Equipment

13

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Equipment

Objectives

- To review the requirements for equipment
  - *selection*
  - *design*
  - *use*
  - *maintenance*
- To discuss problems related to issues around selected items of equipment

Equipment

Principle

- Equipment must be
  - *located*
  - *designed*
  - *constructed*
  - *adapted*
  - *maintained*

to suit the operations to be carried out

13.1

Basic Principles of GMP

- What does
  - *location*
  - *design*
  - *construction*
  - *adaptation*
  - *maintenance*
  - *cleaning*
  - *calibration*

… mean in practice?

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Equipment

Principles

- Equipment layout and design must aim:
  - *to minimize risks of error*
  - *to permit effective cleaning and maintenance*
- To avoid:
  - cross-contamination, dust and dirt build-up
  - any adverse effect on the quality of products
- Equipment must be installed to:
  - minimize risks of error
  - minimize risks of contamination

13.1, 13.2

Equipment

Pipes

- Fixed pipework
  - *clearly labelled*
  - *indicate contents and direction of flow*
- Service pipings and devices
  - *adequately marked*
  - *non-interchangeable connections or adaptors for dangerous gases and liquids*

13.3, 13.4

Basic Principles of GMP

Contents and direction of flow indicated

- e.g. water lines, equipment components, air-handling systems

Equipment

Balances and Measuring Equipment

- Appropriate range and precision available
- In production and quality control
- Calibrated
  - *scheduled basis*
  - *checks*
  - *records maintained*

13.5

Equipment

Production equipment

- Appropriate design
  - *easily and thoroughly cleaned on a scheduled basis*
  - *procedures and records*
- No hazard to the products
  - *contact parts of suitable non-reactive materials*
  - *non additive and*
  - *not absorptive*

13.9, 13.10

Equipment

Production equipment

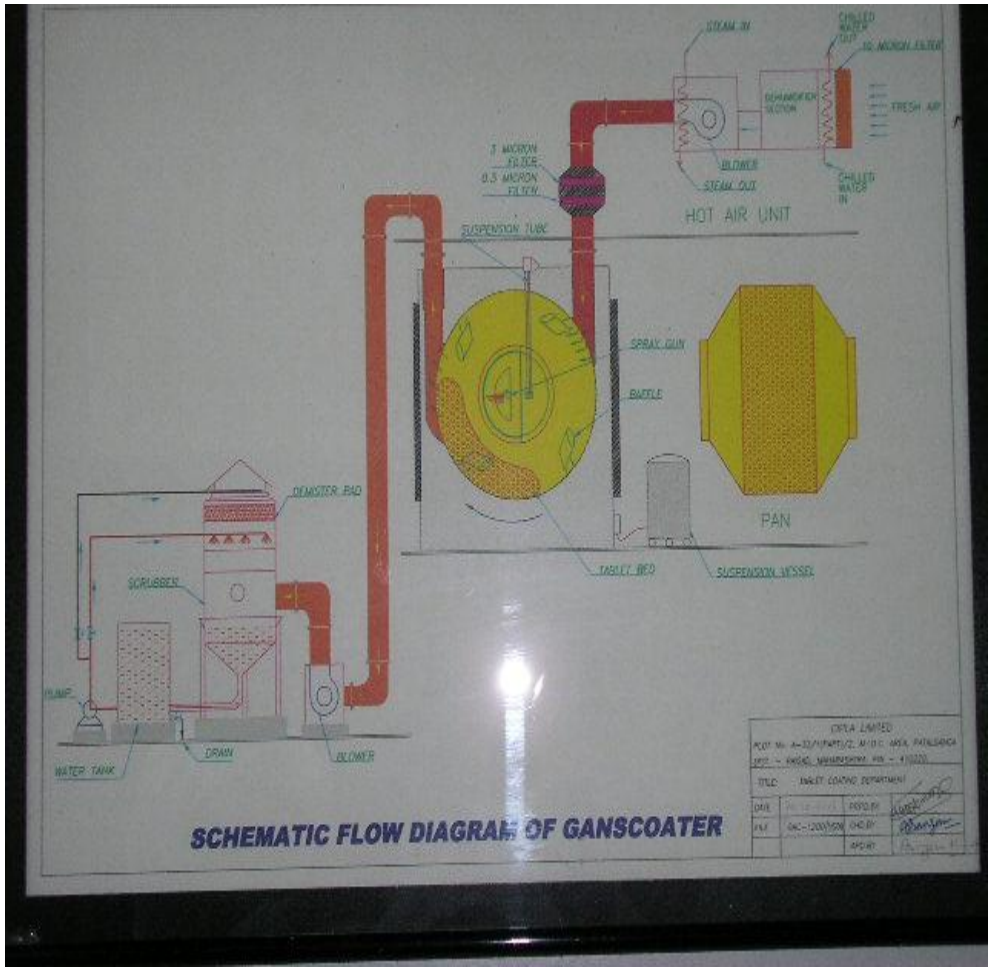
- Closed equipment used when possible
- Open equipment, or when equipment opened, precautions taken to prevent contamination
- Non-dedicated equipment cleaned according to validated cleaning procedures between different products
- Current drawings of critical equipment and support systems maintained

