

# Risk Assessment

## Areas of risk

The following risk scenarios had been identified as part of the process to be granted the Environmental Permit:

- Fire and/or Explosion
- Failure of abatement techniques
- Spillages

## Fire and/or Explosion

Combino Pharm has an Emergency Plan at the disposal of all employees. This document contains details of the actions to be taken in cases of emergency and describes the responsibilities of key personnel. It also deals with external communication protocols.

## Failure of abatement techniques

At Combino Pharm, abatement techniques are relevant with respect to emissions to air and take the form of filters installed at the exhaust ports of equipment. Preventive maintenance is carried out periodically to minimise the risk of failure and a risk assessment approach is adopted to avoid such emergency situations.

The generator operates on diesel fuel and is operated only for maintenance purposes once a month for an hour and in case of a power cut, generally for a maximum of 1-2 hours. The amount of pollutants emitted is therefore minimal.

The ventilation system consists of several HVAC units that provide ventilation to different areas of the facility. The exhaust points of the majority of the units are located in the technical area at first floor. The exhaust of another unit is located on top of the utilities area. The technical area is connected to the outside through grids provided with pre-filters with an efficiency of 90%.

### Fluid Bed Drier outlet

The fluid bed drier is provided with a product retaining filter mounted in the filter housing. This filter is made from polyester and has a mesh size of 19 µm. The filter is product specific and its integrity is checked before each process. The equipment automatically stops in case the pressure through the filters exceeds a certain value.

### Coater outlet

The coater is provided with a de-duster that filters the outlet air prior to it being discharged to the atmosphere. This consists of 3 filter cartridges that are cleaned after or before every process by a blowback cycle. HEPA filters with 99.995% efficiency are installed. A pressure gauge indicates when filters need replacement and in case of a failure of the abatement equipment the machine shuts down automatically.

## Spillages

All drums containing hazardous liquids or wastes are placed on pallets with secondary containment (sump capacity 230 litres, equivalent to 110% capacity of each drum).

A structure to protect waste from the elements is available on the southern side of the plant.

Aqueous pharmaceutical wastes are transferred into containers through a closed system and therefore no transfer of waste takes place outside. The risk of spillages arises during the movement of pallets from one location to another and during loading of the waste. However, such movements are minimal and only occur few times a year.

Spill kits are available at strategic locations around the plant to collect any spilled material.

Transfer of laboratory wastes from smaller containers to the 200L drums is done using funnels and a pedal a pedal pump (closed system) to prevent spillages.

A standard operating procedure governs the actions to be taken in case of spillages.