

Raw Materials

General

All raw materials, as well as finished products are stored in the internal warehouse, shown at location 10 on Annex B-4, page 1.

The warehouse is divided from the production area by an RF-120 wall. Doors connecting both areas are also RF-120. It has a loading and unloading area next to a material reception room. The floor finish is epoxy paint. In the warehouse there is a sampling and dispensing area. The warehouse and the material reception area are 5.60 m high up to the building top slab, while the sampling, dispensing rooms and warehouse office are 3.00 m high.

The warehouse is secure from outside by means of a lockable door which is operated from inside. There is only one route of access from outside.

The materials are stored on a pallet racking system within the warehouse. There is also a shelving system for small containers that are not usually stored on pallets.

Raw materials stored in the warehouse are mostly in powder form other than few excipients. Containers are never opened in the warehouse but only in the sampling and dispensing booth where there are no drains. In case a spillage occurs during the dispensing process no material can escape into the environment.

Provided that the occurrence of a spill in the warehouse is remote, in case of a spill Combino Pharm personnel will promptly prevent the material from entering the drains.

A spill kit is already available in the warehouse and a spill control and prevention SOP is available. Powder materials will be collected by means of a vacuum cleaner and the vacuum cleaner bag will be disposed of as hazardous waste. Spillages of liquids will be addressed with the appropriate absorbent material depending on their nature.

Active Pharmaceutical Ingredients

These are the raw materials of highest environmental concern, due to their chemical nature, toxicity and potency. All active pharmaceutical ingredients (APIs) are solid powders. List of APIs used at Combino is kept confidential since this is considered as proprietary information.

At Combino a chaotic warehouse system is in place, all items can be near each other with no restrictions nor categorization, items which have different batch numbers are stored in separate locations. Everything is stored indoors in a temperature controlled environment. Controlled Substances will be stored in a segregated area under lock and key according to our own procedure.

Other raw materials

A list of other raw materials which may be stored on site and their physical status is to be kept confidential since this is considered as proprietary information.

At Combino a chaotic warehouse system is in place, all items can be near each other with no restrictions nor categorization, items which have different batch numbers are stored in separate locations. Everything is stored indoors in a temperature controlled environment. Only flammable stock items are stored in the safety cabinet inside the same warehouse.

Auxiliary Materials

Diesel is used for the running of the generator (diesel is not used to fuel any vehicles). This is stored inside the generator itself. A spill kit is also provided in the generator room to promptly address any spill. Regular inspections and visual checks for corrosion points are performed on the generator tank.

LPG is used to run the steam boilers of Combino Pharm and Medichem. Combino Pharm is duly licensed by the Regulator for Energy and Water Supply (REWS) to store LPG on site. The LPG vessel is installed below ground level. Ultrasonic non-destructive tests are carried out periodically by an independent, warranted engineer.

Two LPG detectors are connected to the centralised automatic alarm system. One is located in the vaporiser and another one in the boiler room. In case a leak is detected the system will raise immediately the evacuation alarm so that evacuation of the premises can take place. In addition, a solenoid shut-off valve is triggered, isolating the LPG supply.

Other materials in small quantities include laboratory reagents, maintenance oils, additives and lubricants. Secondary containment is available wherever possible and spill kits are placed at strategic locations around the installation. When expired or exhausted, waste materials are duly segregated, handled and treated as per applicable best practices and legal requirements.

Fuel Tank Code	Fuel Type	Maximum Tank Capacity (litres)	Annual Consumption (litres)	Storage Tank Arrangements Containment Measures	Use	Fill Point Code
F1	Diesel	750	400	See in paragraph above	For generator	FP1

F2	LPG	20,000	34,446	See in paragraph above	For boiler at Medichem and Combino	FP2
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Material Safety Data Sheets

MSDS's for all raw materials are stored on the server and are available to all personnel. A file naming convention includes the name of the raw material and the internal item number for easy searching. Links to the folders are available for easy access.