13.11 – 13.13

Basic Principles of GMP

Current drawings of critical equipment

- Verify against qualification protocol and report, as well as supplier's manual
- Check if in accordance with drawing, or changes (change control)
- Verify critical components installed, e.g. filters, control and monitoring devices



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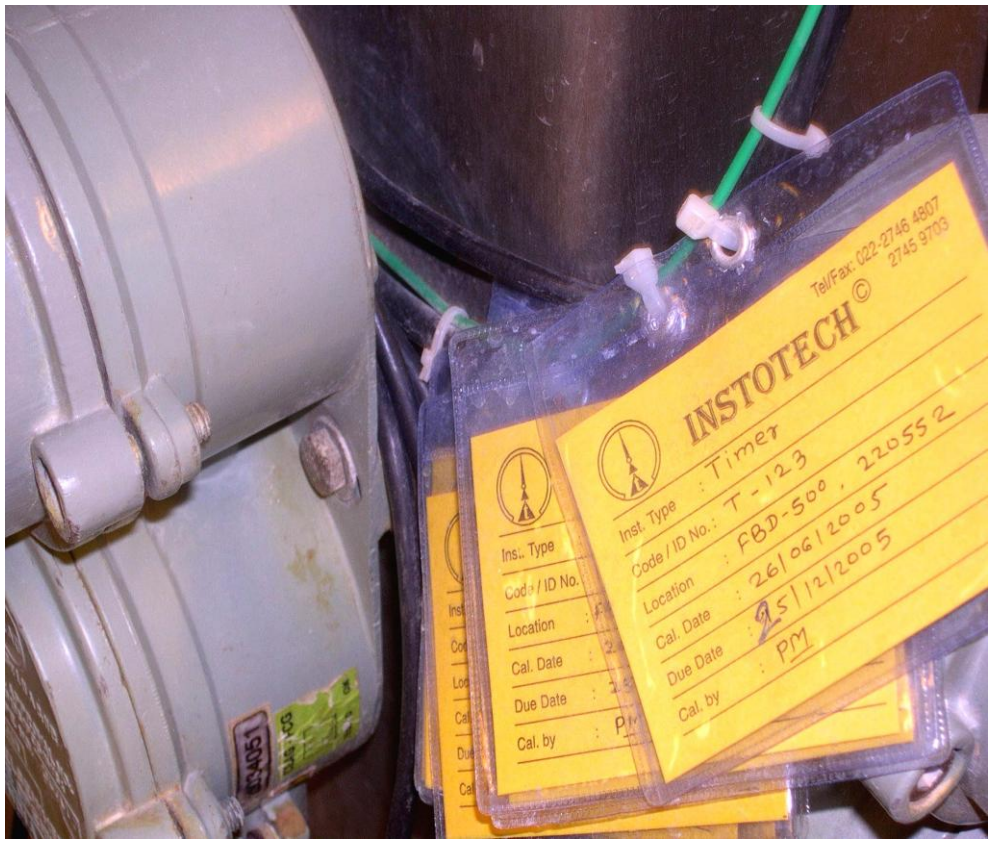
- What are the questions you can ask about this piece of equipment?

Basic Principles of GMP

- And for this one?

Basic Principles of GMP

- What do these labels indicate for this piece of equipment?
- Do you notice any GMP non-compliances here?



