

Part I: To Be Filled In By The Company

SUMMARY OF COMPANY ORGANIZATION AND INSPECTION	Page ___ of ___
INSPECTION of _____	Date _____

Full Address of Company:		
_____ _____ _____ _____ _____ _____		
Tel: _____		
Fax: _____		
Inspection type: mark all that apply external [] routine [] concise [] special [] internal [] annual [] semi-annual [] announced [] unannounced [] follow-up, re-inspection [] pre-licensing []	Name of inspectors-Affiliation: _____ _____ _____ _____ _____ _____	signature: _____ _____ _____ _____ _____ _____
Department(s) being inspected: _____ _____ _____ _____	Date(s) of inspection: From _____ To _____ Normal working hours: _____	Date of most recent previous routine inspection (internal or external): _____

		Type: _____ _____
		QA audit report #: _____
Floor plans of facility available? (Site plan) Y [] N []	Airflow patterns, differential pressures, and classification of production areas indicated? Y [] N []	Flow patterns for personnel, supplies, raw materials, product, and waste for production areas indicated? Y [] N []

Part I: to be filled in by the Company

SUMMARY OF COMPANY ORGANIZATION AND INSPECTION

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INSPECTION of _____ Date _____

SUMMARY OF SENIOR PERSONNEL, A: (use next page if the departmental divisions are not appropriate, or for other department designations)

ADMINISTRATION Position Title _____ _____ _____	Name _____ _____ _____	
RESPONSIBLE PHARMACIST Position Title _____ _____ _____	Name _____ _____ _____	Qualifications & Experience _____ _____ _____
PRODUCTION DEPARTMENT Position Title _____ _____ _____	Name _____ _____ _____	Qualifications & Experience _____ _____ _____
QUALITY CONTROL DEPT. Position Title _____ _____	Name _____ _____	Qualifications & Experience _____ _____
QUALITY ASSURANCE DEPT. Position Title _____ _____	Name _____ _____	Qualifications & Experience _____ _____
ANIMAL FACILITIES Position Title _____ _____	Name _____ _____	Qualifications & Experience _____ _____

ENGINEERING/MAINTENANCE Position Title	Name	Qualifications & Experience
_____	_____	_____
_____	_____	_____

Part I: to be filled in by the Company

SUMMARY OF COMPANY ORGANIZATION AND INSPECTION	Page ____ of ____
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SUMMARY OF SENIOR PERSONNEL, B: (use for additional departments or different organizational divisions)

_____ DEPARTMENT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____ DEPARTMENT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____ DEPARTMENT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____ DEPARTMENT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____

_____ DEPARTMENT		
Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____ DEPARTMENT		
Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____

1) Total area occupied by the firm ?	
2) Total area occupied by the buildings or installations?	
3) Age of the buildings?	
4) Local production capacity in units, per pharmaceutical presentation per batch.	Plain Tablet:

	Sugar coated tablet

	Film Coated Tablet

	Hard Gelatin Capsule

	Syrup

	Vials

	Ampoules

5) Contract manufacturing	Name of holder _____ _____ Products manufactured _____ _____
6) Toll manufacturing	Name of holder _____ _____ Products manufactured _____ _____ Frequency _____
7) Raw materials imported from:	Countries: _____ _____ _____
8) Raw materials exported to:	Countries: _____ _____ _____
9) No of personnel	Total No. _____ Pharmacist _____ Doctor _____ Other Degree _____ Assistant Pharmacist _____ Analyst _____ Mechanic _____ Other Qualification _____

PRODUCTION AND IN-PROCESS CONTROL CHECKLIST

Page ___ of ___

INSPECTION of _____	Date: _____
Area inspected: Building: _____; Room(s) _____;	
Product _____	

PRODUCTION SAMPLES TAKEN:

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Signature: _____

PRODUCTION SAMPLES TAKEN:

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Source: _____ Date: _____

Name of product	Type	No. of Samples	B/No.	Storage condition	Test data
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____
_____	_____	_____	_____	_____	Y/N _____

