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 Page____of____

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____

INSPECTION of _____ **Date** _____

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	☐ Yes	☐ No
- Semi-finished products	☐Yes	☐ No
- Packaging materials	☐ Yes	☐ No
- Finished products	☐ Yes	☐ No
- Returned products (recalls, complaints)	☐ Yes	☐ No
- Rejected materials (under lock)	☐ Yes	☐ No
- Printed labels and packs (under lock)	☐ Yes	☐ 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	☐ Yes	☐ No
-Batch number	☐ Yes	☐ No
-Company logo	☐ Yes	☐ No
-Internal code/reference number	☐ Yes	☐ 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?	☐ Yes	☐ No
Gas?	☐ Yes	☐ No
Dry heat?	☐ Yes	☐ No
Filtration?	☐ Yes	☐ No
Gamma radiation?	☐ Yes	☐ 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: