A Review On Cleaning And Sanitation In Pharmaceutical Industry

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Abstract- *In pharmaceutical industry the cleaning and sanitation is an important part of maintaining environmental control. Cleaning and sanitation is required for to give best pharmaceutical product to peoples without any harmful to them. The microbial contamination is occur if cleaning and sanitation not perform in pharmaceutical industry . due to microbial contamination the pharmaceutical product get contaminated due to this contamination the people get infected which cause dangerous to human health. Proper hygiene is essential in the pharmaceutical industry to prevent any kind of contamination that can affect the quality of medicinal products.For avoiding this health problems we clean and sanitize the pharmaceutical industry .*

We begin by explaining how product may become contaminated and what can be done to prevent contamination through effective cleaning and sanitation procedures.

Keywords- Introduction, Personnel Hygiene, Good Manufacturing Practices, contamination Training, Sanitation

I. INTRODUCTION

Sanitation: As a related concept, sanitation has to do with clearing out microbiological contamination, usually through a chemical sanitation.

Maintaining environmental control including microbiological contamination in a pharmaceutical manufacturing environment is primarily dependent on the facility sanitization program. Sanitization considerations are specific for facility rooms, equipment, and personnel. Sanitization comprises cleaning and disinfection. Cleaning is necessary prior to the application of disinfectant to enable sufficient contact time of the disinfecting agent with the surface. In a news paper, Tim Sandler provides an introduction to the sanitization and bio-decontamination of pharmaceutical manufacturing facilities. This topic is especially relevant for manufacturing of sterile products.

The Essential Role of Cleaning and Sanitization in Pharmaceutical Manufacturing. The cleaning validation guidelines by the FDA require that pharmaceutical manufacturers not only sanitize equipment to prevent contamination but also thoroughly establish written procedures for doing so.

The aim of sanitation and hygiene measures is to eliminate all potential sources of contamination and cross-contamination from all areas where the contamination occurs.

Objective:

1. Review measure to ensure the good sanitation:
   - Premises and personal
   - Equipments and apparatus
   - Process, materials and containers
2. Review on measure to ensure the good personal hygiene.

Scope:

1. High level of sanitation and cleaning it covers
2. Personal
3. Premises
4. Equipments and apparatus
5. Production materials and containers
6. Product for cleaning and disinfection
7. All positional sources of cross contamination.

Basic steps for cleaning and sanitation in pharmaceutical industry.

Wash hands before entering production areas and also use disinfectant.

Personal hygiene:

1. Open lesions:
   a) may affect the quality of products
   b) should not handle starting materials, intermediates or finished products etc
   c) Instructions and encouragement to report to supervisors.
2. Direct contact between product and operators:

a) Should be avoided
b) Starting material, primary packaging materials, intermediates and bulk products.

3. Protection of product from contamination:
   a) Clean clothes appropriates to personal activities
   b) Including hair covering i.e. caps.

4. Check change rooms / facilities:
   a) Hand washing, signs, drying of hands.
   b) Used clothing stored in separate closed containers while awaiting cleaning.
   c) Laundering of clean area clothing according to an SOP and in an appropriate facility
   d) Procedure for disinfecting and sterilizing when required.

A. Production operation : Cleaning:

1. Design of premises :

- Design: walls, floors, ceilings, ledges,drains, air supply, dust extraction.
- Prevention of build up of dirt and dust to avoid unnecessary risks of contamination, cleaning programme , appropriate cleaning , cleaning records.
- Effective cleaning and disinfection: choice of materials and chemicals, validation.
- Drains: prevent backflow.

2. Avoidance of cross contamination:

- Special precaution should be taken to prevent generationgeneration and dissemination of dust.
- Proper air control, supply and extraction, suitable quality.
- Due to uncontrolled release of dust, air, particles, sprays, residue insects.
- Ventilation system and airlocks :
- Appropriately designed ventilation system with air supply and extraction systems.
- Recirculation of air versus 100% fresh air supply
- Proper airflow patterns.

B. Production operation : sanitation:

- Cleaning and cleaning validation:
- Degree of cleaning depends on whether consecutive batches are of same or different product.
- Check cleaning agent is fully removed.
- If possible hot water alone used for cleaning.
- Final rinse with purified water or water for injection.
- Full records kept.
- SOP for cleaning and sanitization of the water purification system should include distribution time.
- Area clearance by QC.

II. CONCLUSION

In pharmaceutical industry cleaning and sanitation is necessary for avoiding the any contamination.

Effective cleaning and sanitization of equipment is important because equipment may not be amenable to visual inspection and it may be prone biofilm formation. Benefits and importance of sanitation and cleaning be over emphasized in order to assure quality of the products.

Cleaning and sanitation operation should be organized to prevent the contamination of foods and clean rooms and equipments.

By using cleaning validation in pharmaceutical industry, we avoid the contamination which occurs during production of dosage form. To achieve the high quality, purity, safety of product, it is necessity to do the cleaning validation of any product.

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