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"A review on the job responsibilities of production personnel in injectable plants"

V.R.Pandav, N.P.Sawadadkar, N.A. Lodhe, A.B. Mante*, Dr. H. A. Sawarkar
Dr. R.N. Lahoti institute of pharmaceutical education and research center, Sultanpur, Tq. lonar Dist. Buldhana, Maharashtra

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ABSTRACT
Pharmaceutical Industry aims to make products with good quality and quantity. This can be achieved by production department along with co-ordination from other departments in pharmaceutical industry. The production personnel plays important role in the production department to achieve quantity of product along with quality. The production personnel during the manufacturing process perform effectively the whole applied process at the every stage of the finished pharmaceutical products by according to Standard Operating Procedures (SOPs) and guidelines provided by the various regulatory agencies. Production personnel play key role in the manufacturing of the various dosage forms. Apart from other dosage forms injectable dosage forms involves critical steps so during production of injectables additional precautions have to be taken than the other dosage forms.This article expresses a comprehensive review on production personnel responsibilities during manufacturing of injectables.

Keywords :-Quality, Quantity, Production, injectables, QA

I. INTRODUCTION

The Pharmaceutical Industry, as a vital segment of the health care system conducts research, manufacturing and marketing of pharmaceutical products used for the treatment and diagnosis of diseases. Injectable pharmaceuticals are drug product delivery systems that can be used as an alternative to oral drugs and are more effective because of how fast they work. Inectable pharmaceuticals are passed into the human body through syringes to the bloodstream and other parts of the body. The production of a injectable product is a critical process involving dispensing, preparation of solution, filling and sealing, sterilization, packing and labeling etc.As these are a critical processes so production personnel involve in these operations should aware of his responsibilities properly and he should follow all his responsibilities regularly in proper manner. This article provides brief introduction for the responsibilities of the production personnel working in injectable production[2].

Objectives of Production Personnel Responsibilities For Production Of Injectable

- To perform the whole applied technological procedure.
- To perform applied operations at the every stage of the finished pharmaceutical injectable products.
- To provide Quality and quantity of products[1,2]

Production Personnel Responsibilities

- Implementation of cGmp and Good manufacturing practices.
- Conducting and participating in training program
- Read and follow the SOP displayed
- Responsible for exhibition day-to-day production activities as per the production plan
- To ensure that the entire production activities are carried out as per the same cGMP norms and other international standards
- Responsible for production documentation and maintenance of documentation
- Responsible for maintaining discipline in all production related area.
- Responsible for maintenance of equipment
- Responsible for environmental control and monitoring
- Responsible of verification of equipment and records
- To monitor and control all process to ensure product quality and yield as per the BMR
- To follow strict cleaning procedure of area, equipment, surrounding and restricted areas and maintain record for all such

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activities[1,2,3,5,8]

Steps involved in production of injectable-

1)Dispensing
2)Preparation of solution
3) Filtration and filling
4)Sterilization
5) packing[2]

Responsibilities of the production personnel in dispensing stage

Weighing or measuring of active pharmaceutical ingredients, excipients, diluents or vehicle should be done under the suitable conditions which do not affect their conformity of use. Appropriate and calibrated equipment / instrument should be used for the above purpose.

Weighing, measuring, or subdividing operations should be done by production personnel in presence of QA personnel. Prior to use in manufacturing process, production personnel should verify all the materials against the batch manufacturing record. Materials should be appropriately controlled to prevent unauthorized use. Following information being available on the label:-

- Material Name, Material Code, Control No. or A.R. No
- Weight or volume of material in the new container,
- Re-test date if required.

All ingredients, API are crosschecked for weight at initial stage by production personnel and preparation of solution should be continued after verifying the area for cleanliness followed by line clearance from QA department for further process. All checkpoints should be checked before line clearance. Product transferred from manufacturing to filtration and the yield should be compared with BMR, if problems or deviations are observed the remarks and reasons are mentioned. If the deviation is not within the acceptable limits further manufacturing process should be continued only after QA / QC clearance and proper records should be maintained either by computer control systems, or alternative means[1,2].

Responsibilities of production personnel during preparation, filling and sealing, sterilization:

- To follow cGMP practices.
- To maintain cleanliness of area and equipment and record must be maintained.
- Check environmental monitoring it should be performed and record must be maintained.
- To check all parameters during process.
- To follow standard operating procedure.
- To perform in process check such as PH checking of solution, volume, sealing, tunnel temperature.
- To check WFI pressure, compressed air pressure during washing cycle of container.
- To prepare solution according to batch size as per prescribed procedure given in batch manufacturing record.
- To filter solution through 0.2 micron filter and provide sample for sterility testing and for chemical analysis.
- To check and record temperature, room pressure,humidity,hepa filter pressure.
- To check filled volume,sealing,ampoule height, clearity during filling and sealing and record it in BMR.
- To perform autoclave VLT and Bowie-Dick test and record it.
- To maintain shop floor discipline while performing production activity[1,2,5,8].

Production personnel responsibilities during packing:

- Check environmental monitoring it should be performed and record must be maintained.
- Check the area of cleanliness, all unwanted material of previous batches should be absent.
- Check that the packing materials are received from approved vendors.
- Check that the packing material should be tested by quality control dept and status labels.
- Check the status labels on equipment, area & in-process containers.
- Check the Name, Strength, Volume and Composition on the printed packing material.
- Check the over printing quality on the primary & secondary packing material
- Check the Batch coding details on primary and secondary pack (B. No, Mfg. /date, Exp. /date, M.R.P. /bar code, etc.)
- Check the Mfg. License number printed on the packing material.
- Check and confirm that the Storage condition details are available in the packaging materials are according to particular product and same condition should be available on all printed items.
- Check the directions for use are available on the packaging items and warnings or caution

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against wrong administration is provided in the packing items.

The Good Manufacturing Practices follow to eliminate the risks at every stage of manufacturing process Good Documentation Practices and Good Review Practices should be follows during the production activity to maintain the records. [2,8]

In process control parameter checks performed by production personnel.

Parenterals- Injectables (liquid-SVP & LVP)

Appearance, Clarity, Fill Volume, pH,
Filter Integrity Tests, Particulate Matter, Shape Of Container, Sealing Quality Of Container,
Leak Testing Of Container, Pre-Filtration or Post-Sterilization, Bio-Burden Testing, