, to the operations undertaken within them and to the external environment.

11. Quality control area

Premises for quality control laboratories shall, as appropriate, be separated from production areas. This is particularly important for laboratories for the control of biological, microbiological and radioisotopes, which shall also be separated from each other.

12. Equipments

1) Equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products.
2) The equipments shall be made up of suitable materials that the surfaces contact components are not reactive, additive and absorptive.
3) Equipment used for manufacturing shall be situated in an area conducive for the practice of preparation, easily cleanable to minimize potential contamination and shall have status label and identification number.
4) Rooms shall be furnished with all necessary equipments according to their product type for sampling, mixing, preparation, water treatment, measurement, quality test, capacity of production and other related requirements.
5) All instruments and other devices shall be calibrated on a regularly scheduled basis and documentation showing proof of calibration.

13. Water treatment

1) Water treatment and storage shall be designed, installed, and maintained to ensure the reliable production of water of an appropriate quality. Water shall be produced and stored in a manner that prevents unacceptable microbial, chemical or physical contamination.
2) Where appropriate, purified water shall be used and the purification method, or sequence of purification steps, shall be appropriate to the intended purpose. The following shall be considered when selecting the water treatment method:

    a) the water quality specification;
    b) the yield or efficiency of the purification system;
    c) feed-water quality and the variation over time (seasonal changes);

14. Personnel

1) The manufacturer shall have an adequate number of personnel with necessary qualifications and practical experience. The responsibilities placed on any one individual shall not be so extensive as to present any risk to the quality of product.
2) The manufacturer shall have the following technical personnel:

    a) Technical manager should be a pharmacist having at least three years experience or chemist with upgrade in pharmacy professions and two years experience in pharmaceutical products.
    b) There should be a pharmacist or chemist for quality control unit.
    c) As may be required by the type of preparations performed in the small scale medicine manufacturer, other assistance technical staffs such as pharmacist, chemist and druggists may involve in the production process.

3) The manufacturer shall have a job description for all its technical staffs.

15. Practice

1) Quality control and assurance

The quality control and assurance personnel shall:

a) distinguish raw materials requiring specialized handling or storage;
b) ensure quality of the raw materials used for manufacturing, and finished products before marketing;
c) establish written operational procedures for approval of all raw materials and finished products;
d) establish written operational procedures governing the calibration of instruments, devices, meters and recording apparatuses;
e) develop and retain batch manufacturing recording for each lot and type of product;
f) develop a written quality assurance plan
g) ensure availability of stability study protocol and commitment for each product (if applicable), and
h) have written policies and procedures for all activities should be documented.

2) Technical manager personnel

The technical manager shall be responsible for the content, strength and safeties of products and to ensure that a training program has been implemented and properly documented.

3) Sanitation

a) The small scale medicine establishments shall have a written sanitation program include for the premises and equipment,

b) There shall be cleaning standard operating procedures to be followed for equipments and premise.
c) Mixing and packing containers and other utensils used in the small scale medicine manufacturer process shall be cleaned before and after each preparation to avoid cross contamination.
d) Every employee shall keep uniform neat and in good repair.
e) No open toe shoes shall be worn and natural nails must be kept short and clean.
f) Hair must be worn in a way that prevents contamination and does not present a safety hazard.

4) Labelling requirements

Product labels shall have the following information, including but not limited to:

a) Name and manufacturer address;
b) Name and strength of active ingredients;
c) Generic name of the product;
d) volume or weight of the finished product;
e) Lot number;
f) Production date(if applicable), expiry date and/or best before date; and
g) Storage condition and instruction, as needed.

5) Packaging requirement

a) The manufacturer shall ensure that the containers and container closures used in packaging of preparations meet applicable packaging requirements.

b) The containers and container closures shall be made of clean materials that are not reactive, additive, and absorptive and shall be appropriate for the stability of the product.

c) Packing should be done using appropriate packaging devices or machinery as specified on the work sheet, and following approval from an authorized person.

6) Storage and transportation

a) Raw material shall be stored and transported in a manner that it prevents the alteration to the potency, purity and physical characteristics of the raw material.
b) Transportation of the prepared product shall be appropriate in accordance with the nature of the product.

7) Record and documentation

a) Certificate of Analysis (COA) for raw materials and reagents shall be available.
b) The manufacturer shall maintain standard operating procedures, policies and manuals and other related technical documents.
c) Deviations from written preparation process should be avoided. If deviations occur, the responsible personnel should describe the deviation and the rationale and maintain these records for a minimum of 2 years from the date manufacture.
d) Standard operating procedure of each process for production (like, raw material receiving, cleaning, dispensing of raw materials and distribution of finished products, method of preparation, batch numbering system, water purification process SOP, etc should be documented and available on requested by the authority inspectors.

8) Change of premises address notification and signboard

a) Any change of location (shift of premises), trade name of the premises, ownership or any other change of registered premises, needs prior notification and approval by the Authority.
b) An intention to change location of registered premises shall be made in writings to the Authority before the change is made and the Authority shall notify the applicant on the procedure to be followed.

c) The premises shall have a sign board conspicuously displayed at the main entrance.

16. Maintenance and post approval inspection

1) Premises shall be carefully maintained, and it shall be ensured that repair and maintenance operations do not present any hazard to the quality of products.
2) Premise, professional, and practice requirements necessary for the issuance of certificate of competence shall continually be complied with even after the granting of the certificate of competence.
3) Unless found to be necessary to perform incidental inspection, every small scale manufacturer premise shall be inspected every year as part of renewal of the certificate of certificate.

PART THREE
ADMINISTRATION MEASURE AND COMPLIANT HANDLING

17. General

1) Products, the manufacture or individuals who violate requirements of this directive or other applicable laws may be subjected to appropriate administrative measure in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
2) The person against whose product or whom an administrative measure is taken in accordance with sub-article (1) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
3) Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee. The complaint shall be submitted within 30 days from the time when administrative measure is taken.
4) Without prejudice to sub-article (1) of this article, the following may be used as illustrative lists for suspension and revocation:

18. Suspension of a license

1) The Authority may suspend certificate of competence or take such other appropriate administrative measures as it may find necessary, in accordance with the Directive on Administrative Measure Taking and Complaint Handling.
2) Without prejudice to grounds of suspension provided under relevant laws, and based on the severity of the violation, the Authority shall suspend manufacturer's certificate of competence if, but not limited to,:

    a) the manufacturer allows a professional who is not duly licensed or who has been suspended from practicing by a competent authority from practicing his/her profession;
    b) it fails to allow inspection pursuant to applicable laws;
    c) the manufacturer is suspended by other government organ;
    d) it fails to submit, accurately or on time, or falsify information requested by the Authority;
    e) it is found manufacturing products with the absence of authorized personnel or technical manager;
    f) it fails to notify the Authority of any change to professionals or premises design and/or place without approval; and
    g) any of its permanent professionals is found registered or employed as a permanent staff in any other facility except where dual appointment is permitted by law.

19. Revocation of a License

Without prejudice to grounds of revocation provided under relevant laws, and based on the severity of the violation, the Authority shall revoke manufacturer's certificate of competence if, but not limited to,:

1) engage in any act which constitutes a serious violation in accordance with the directive on Administrative Measure Taking and Complaint Handling and the violation is subject to revocation measure;
2) engages in manufacturing products other than permitted by the Authority;
3) the manufacturing permit is not annually renewed within three months from the start of the Ethiopian budget year,
4) its certificate of competence is proved to have been obtained by submitting false information intended to deceive the Authority or it is obtained in other illegal manner.

20. Public and media disclosure

1) Disclosure of administrative measure shall only be allowed after 30 days of the final decision by the Authority or if the case is under complaint procedure after the final decision on the complaint.
2) Notwithstanding sub-article (1) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.
3) Publication in accordance with sub-article (2) of this article shall be approved by the Director General of the Authority.

PART FOUR
MISCELLANEOUS

21. Pharmaceutical waste disposal procedure

1) All rejected materials shall be clearly identified, recorded and stored separately and announce the Authority before disposal

2) The materials unfit for distribution whether starting material, packaging and/or finished products shall be disposed as per the Health care waste management Directive No.16.

22. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority.

23. Inapplicable laws

Any directive which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

24. Effective date

This directive shall come in to effect as of, october.11/.2014.

Yehulu Denekew

Director General

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

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Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Annex I

Application Form for Manufacturing Premises Licensing

All the information required in this form shall be filled accurately and submitted with cover letter and copy of valid identification card to the Authority.