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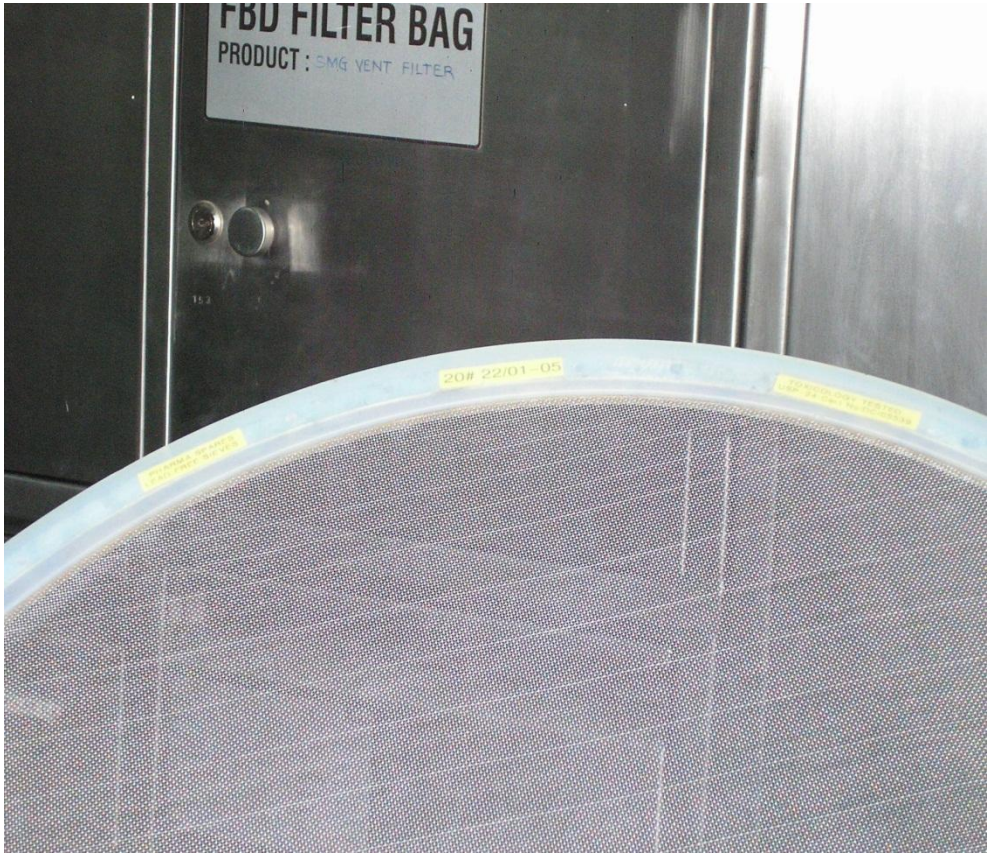
Basic Principles of GMP



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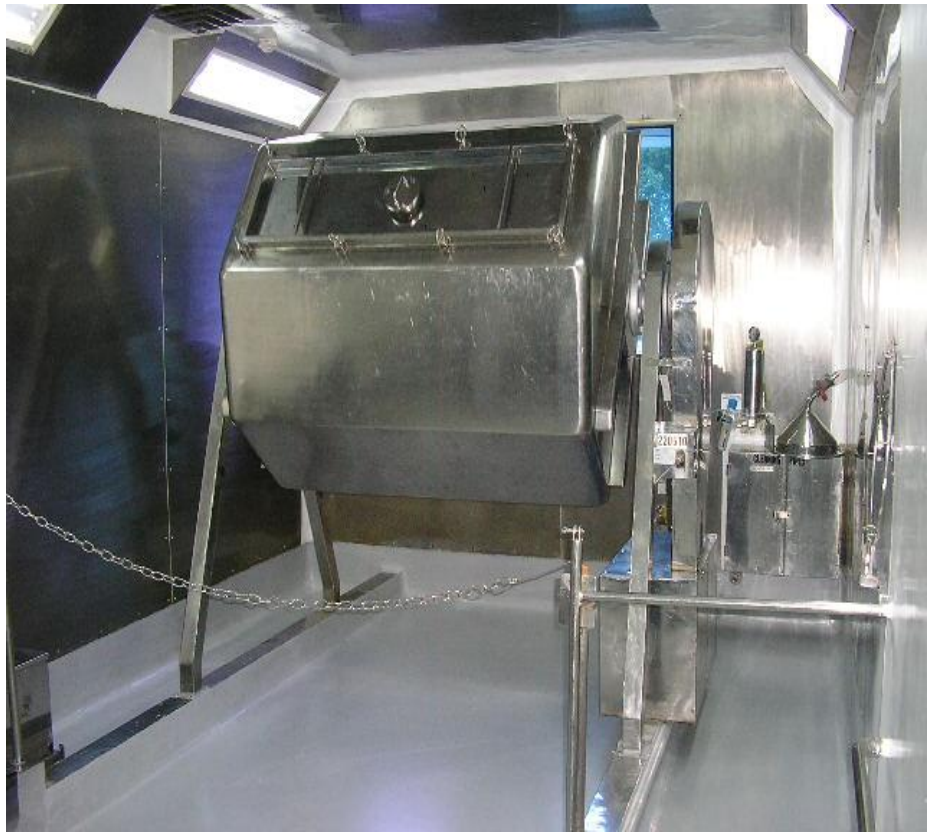
- What are some of the key questions you can ask about the blender?