Signature:

PartII: To Be Filled By The Inspectors

GMP Inspection Checklist

Date of Establishment:

From ----- To -----

The Manufacturing Plant:

1. Date of Establishment:-----
2. Name and address of the manufacturing plant:-----

-----Tel:-----Fax:-----
3. Total area occupied by the firm? -----
4. Type(s) of pharmaceutical formulation(s) produced during the inspection:-----

5. Local production capacity in units, per pharmaceutical presentation per batch: Plain tablet:-----Sugar coated tablet:-----Film coated tablet:-----Hard gelatin capsules:-----Syrup:-----Vials:-----Ampoules:-----

6. Details of products being manufactured during the inspection:

Prod.name:	Type:	B.N.:	Storage conditions:	Raw.Mat imported from:

Personnel:

7. Number of Personnel:

Total: -----

Management: -----

Specialized personnel with min. of Bachelor degree: -----

Technicians: -----

Workers: -----

8. Job descriptions of key personnel:

Available

Not Available.....why?

9. Key personnel occupy full-time positions:

Yes

No

10. Positions of key personnel and their qualifications:

Technical manager: -----

Qualification: -----

Production Manager: -----

Qualification: -----

Quality Control Manager: -----

Qualification: -----

11. An up-to-date organizational chart showing all personnel with their qualifications and practical experiences:

Yes

No

Training:

12. Training is provided for all the personnel in GMP

Yes

No,

In areas where contamination is a hazard

Yes

No,

When critical changes in SOPs take place

Yes

No

Personnel Hygiene:

13. All personnel undergo a medical examination upon :

(a) Recruitment:

Yes

No

(b) Periodical examination:

Yes

No

Premises and Equipments:

General:

1. Premises are situated in an environment that presents minimal risk of causing contamination of materials or products:
 Yes No

2. Premises and equipment are well maintained so that they do not present any hazard to the quality of the product:
 Yes No

3. Lighting, temperature, humidity, and ventilation are appropriately maintained so that they do not adversely affect the medicinal product or equipment:
 Yes No

4. Premises are designed so as to afford maximum protection against the entry of insects or other animals:
 Yes No

5. Entry of unauthorized people is forbidden:
 Yes No

6. Is there any program for controlling of rodents, insects and birds?
 Yes No

Layout and Work Flow:

1. Is a plan available to show the layout, workflow, airflow etc?
 Yes No

2. Is the layout and work flow arranged logically?
 Yes No

3. Does the design minimize the risk of cross contamination and confusion?
 Yes No

Water Station:

1. Source of water supply:-----

2. Type of water used:-----

3. Water samples are taken from clearly labeled sampling points:
 Yes No
4. Water purifying process:
 cyclic stagnant
5. Direction of the water flow is clearly labeled:
 Yes No
6. Distilled, de-ionized and, other water pipes are sanitized according to written procedures:
 Yes No
7. Written procedures are available which clearly state the action limits for microbiological contamination and the measures to be taken:
 Yes No
8. SOP's of all tests for water specifications that ensure the safety and quality of the water used within the manufacturing plant:
 Available Not available
9. Tests performed on water samples are:
 Periodic Randomized

Raw Materials Warehouse:

1. Availability of SOP's for receiving of raw materials:
 Yes No
2. Availability of SOP's for analysis of raw materials:
 Yes No
3. Are there clearly defined areas for:

- Raw materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Semi-finished products	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Packaging materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Finished products	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Returned products (recalls, complaints)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Rejected materials (under lock)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
- Printed labels and packs (under lock)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

4. Receiving and dispatch protects raw materials from the weather: (reception areas are equipped in such a way to allow the containers for starting materials to be cleaned before storage)
 Yes No
5. Method of storage:
 On numbered shelves Yes No
 On the floor Yes No
6. Raw materials are well packaged in a way that prevents access of contamination or foreign particles into the container:
 Yes No
7. Storage information are well documented:
 Yes No

If yes, the method of saving the documents:

- Computer files Manual

8. Is there a quarantine area for raw materials and active ingredients under test?
 Yes No
9. Are there separated areas for toxic substances, psychotropic agents, and the like?
 Yes No
10. Are the areas of adequate size for amount of materials stored?
 Yes No
11. Are warehouse lighting and ventilation adequate?
 Yes No
12. Are there warehousing SOP's?
 Yes No
13. Quality Control Labels:
 13.1 Are they of different colour (quarantine, under test, release and rejected)?
 Yes No

13.2 Are the following information mentioned on the labels?

- | | | |
|---------------------------------|------------------------------|-----------------------------|
| -Name of material | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| -Batch number | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| -Company logo | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| -Internal code/reference number | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- Status of content (eg,in quarantine etc) Yes No
- Analysis number Yes No
- Date released/rejected Yes No
- Retest date/Expiration date Yes No
- Signature of analyst Yes No

14. Temperature readings are regularly checked, recorded and monitored:

- Yes No

15. Humidity readings are regularly checked, recorded and monitored:

- Yes No

16. Sampling

16.1 Area available Yes No

16.2 Dust extraction system available Yes No

16.3 Are they performed by Quality Control or other employees approved by Quality Control?

- Yes No

16.4 Are there sampling procedures? Yes No

Are the following information mentioned on each sample taken

-Name of person who performed the sampling Yes No

-Number of samples taken Yes No

-Number of containers sampled Yes No

-Date of sampling Yes No

17. Is there a stock rotation program? (i.e. first in first out-FIFO)

- Yes No

18. Finished good labels:

18.1 Are they stored in orderly neat storage, well separated to prevent mixing?

- Yes No

18.2 Are they recorded on stock cards? Yes No

19. Is an exterior storage available? Yes No

19.1 Solvent storage area? Yes No

19.2 Inflammable material storage area? Yes No

20. Is the vendor (supplier) controlled programme available?

- Yes No

20.1 Are vendors periodically inspected according to a written procedure?

- Yes No

20.2 Is the procedure for confirming vendor test results written and followed?

- Yes No

21. Quarantine areas clearly marked and their access restricted to authorized personnel:
 Yes No
22. Availability of SOP's for dealing with rejected materials:
 Yes No
23. There is a separate sampling area for starting materials:
 Yes No
24. Segregated area for storage of rejected, recalled or returned materials or products:
 Yes No
25. Samples are taken by quality control personnel for quality control analysis:
 Yes No
26. Procedure carried out to ensure:
 The identity of the contents of each container of starting materials.
 Only starting materials released by quality control department and which are within their shelf life can be used.
27. Weighing and measuring of starting materials are performed by competent people and according to written procedures:
 Yes No

Weighing and Processing Areas:

1. Separated from warehouse by:
 Airlocks
 Normal Doors
 Separated from production areas.
2. All scales are calibrated according to SOP's and their records are maintained:
 Yes No
3. Return of materials after weighing is carried out in accordance with the available SOP:
 Yes No
4. Weight re-checking is performed: Yes No
5. Is the area physically separated from the other rooms by walls, or other types of separation? Yes No

6. Are personnel wearing appropriate protective clothing, gloves, caps, masks etc?
 Yes No
7. Is there danger of cross-contamination during the weighing process?
 Yes No
8. After weighing, are these containers well sealed?
 Yes No
9. Are raw materials or components for each batch properly identified and segregated after weighing?
 Yes No

Production Area:

1. Entries and exits of personnel:
 Only through changing rooms.
 There are other entries and exits.
2. Positions of washing and restrooms:
 Within the changing rooms.
 Within the production area.
3. Restaurants and Café's:
 Within the production area
 Outside the production area
 Can be reached without full gowning
4. Floors and ceilings are smooth and free from exposed surfaces for ease of cleaning:
 Yes No
5. Effective process validation is carried out in all production lines to ensure optimum production quality:
 Yes No
6. Monitoring of working environment to ensure that its free from microorganisms or foreign particles:
 Yes No
7. Temperature and humidity monitoring in all production areas to ensure their suitability for the products being processed:
 Yes No

Production and Processing Control

1. Is each batch formulated to provide not less than 100% of the labeled, or established amount of active ingredient?
 Yes No

2. Is the adding of components verified separated by two individuals?
 Yes No
3. Is the major equipment used identified on each batch record?
 Yes No
4. Are any deviations from approved procedures authorized and documented?
 Yes No
5. Are appropriate in-process controls being performed?
 Yes No

HVAC System:

1. Maintenance and checking of HEPA filters:
 - Periodical according to the SOP.
 - Randomized according to SOP.
 - No SOP available
2. Sufficient and good monitoring of the atmospheric pressure:
 Yes No
3. what are the limits for changing the filters? Yes No
4. If filter integrity is checked and records are available?
 Yes No

Equipments:

1. Manufacturing equipment are designed, located and maintained to suit its intended purpose:
 Yes No
2. Manufacturing equipment are used effectively in accordance with the SOP:
 Yes No

Finished Product Warehouse:

1. Is there a procedure to ensure that finished products remain in quarantine until their final release?
 Yes No
2. Availability of SOPs for all operations in the finished product warehouse:
 Yes No
3. There is a segregated area for storage of rejected, recalled or returned materials:
 Yes No

4. Rejected products are clearly labeled with RED to be distinguished from approved products:

Yes

No

5. Finished products are stored in:

Numbered shelves

On the floor

6. Warehouse is separated from the production areas by airlocks:

Yes

No

If no, how are they separated?

7. Finished product is well packaged in a way that protects it from any microbial contamination or foreign particles:

Yes

No

8. Identification cards are used and products are clearly labeled with:

Product name

Yes

No

Batch No.

Yes

No

Internal code or reference no.

Yes

No

Status of content (e.g. approved, rejected....etc)

Yes

No

Manufacturing date

Yes

No

Expiry date or date beyond which retesting is necessary

Yes

No

9. Temperature readings are monitored within the warehouse:

Yes

No

10. Humidity readings are monitored within the warehouse:

Yes

No

11. Samples are taken by quality control personnel:

Yes

No

12. Cleanliness and organization of the warehouse:

Acceptable

Unacceptable

13. Is there a procedure to restrict the reprocessing of rejected products? NB: this should be exceptional. Record should be kept for the reprocessing.

Yes

No

14. Is there a procedure (any records kept) for this recovery that deals with the risks involved, including any possible effect on shelf life?

Yes

No

Quality Control Department:

1. The company has an independent *quality control department*:

Yes No

2. Adequate resources are available (staff, equipment...etc):

Yes No

3. Analytical chemistry laboratory:

Available Not Available

4. Analytical microbiology laboratory:

Available Not available

5. Is a written protocol/programme available for stability studies?

Yes No

6. Does this include:

a. sample storage condition? Yes No

b. Room temperature? Yes No

c. RH? Yes No

d. Accelerated aging test? Yes No

e. Sample size and test intervals? Yes No

f. Reliable and specific test methods?
 Yes No

g. Testing in the same container closure system as that in which it is marketed? Yes No

h. Data to show appropriate storage conditions when marketed and expiration date? Yes No

7. Quality control personnel have free access to production areas for sampling and investigation:

Yes No

G. Complaints and Product Recalls:

Complaints:

1. Is a person designated responsible for handling the complaints and deciding the measures to be taken?

Yes

No

-Is the Senior Technical Manager, always made aware of any complaint, investigation or recall

Yes

No

2. Is there a written procedure describing the action to be taken (including the need to consider a recall) in the case of a complaint concerning a possible product defect:

Yes

No

3. Are complaints concerning a product defect recorded with all the original details and thoroughly investigated?

Yes

No

Product Recalls:

1. Is there a person designated as responsible for execution and coordination of recalls?

Yes

No

-Do they have the staff and resources to act with the appropriate degree of urgency?

Yes

No

-Is this responsible person independent of the sales and marketing organization?

