

STATE OF CONNECTICUT – DEPARTMENT OF CONSUMER PROTECTION  
 DRUG CONTROL DIVISION  
 165 CAPITOL AVENUE, HARTFORD, CT 06106  
 TELEPHONE: (860) 713-6065

MANUFACTURER INSPECTION REPORT

Firm Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address: \_\_\_\_\_

Manager: \_\_\_\_\_ Operations Supt.: \_\_\_\_\_

Personnel Contacted (titles): \_\_\_\_\_

No. of Pharmacists/Chemists: \_\_\_\_\_ Phone #: \_\_\_\_\_

Trade Names & Subsidiary Firms: \_\_\_\_\_

License Numbers: DCP \_\_\_\_\_, FDA \_\_\_\_\_, DEA \_\_\_\_\_

Type of Products Manufactured: Devices \_\_\_\_\_, Cosmetics \_\_\_\_\_, Legend Drugs \_\_\_\_\_

Proprietary Drugs \_\_\_\_\_, Controlled Substances: I \_\_\_\_\_, II \_\_\_\_\_, III \_\_\_\_\_, IV \_\_\_\_\_, V \_\_\_\_\_

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RAW MATERIALS

Names: \_\_\_\_\_

Storage	Acc.	N. Acc.
Quarantine		
Temperature		
Security		
Release		
Rotation		

Handling	Acc.	N. Acc.
Labeling		
Sampling		
Analysis		
Dates		
Assignment		
Use		

Records	Acc.	N. Acc.
Properly Kept		
Checked		
Available		
Cross Reference		

FINISHED PRODUCTS

Storage	Acc.	N. Acc.
Quarantine		
Temperature		
Security		
Release Method		
Rotation		
Code (bottle & carton)		

Distribution	Acc.	N. Acc.
Wholesale		
Direct		
Retail		
Recall Procedures		

Dated Products	Acc.	N. Acc.
Checked		
Rotated		
Responsibility		

Return Goods	Acc.	N. Acc.
Reworked		
Destroyed		
Salvaged		
Resold		

MANUFACTURING PROCESSES

	Acc.	N. Acc.
Formulation		
Ingredients		
Quantities		
Checks		
Personnel		
Control Records		
Batch Records		
Yields		

Equipment	Acc.	N. Acc.
Proper Size		
Use		
Maintenance		
Types		
Scales		
Graduates		
Deionizer		

Quality Control	Acc.	N. Acc.
In Process		
Finished Product		
Yield		

Packaging Operation	Acc.	N. Acc.
Proper Count		
Filling		
Breakage		
Containers		

Labeling	Acc.	N. Acc.
Correctness		
Count		
Records		
Codes		
Responsibility		

GENERAL SANTITARY CONDITIONS

Employees	Acc.	N. Acc.
Uniforms		
Health Check		
Locker Rooms		
Toilet Facilities		

Maintenance	Acc.	N. Acc.
Personnel Responsible		
Outside Service		
Employees		

Physical Plant	Acc.	N. Acc.
Location		
Walls		
Floors		
Ceiling		
Windows		
Screens		
Pipes		
Pallets		
Vents		
Lighting		
Partitions		
Filters		
Temperature		
Washing		
Equipment		
Shelves		
Aisles		
Rooms		

REMARKS: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

See attached page for Controlled Substances: Yes \_\_\_\_ No \_\_\_\_

License Recommended: Yes \_\_\_\_ No \_\_\_\_, if No, give reason \_\_\_\_\_

Dates of Inspection: \_\_\_\_\_ to \_\_\_\_\_

\_\_\_\_\_  
 Report Received By (Signature)

\_\_\_\_\_  
 Agent, Drug Control Division (Signature)

MANUFACTURER INSPECTION REPORT FOR CONTROLLED SUBSTANCES

Controlled Substances Handled (Raw Material) Schedules: II, III, IV, V (circle)
Controlled Substances Produced, Yes \_\_\_\_, Schedules: \_\_\_\_\_ No \_\_\_\_
Controlled Substances Used in Manufacturing: Yes \_\_\_\_, No \_\_\_\_

Persons Responsible for Controlled Substances

Name: \_\_\_\_\_ Address: \_\_\_\_\_ Title: \_\_\_\_\_
Name: \_\_\_\_\_ Address: \_\_\_\_\_ Title: \_\_\_\_\_

Physical plant (alarm, guards, etc.) \_\_\_\_\_

Schedule II Raw Materials \_\_\_\_\_ In process \_\_\_\_\_ Finished prod. \_\_\_\_\_

Quality control lab \_\_\_\_\_ Batch shelf samples \_\_\_\_\_

Schedule III, IV, V Raw Materials \_\_\_\_\_ In process \_\_\_\_\_ Finished prod. \_\_\_\_\_

Quality control lab \_\_\_\_\_ Batch shelf samples \_\_\_\_\_

Finished Product distribution \_\_\_\_\_ packing \_\_\_\_\_

order checking \_\_\_\_\_ shipping \_\_\_\_\_

RECORDS

Raw Materials

Batch Shelf Samples

Schedule II order forms \_\_\_\_\_ Inventories \_\_\_\_\_

Inventories (fed forms) \_\_\_\_\_ Receipts \_\_\_\_\_

Receipts \_\_\_\_\_ Dispositions \_\_\_\_\_

Dispositions \_\_\_\_\_

In Process

Quality Control Lab

Receipts \_\_\_\_\_ Inventories \_\_\_\_\_

Dispositions \_\_\_\_\_ Receipts \_\_\_\_\_

Dispositions \_\_\_\_\_

Finished Products

Batch Samples \_\_\_\_\_

Inventories (fed forms) \_\_\_\_\_ Records separately maintained Yes \_\_\_\_

Production records \_\_\_\_\_ No \_\_ (explain) \_\_\_\_\_

Records readily available Yes \_\_\_\_

Dispositions \_\_\_\_\_ No \_\_ (explain) \_\_\_\_\_

Records securely kept Yes \_\_\_\_ No \_\_\_\_

(explain) \_\_\_\_\_

Audit conducted Yes \_\_\_\_ (see below) No \_\_\_\_

item \_\_\_\_\_ dates (from) \_\_\_\_\_ (to) \_\_\_\_\_ result \_\_\_\_\_

item \_\_\_\_\_ dates (from) \_\_\_\_\_ (to) \_\_\_\_\_ result \_\_\_\_\_

item \_\_\_\_\_ dates (from) \_\_\_\_\_ (to) \_\_\_\_\_ result \_\_\_\_\_