S/N	Application for Licensing of Manufacturing Premises	To be printed in the space provided
1	**Information on the applicant**	
	Name of the applicant	
	Postal address	
	City,Sub-city/Kifleketema	
	Particular name of the area	
	Telephone	
	E-mail and/or website	
2	**Name of business partner (if any)**	
3	**Type of application (mark as applicable)**	
		General product manufacturer ☐
		Sterile product manufacturer ☐
		Penicillin's and other ☐
		Other (specify)
5	**Information on the contact person**	

	Title of the contact person	Mr/Ms/Mrs/Dr/PhD
	Name of the contact person	
	Professional qualification	
	Address (Telephone, e-mail etc)	
	Professional registration number	
6	**Proposed name of the premises**(attach any official document, gazette etc)	
7	**Declaration by the applicant**	
	If my premise is permitted I shall keep it in hygienic condition and good state of maintenance as required under the act and regulations of Ethiopian Food, Medicine and health care Control Authority (EFMHACA) and in accordance with the National and International GMP requirement. I have not been convicted at any offence relating to any provision of Ethiopian Food, Medicine and health care Control Authority (EFMHACA) there under or any other written law related to the business being applied for within 12 months immediately preceding this application and have not been disqualified from holding a manufacturing certificate of competence and my permit is not suspended. Name_____ Signature_____ Date_____	
8	**To be completed by the Authority's Inspector**	
	I (name) Mr. /Mrs./Ms./Dr./Prof……Inspector of the Authority hereby certify that, I have reviewed all pre-licensing information and/or inspected the ☐ ove mentioned premis ☐ er attached inspection checklist and found that it (complies does not comply) with standards prescribed for Licensing of premises National and International GMP Directive . I confirm that the following documents reviewed and complete as recommended by the Directive s. Premises and production design layout ☐ Pre-licensing Inspection checklist ☐ Qualification document ☐	
9	**Summary of Reason for non-compliance (if any):**	

10	**Nameof Inspector (Assessor) (s)** 1)_____ 2)_____3) _____ Signature 1)_____2)_____3)_____ Date _____
11	**For Official Use Only**
	Certificate of Competence Granted Not Granted
	Summary for Deniale of Certificate of Competence (where applicable)
	Certificate of Competence Number:
	Date of Registration:
	Signature of the Authority and Date:

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Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Annex-II

Inspection checklist of Small Scale Medicine Manufacturing Premises

This form must be carefully completed and submitted to the Authority along with the application form provided as an annex I of this directive for the purpose of registration of new premises and/or change in the location of premises. Normally, the checklist needs to be completed by the applicant at the time of pre-licensing and where applicable should be completed by the inspector after licensing of the premises. By considering the type of product all the applicable section of the checklist should be completed and/or properly justified. The operational procedure and activity of the checklist may not be applicable at the time of licensing application for the premises licensing.

S/N	Description	Notes/Observation/Response
1.	**Office/Owner Address**	Name:
		Subcity/Kifleketema
		Particular area name
		Telephone
		E-mail:
2.	**Physical address of the establishment**	Name:
		Sub city/Kifleketema
		Particular area name

		Telephone	
		E-mail:	
3.	**Purpose of the establishment premises**	Disinfectant ☐	
		Cosmetics ☐	
		Medical supplies ☐	
		Other (specify)	
		Compliance,√[1],X,~	**Remark**
4.	**PERSONNEL**		
	Qualified and adequate personnel available?	☐ ☐ ☐	____
	Organization chart available?	☐ ☐ ☐	____
	Job description available?	☐ ☐ ☐	____
	Responsibilities clearly defined?	☐ ☐ ☐	____
	Key personnel		
	• Quality Control/Assurance Head	☐ ☐ ☐	____
	• Production Head	☐ ☐ ☐	____
	Are they independent from each other?	☐ ☐ ☐	____
	Are joint functions clearly defined?	☐ ☐ ☐	____
	Are the key personnel working full time?	☐ ☐ ☐	____
	Training		
	Continuous training program for all staff?	☐ ☐ ☐	____

√ = Complete, × = incomplete, ~ = Partially completed

	Induction training for all staff?	☐ ☐ ☐	____
	External training courses for all staff?	☐ ☐ ☐	____
5.	**Hygiene**		
	Personnel Hygiene		
	Detailed written hygiene programs for		
	• Clothing?	☐ ☐ ☐	____
	• Gloving?	☐ ☐ ☐	____
	• Showering?	☐ ☐ ☐	____
	• Behaviour in production areas?	☐ ☐ ☐	____
	Medical examination		
	• On recruitment?	☐ ☐ ☐	____
	• Regular examination?	☐ ☐ ☐	____
	Instructions for appropriate working clothes?	☐ ☐ ☐	____
	Absence of food and drinks (chewing gum) in the working area?	☐ ☐ ☐	____
	Measures against contact with open product (e.g. gloves,etc)?	☐ ☐ ☐	____
	Change of clothes when entering and leaving the production?	☐ ☐ ☐	____
	Change rooms and toilets easily accessible?	☐ ☐ ☐	____
	Toilet and refreshment rooms adequately separated from production areas?	☐ ☐ ☐	____
6.	**WAREHOUSE**		
	Suitable for intended purpose?	☐ ☐ ☐	____
	• Adequate size?	☐ ☐ ☐	____
	• Clean?	☐ ☐ ☐	____
	Located and designed to exclude external contamination?	☐ ☐ ☐	____

	Maintenance work possible without contamination risk?	☐ ☐ ☐	____
	Appropriate lighting and air conditioning?	☐ ☐ ☐	____
	Controlled access for authorized person only?	☐ ☐ ☐	____
	Protection against entry of insects or other animals?	☐ ☐ ☐	____
	Rooms, Special requirement		
	Segregation of material is sufficient?	☐ ☐ ☐	____
	Provision for different storage condition and mapping (T,RH)?	☐ ☐ ☐	____
	Quarantine area sufficiently segregated with controlled access?	☐ ☐ ☐	____
	Separate, protected area for sampling?	☐ ☐ ☐	____
	Separate and safe storage area for		
	• Rejected material?	☐ ☐ ☐	____
	• Returned goods?	☐ ☐ ☐	____
	• Recalled goods?	☐ ☐ ☐	____
	Separate and safe storage of highly active, toxic, or dangerous substance?	☐ ☐ ☐	____
	Safe storage of printed packaging materials?	☐ ☐ ☐	____
	Security measurement against theft?	☐ ☐ ☐	____
	Fire extinguishing system?	☐ ☐ ☐	____
	Procedure and activity:		
	Reception, Sampling and labelling written procedure available?	☐ ☐ ☐	____
	Sampling procedure available?	☐ ☐ ☐	____
	Cleaning of incoming containers?	☐ ☐ ☐	____
	Investigation and corrective action for damaged container?	☐ ☐ ☐	____
	FIFO/FEFO procedure?	☐ ☐ ☐	____

	Incoming goods conformity with approved supplier list?	☐ ☐ ☐	____
	Labelling of incoming containers with		
	• Internal name and code?	☐ ☐ ☐	____
	• Allocated batch number?	☐ ☐ ☐	____
	• Status labelling (quarantine, approved etc)	☐ ☐ ☐	____
	• Expiry date or re-test date?	☐ ☐ ☐	____
	Identity test for each incoming container?	☐ ☐ ☐	____
	Marking of sampled container?	☐ ☐ ☐	____
	Safe storage of printed packaging material?	☐ ☐ ☐	____
	Lot tracing of all packaging materials?	☐ ☐ ☐	____
7.	**Manufacturing Room**		
	Rooms/cubicle, general		
	Suitable for the intended purpose?	☐ ☐ ☐	____
	• Adequate size?	☐ ☐ ☐	____
	• Clean?	☐ ☐ ☐	____
	Designed and located to exclude contaminants?	☐ ☐ ☐	____
	Proper maintenance	☐ ☐ ☐	____
	Maintenance work possible without contamination risk?	☐ ☐ ☐	____
	Appropriate lighting and ventilation?	☐ ☐ ☐	____
	Recording of temperature and humidity?	☐ ☐ ☐	____
	Protection against entry of insects or other animals?	☐ ☐ ☐	____
	Controlled access for authorized personnel only?	☐ ☐ ☐	____
	Equipment		

