

# PCP Sample Answers



## Poisons Control Plan for a Licence: To Manufacture and Sell or Supply by Wholesale – Part Three – Sample Answers

### 14. Manufacturing Activities

#### *14.1 Indicate the type(s) of manufacturing activity to which the licence may apply;*

- complete manufacture from raw materials
- blending liquids and/or powders
- manufacturing tablets/capsules
- repacking from bulk containers
- relabelling imported products
- manufacture of "own brand" products
- toll or contract manufacture

#### *14.2 Indicate if a TGA licence is held;*

- Insert TGA Licence Number if applicable.

### Raw Materials

#### *14.3 Indicate what quality assurance methods are to apply to raw materials;*

- Obtained only from approved/licensed suppliers
- Certificates of analysis obtained from suppliers
- Raw materials are subject to internal quantitative analysis

### Finished Goods / Batch Documentation

#### *14.4 Indicate the type of batch records to be used;*

- Computerised records
- Documents that are manually completed during manufacture
- Daily work book
- All documentation in accordance with ISO 9002 accreditation

#### ***14.5 Indicate how batch numbers are to be generated and attached to finished goods;***

- Batch numbers are to be generated using the date of manufacture and are to be attached to the container using a label gun.
- Batch numbers are to be sequential and are to be printed/stamped onto labels during manufacture.
- Stock, which is merely repacked, is to be labelled with the manufacturer's original batch number.

### **Finished Goods / Quality Assurance**

#### ***14.6 Indicate the intended extent of quality control testing;***

- All products to be subject to quarantine procedures.
- Some products (as specified) are to be subjected to testing of physical parameters.

#### ***14.7 Indicate the types of quality control testing to be performed on manufactured products;***

- Quantitative analysis using a gas chromatograph
- Quantitative and qualitative analysis in on-site laboratory
- Specific gravity measurements
- Colour comparison
- pH testing

#### ***14.8 If retention samples are to be kept, indicate the intended duration, storage conditions and types of records to be maintained;***

- Retention samples are to be kept for 12 months and documented in a logbook.

### **Labelling & Packaging**

#### ***14.9 Indicate how label content is to be verified;***

- Samples of all labels are to be maintained on a master file and reviewed periodically by the Regulatory Affairs Unit.
- All product labels are to be subject to approval by an external authority (specify).
- Label content is to be reviewed before new labels are printed.
- When manufacturing or packing a product for a client, compliance with labelling specifications is to be confirmed and NOT merely assumed to be correct.
- An external consultant is to be employed to design and verify labels.

#### ***14.10 Indicate how labels are to be prepared;***

- Computer generated, using a laser printer, at the licensed premises
- Printed by an external contractor
- Photocopied onto standard format labels prior to batch manufacture

***14.11 Indicate the procedures intended to ensure that the correct label is attached to a manufactured product;***

- Rolls of printed labels are to be stored in clearly segregated areas.
- Labels are to be printed specifically for each batch without producing any excess labels.
- Label reconciliation procedures are to be included in the batch documentation.

***14.12 Indicate how compliance with container specifications is to be achieved;***

- Container specifications, which may vary for Schedule 5, 6 and 7 poisons, are to be reviewed periodically by the Regulatory Affairs Officer.
- Appropriate containers, embossed with the necessary (different) precautionary statements, are to be available for both S5 and S6 poisons.
- Details of poisons requiring child-resistant closures are to be reviewed periodically by the Regulatory Affairs Officer. Child-resistant closures are to be used when required.
- Details of required containers and closures are to be included in batch documentation.
- When manufacturing or packing a product for a client, compliance with packaging specifications is to be confirmed and NOT merely assumed to be correct.
- Products are intended **solely** for industrial / laboratory use and are packaged in accordance with other standards

## **Prevention of cross contamination**

***14.13 Indicate how cross contamination of chemicals is to be prevented;***

- Dedicated mixing vessels are to be used for certain products or product types.
- Isolated areas of the factory are to be used for manufacturing powder products.
- Manufacturing equipment is to be cleaned thoroughly between different products/batches.
- Manufacturing equipment and/or areas are to be subject to documented cleaning procedures.
- Manufacturing procedures are to be subject to external auditing in accordance with the Code of Good Manufacturing Practice.

## **15. Laboratory Chemicals**

***15.1 Indicate the type(s) of activities for which poison(s) may be required in the laboratory. Please provide examples;***

- A range of scheduled poisons are required for use in the preparation of standards / and or reagents for quantitative and/or qualitative analysis as part of the Quality Assurance process.

***15.2 Indicate how poisons may be purchased or obtained in addition to the position(s) or role(s) of the person(s) to be responsible for ordering;***

- All external purchases must be approved by the Laboratory Manager or Supervisor.
- QA samples are extracted from batches in accordance with the batch documentation.

***15.3 Indicate what records are to be retained in relation to the acquisition of poisons;***

- Copies of all invoices are to be retained for a period (specify).
- To be contained within batch documentation

## 16. Laboratory Storage Facilities

### Schedule 8 or Schedule 9 poisons [if any]

#### *16.1 Indicate how Schedule 8 or 9 poisons are to be stored;*

- A Drug of Addiction cabinet, attached to a brick wall by four bolts.

### Schedule 4 poisons [if any]

#### *16.2 Indicate how Schedule 4 poisons are to be stored;*

- S4 poisons are to be stored in a lockable metal cabinet / lockable storeroom.

### Listed Regulated Poisons in Schedule 7 [if any]

#### *16.3 Indicate how Listed Regulated Poisons in Schedule 7 are to be stored;*

- Cyanide is to be stored in a padlocked metal cabinet with prominent warning signs.

### Access to storage facilities

#### *16.4 Indicate how unauthorised or unsupervised access is to be prevented;*

- The combination to the safe is to be known only to a limited number of Laboratory Supervisors and is to be changed whenever one of the supervisors leaves the company.
- The key is to be held on the person of the Laboratory Manager.

## 17. Records of Transactions

### Schedule 8 or Schedule 9 poisons [if any]

#### *17.1 Indicate how records of transactions, for Schedule 8 or 9 poisons, are to be maintained and validated;*

- Records are to be kept in the form of a bound book with consecutively numbered pages, i.e. a Drug of Addiction register.
- Physical stock checks are to be performed periodically (specify frequency).

### Schedule 4 poisons and Listed Regulated Poisons in Schedule 7 [if any]

#### *17.2 Indicate how records of transactions, for Schedule 4 or 7 poisons, are to be retained;*

- A bound book is to be used to chronologically record the use of all Schedule 4 poisons and/or Schedule 7 poisons.
- Contained within batch records.