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- Transfer of material to the compression machine through a closed system is preferred to prevent possible contamination
- It also helps to contain dust

Basic Principles of GMP

- Remember to look at punches and dies
- Are there specifications for these?
- How are they cleaned, stored, issued for use and returned to storage?
- Are they in a good condition and checked at regular intervals?

Basic Principles of GMP

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Basic Principles of GMP

Coating of tablets

- Is qualification of a coating machine necessary?
- If so, what has to be done?
- What about maintenance?
- And cleaning validation?

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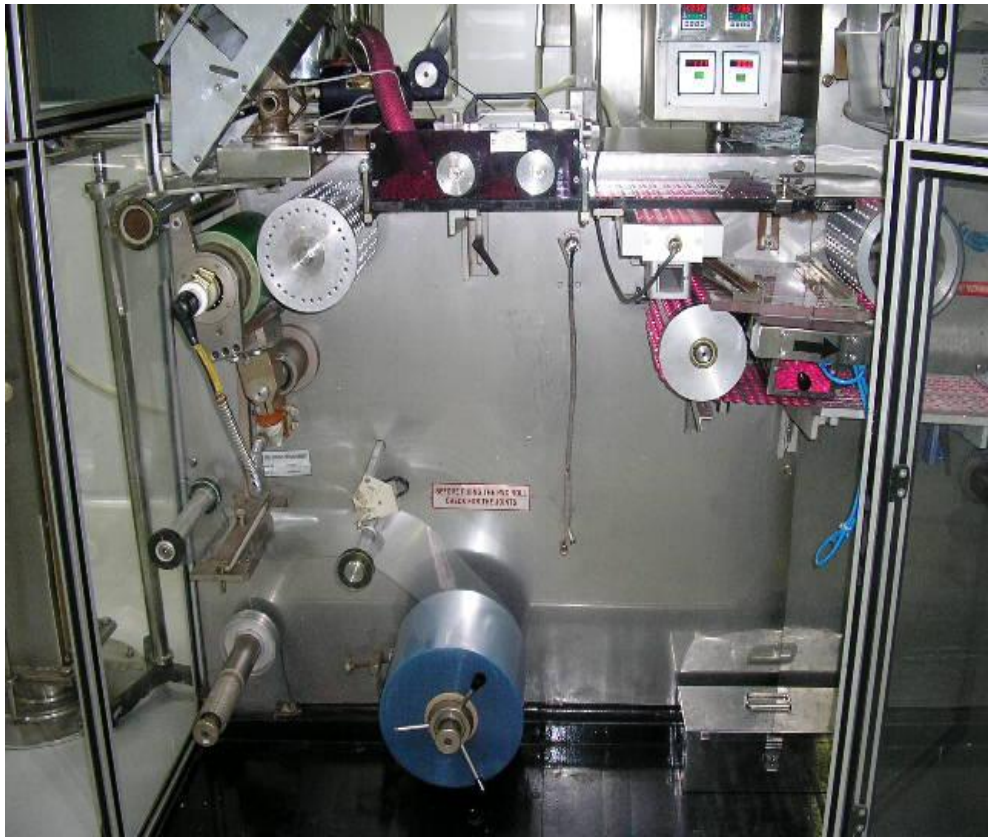
- Don't forget the packaging lines!



Equipment

- Quality control equipment and instruments
  - *suitable for the tests to be performed*
- Defective equipment in production and quality control should be
  - *Removed; or*
  - *Labelled (to prevent use)*

13.7, 13.10

Equipment

Washing, cleaning and drying

- Equipment used for washing and drying – not the source of contamination
- Equipment design should promote easy cleaning
- Cleaning on scheduled basis, procedures and records
- Washing and cleaning
  - *manual*
  - *automated (Clean in place (CIP), Steam in place (SIP))*

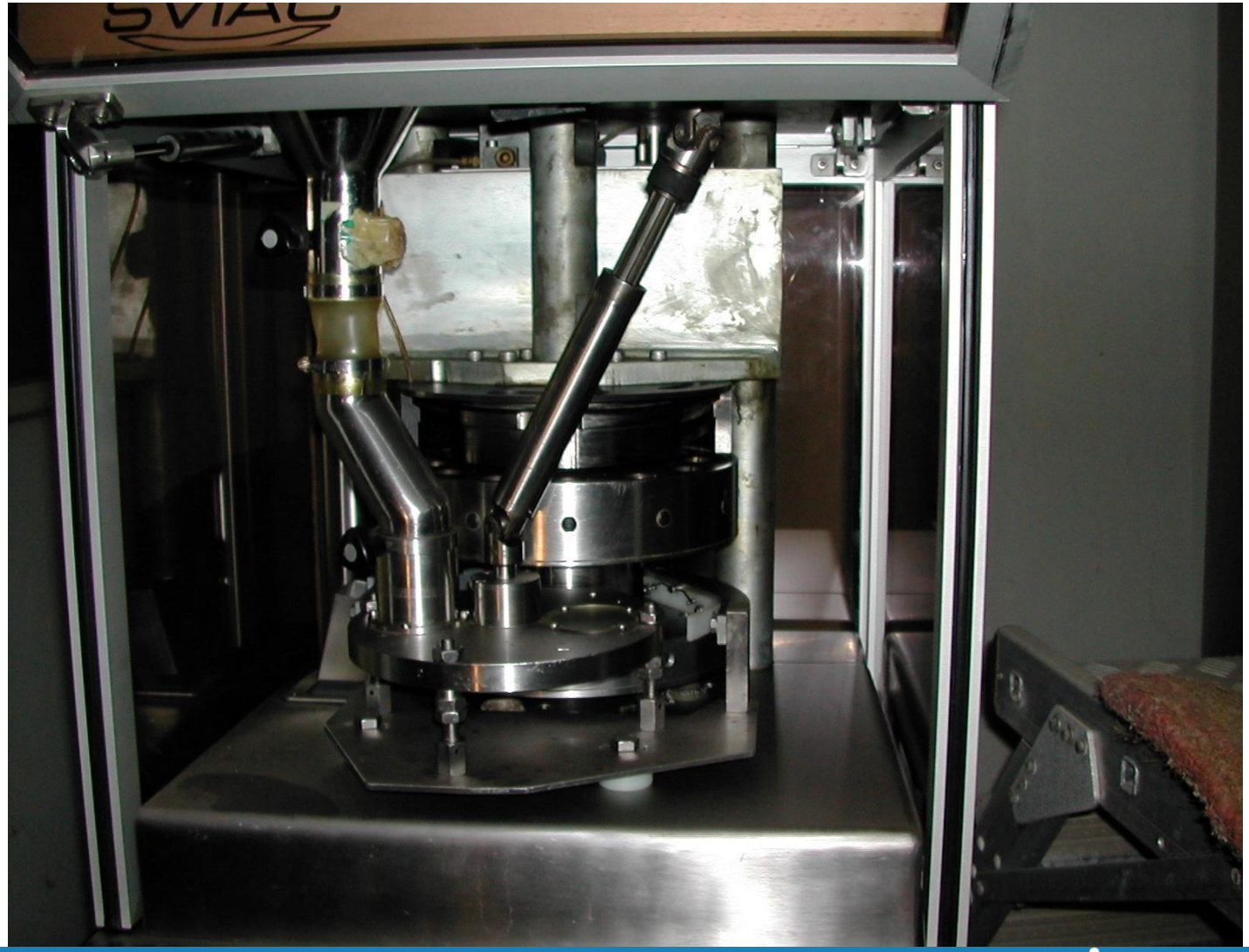
13.6, 13.8

Equipment

Group Session

- For the given type of equipment
  - *What would your concerns be in relation to the manufacture of products, when inspecting this particular piece of equipment?*
  - *What are the signs of poor practice in cleaning, operation and maintenance?*

Basic Principles of GMP



Equipment

Possible Issues

- Poor design
- Lack of safety
- Poor quality finishes
- Lack of cleaning
- Lack of maintenance
- No usage log or record
- Use of inappropriate weighing equipment
- Open-plan location of compressing machines