Yes

No

Self inspection:

1. Are all examined at intervals following a prepared programme in order to verify their conformity with the principles of quality assurance? Yes No

2. Are self-inspections conducted in an independent and detailed way by designated competent person(s) from the company? (Independent audits by external experts may also be useful)

Yes

No

H. Documentations:

1. Are there Master Procedures to cover all aspects of drug manufacturing?

-Receiving, storage, distribution?

Yes

No

-Processing and production operations?

Yes

No

-Packaging and labeling?

Yes

No

-Recalls and complaints?

Yes

No

-Cleaning and sanitations?

Yes

No

-Engineering and maintenance?

Yes

No

-Personnel qualifications and training?

Yes

No

- Water supply system and quality? Yes No
- 2. Have these procedures been prepared, dated, and signed by responsible person? Yes No
- 3. Have these procedures been reviewed, dated and signed by a second qualified person? Yes No

PREMISES

- 1. Are floors, walls and ceilings constructed of materials which can readily be cleaned and disinfected? Yes No
- 2. Are areas for sterile production free from defects as holes, chips, dust collecting ledges, etc? Yes No
- 3. Are there written procedures for operation and control of sterile production areas? Yes No
- 4. Are there procedures for washing and disinfection? Yes No

EQUIPMENT

- 5. Are transmission lines and pipeworks made of non-reactive material or stainless steel or equivalent? Yes No
- 6. Filtration:
 - i. Are filters cleaned after use? Yes No
 - ii. Are they checked for damage? Yes No
- 7. Are there sterilization procedures? Yes No
- 8. Are sterilizers adequate for stated use? (time, temperature and pressure). Yes No
- 9. Are sterilizers controlled manually or automatically? -----.

PRODUCTION

- a. Are there standard operating procedures for sterilization? Yes No
- b. Are manufacturer's instruction manuals available? Yes No
- c. Are there procedures for validation of all sterilizers used:
 - i. For initial validation? Yes No
 - ii. For revalidation? Yes No
- d. Methods of sterilization

Which method is being used:

- | | | |
|------------------|------------------------------|-----------------------------|
| Steam? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Gas? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Dry heat? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Filtration? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Gamma radiation? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

e. Are charts for time and temperature available for each sterilizer load?
 Yes No

f. Is each sterilizer load of a drug product given a unique identification number?
 Yes No

g. Are there procedures to prevent growth and contamination of filters?
 Yes No

h. Are chemical indicators used? Yes No
Which type?-----

FILLING AND PACKAGING

i. Is air controlled at filling point for both viable and non-viable particulates (fiber, and micro-organisms)? Yes No

j. Are capping and sealing done in sterile area?
 Yes No

If not, where? -----

k. Are in-process checks for fill and seal conducted?
 Yes No

l. Is there examination for particulates (fibers)?
 Yes No

QUALITY CONTROL

m. Are there adequate equipment and facilities for conducting sterility tests?
 Yes No

n. Pyrogen testing; Which method is being used?
Rabbit? Yes No
LAL (Limulus Amebocyte Lysate)? Yes No

- o. Are there specifications and limits for non-viable particulates (fibers)?
 Yes No
- p. Procedures for control of biological indicators:
- Are there positive control? Yes No
 - Are D-values determined by firm or do they rely on labeled value only?
 Yes No
 - Are filled, sealed ampoules leak tested?
 Yes No

I. Conclusion of the inspection process:

The manufacturer *complies/does not comply* with GMP regulations and is *legible/illegible* for approval by the GCC Central Registration committee.

Approved production line is:

- Solid dosage forms (Tablets, capsules, liquids)
- Liquid formulations (Solutions, suspensions, syrups, elixirs..)
- Semisolids (ointments, creams, emulsions, suppositories)
- Parenteral products (Intravenous and intramuscular products)
- Vaccines

Others, specify: -----

Inspection Team:

Head of inspection team::

Signature:

Date:

Member of inspection team:

Signature:

Date:

Member of inspection team:

Signature:

Date: