

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.