	Suitable for the intended use?	☐ ☐ ☐	____
	Well maintained?	☐ ☐ ☐	____
	Written cleaning procedures?	☐ ☐ ☐	____
	Maintenance without contamination risk?	☐ ☐ ☐	____
	Material make up for equipment in contact with the product?	☐ ☐ ☐	____
	Calibration procedure?	☐ ☐ ☐	____
	Calibration records?	☐ ☐ ☐	____
	Contents and flow direction marked on pipes?	☐ ☐ ☐	____
	Pipes for distilled and demineralised water regularly monitored and sanitized?	☐ ☐ ☐	____
	Status labelling of not functioning equipment?	☐ ☐ ☐	____
	Equipment cleanliness status?	☐ ☐ ☐	____
	Equipment ID, name?	☐ ☐ ☐	____
	Procedure and activity		
	Written procedure available for all manufacturing steps	☐ ☐ ☐	____
	Are all manufacturing steps recorded with actual parameters?	☐ ☐ ☐	____
	Check of each single container of the starting materials (contents, weight, identity)	☐ ☐ ☐	____
	Only one batch of product processed at a time?	☐ ☐ ☐	____
	Protection against contaminant (e.g. microbial, etc)	☐ ☐ ☐	____
	Appropriate measure against generation of dust (e.g. closed system)	☐ ☐ ☐	____
	Correct labelling of containers, materials, equipment, rooms with		
	• Product name and batch number	☐ ☐ ☐	____

	• Quarantine status	☐ ☐ ☐	____
	Deviations from standard procedures recorded and appropriate corrective measures taken?	☐ ☐ ☐	____
	Line clearance?	☐ ☐ ☐	____
	Investigation of deviation in the yield?	☐ ☐ ☐	____
	Validated procedure when reworking of rejected batches?	☐ ☐ ☐	____
	Special release procedure for those batches?	☐ ☐ ☐	____
	Use protective clothing (hair cover, shoes, masks, gloves?	☐ ☐ ☐	____
	In Process Control		
	Who performs IPC		
	Type of tests		
	Frequency of tests		
8.	**Packaging (Primary)**		
	Rooms/Cubicles		
	Suitable for the intended purpose?	☐ ☐ ☐	____
	• Adequate size?	☐ ☐ ☐	____
	• Clean?	☐ ☐ ☐	____
	Designed and located to prevent contamination?	☐ ☐ ☐	____
	Proper maintenance?	☐ ☐ ☐	____
	Maintenance possible without contamination?	☐ ☐ ☐	____
	Appropriate lighting and air conditioning?	☐ ☐ ☐	____
	Controlled access for authorized personnel only?	☐ ☐ ☐	____
	Proper segregation of packaging lines?	☐ ☐ ☐	____
	Packaging procedure and activity		

	Only one product packaged per line at one time?	☐ ☐ ☐	____
	Line clearance checklist before starting another product?	☐ ☐ ☐	____
	Labelling of the packaging line (product name and code)?	☐ ☐ ☐	____
	Material checklist delivered to the line (quantity, identity, conformity with order)?	☐ ☐ ☐	____
	Cleaning of primary packing materials?	☐ ☐ ☐	____
	Immediate labelling after filling?	☐ ☐ ☐	____
	Checking of all printing process (code, expiry date)?	☐ ☐ ☐	____
	Special safety measures for off-line printing?	☐ ☐ ☐	____
	Control of printing devices (code reader, counter, etc)?	☐ ☐ ☐	____
	Printings clear and permanent?	☐ ☐ ☐	____
	Balancing of printed packaging materials and bulk?	☐ ☐ ☐	____
	Destruction of left over coded material?	☐ ☐ ☐	____
	Quarantine of finished product before release?	☐ ☐ ☐	____
	Appropriate storage after release?	☐ ☐ ☐	____
9.	**In process Control**		
	Check on identity of bulk and packaging materials?	☐ ☐ ☐	____
	Regular checks on:		
	• Aspect of the packages	☐ ☐ ☐	____
	• Completeness	☐ ☐ ☐	____
	• Conformity of quantity and quality of materials with order	☐ ☐ ☐	____
	• Correct imprint	☐ ☐ ☐	____
	• Correct function of control devices	☐ ☐ ☐	____

	Are the following IPC performed:	☐ ☐ ☐	____
	• Leakage	☐ ☐ ☐	____
	• Release torque of screw caps	☐ ☐ ☐	____
10.	**Documentation**		
	Specifications		
	Specifications for raw/packaging materials?	☐ ☐ ☐	____
	Do specification include:		
	• Internal name and code	☐ ☐ ☐	____
	• Name of supplier and/or manufacturer	☐ ☐ ☐	____
	• Reference sample (printed packaging materials)	☐ ☐ ☐	____
	• Sampling procedure?	☐ ☐ ☐	____
	• Qualitative/quantitative parameter with limit?	☐ ☐ ☐	____
	• Storage conditions?	☐ ☐ ☐	____
	• Maximum storage period?	☐ ☐ ☐	____
	Good receiving?		
	Written procedure for the reception of materials?	☐ ☐ ☐	____
	Do records receipt include:		
	• Product name on labels and delivery note?	☐ ☐ ☐	____
	• Internal name and code?	☐ ☐ ☐	____
	• Receiving date?	☐ ☐ ☐	____
	• Name of supplier and/or manufacturer?	☐ ☐ ☐	____
	• Batch number of supplier?	☐ ☐ ☐	____
	• Total quantity and number of containers?	☐ ☐ ☐	____

	• Allocated internal code	☐ ☐ ☐	____
	SOPs for labelling, quarantine and storage of all incoming materials?	☐ ☐ ☐	____
	Sampling SOPs include		
	• Authorized sampling personnel?	☐ ☐ ☐	____
	• Method, equipment and quantities?	☐ ☐ ☐	____
	• Safety measure	☐ ☐ ☐	____
11.	**QUALITY CONTROL**		
	General requirement		
	Independent QC department available	☐ ☐ ☐	____
	Head of QC well qualified and sufficiently experienced?	☐ ☐ ☐	____
	Qualified personnel available?	☐ ☐ ☐	____
	Organization charts available?	☐ ☐ ☐	____
	Job description available?	☐ ☐ ☐	____
	Responsibilities clearly defined?	☐ ☐ ☐	____
	Continuous training for QC personnel?	☐ ☐ ☐	____
	Initial job training for all employees?	☐ ☐ ☐	____
	Training records?	☐ ☐ ☐	____
	QC personnel admitted to the production rooms for sampling etc?	☐ ☐ ☐	____
	QC Laboratories		
	Suitable for the intended use?	☐ ☐ ☐	____
	Laboratories of adequate size?	☐ ☐ ☐	____
	Appropriate level of maintenance?	☐ ☐ ☐	____
	Adequate separation from production area?	☐ ☐ ☐	____

	QC documentation		
	Do procedures exist for	☐ ☐ ☐	____
	• Self-inspection	☐ ☐ ☐	____
	• Release or rejection of products or materials	☐ ☐ ☐	____
	• Recalls	☐ ☐ ☐	____
	• Complaints	☐ ☐ ☐	____
	• Stability testing	☐ ☐ ☐	____
	Specification available for raw material, bulk product, packaging materials?	☐ ☐ ☐	____
	Analytical procedures for every product?	☐ ☐ ☐	____
	Sampling procedure available for raw, bulk, packaging materials?	☐ ☐ ☐	____
	Supplier certificate available	☐ ☐ ☐	____
	Sample retention system (expiry+ 1year minimum)	☐ ☐ ☐	____
	Calibration program for analytical instrument?	☐ ☐ ☐	____
	Batch records kept for expiry +1yr or 5 year minimum?	☐ ☐ ☐	____
	Procedure for traceability of original analytical record from analytical report number or batch number?	☐ ☐ ☐	____
	Procedure for trend analysis for analytical results, yields and environmental monitoring data?	☐ ☐ ☐	____
12.	**Sampling**		
	Written procedure for taking samples	☐ ☐ ☐	____
	Do procedure define		
	• Method of sampling?	☐ ☐ ☐	____
	• Necessary equipment?	☐ ☐ ☐	____

	• Quantity of sample?	☐ ☐ ☐	____
	• Subdivision of sample?	☐ ☐ ☐	____
	• Sample container?	☐ ☐ ☐	____
	• Labelling of samples?	☐ ☐ ☐	____
	• Storage conditions?	☐ ☐ ☐	____
	• Cleaning and storage of sampling of equipment?	☐ ☐ ☐	____
	• Identification of containers to be samples?	☐ ☐ ☐	____
	Are samples representative for the batch (sampling plan)	☐ ☐ ☐	____
	Sampled container labelled with name of content, batch number, date of sampling and batch containers sampled?	☐ ☐ ☐	____
	Are samples taken by authorized?	☐ ☐ ☐	____
	Storage of reference samples under the recommended storage condition?	☐ ☐ ☐	____
	Finished product stored in the final packaging?	☐ ☐ ☐	____
	Retained samples allow 2 possible complete analyses?	☐ ☐ ☐	____
	Sample retention room access secured?	☐ ☐ ☐	____
	Testing		
	Are the methods validated/verified?	☐ ☐ ☐	____
	Are all results recorded and checked for correctness?	☐ ☐ ☐	____
	Are all calculation checked?	☐ ☐ ☐	____
	Do the analytical testing protocol contains:		
	• Batch number?	☐ ☐ ☐	____
	• Specification reference number?	☐ ☐ ☐	____

	• Method reference number?	☐ ☐ ☐	____
	• Date of analysis?	☐ ☐ ☐	____
	• Name of the analyst?	☐ ☐ ☐	____
	• Statement of release or rejection?	☐ ☐ ☐	____
	• Date and signature of person authorized for release?	☐ ☐ ☐	____
	Are all IPC in production approved by QC?	☐ ☐ ☐	____
	Reference standard labelled with name and potency, date of expiry, supplier name	☐ ☐ ☐	____
13.	**COMPLIANTS AND PRODUCT RECALLS**		
	Complaints	☐ ☐ ☐	____
	Does written compliant procedure exist?	☐ ☐ ☐	____
	Are product compliant carefully reviewed?	☐ ☐ ☐	____
	Is a person designated to handle complaints and to decide on measures to be taken?	☐ ☐ ☐	____
	Are product complaints thoroughly investigated?	☐ ☐ ☐	____
	Procedure to inform regulatory authority on serious quality problem	☐ ☐ ☐	____
	Recalls		
	Does written procedure exist?	☐ ☐ ☐	____
	Is a person designated for execution and coordination of recall?	☐ ☐ ☐	____
	Responsible person independent of marketing and sales?	☐ ☐ ☐	____
	Are the authority informed of an imminent recall?	☐ ☐ ☐	____
	Does the person responsible for recall have access to the distribution records?	☐ ☐ ☐	____

	Do the distribution records contain sufficient information on customers with address, phone, batch and amount delivered medical samples?	☐ ☐ ☐	____
	Are recalled products stored in secured area?	☐ ☐ ☐	____
	Is the final record made including reconciliation between the delivered and recovered quantities?	☐ ☐ ☐	____
14.	**SELF INSPECTION**		
	Does a self-inspection procedure exist, which defines frequency and program?	☐ ☐ ☐	____
	Are self-inspections carried out to check compliance with GMP rules	☐ ☐ ☐	____
	Is the self-inspection conducted in an independent and detailed way?	☐ ☐ ☐	____
	Are the self-inspection recorded and appropriate corrective action taken?	☐ ☐ ☐	____
15.	**CONTRACT MANUFACTURING AND ANALYSIS**		
	Written contract between contract giver and contract acceptor available?	☐ ☐ ☐	____
	Are responsibilities and duties clearly defined?	☐ ☐ ☐	____
	All arrangements in accordance with marketing authorization of the concerned product	☐ ☐ ☐	____
	The contract giver		
	Competence of the acceptor to carry out the work successful and according to GMP assessed?	☐ ☐ ☐	____
	Acceptor informed of safety aspects?	☐ ☐ ☐	____
	Conformance of products quality supplied by the acceptor ensured?	☐ ☐ ☐	____

	Products released by a qualified person on the acceptor's side?	☐ ☐ ☐	____
	The contract acceptor		
	Does the acceptor have adequate premises, equipment, knowledge, experience, competency and manufacturing authorization?	☐ ☐ ☐	____
	Does the acceptor ensure that all products or materials delivered to him are suitable?	☐ ☐ ☐	____
	There must be no work passed to a third party without the permission of the giver?	☐ ☐ ☐	____
	If the third party involved it must have the necessary manufacturing and analytical information.	☐ ☐ ☐	____
16.	**Any other observation and comments**		
17.	**Declaration by the applicant**		
	I the undersigned certify that all the information in the accompanying documentation concerning the inspection checlist of: Name of the company_____duly authorized to represent (Applicant company name) _____ is correct and true, and reflects the total information available. I further confirm that the information referred to in the check list is available for verification. I also agree that I am obliged to comply with the requirements of the Authority related to GMP any time point in future. Name _____ Signature _____ Position in company _____		

	Date: _____	
18.	**Recommendation of the inspector:**	
19.	**Name and Signature of inspector**	
		Name: _____ Signature: _____ Date_____
		Name: _____ Signature: _____ Date_____
		Name: _____ Signature: _____ Date_____
20.	**Certification by owner/designated person**	
	I (Full Name of owner/designated person) _____ Certify that my proposed site/premises/plan has been reviewed/ inspected by above named inspector(s) and I agree with the information provided in the checklist and report. Signature_____ Date _____	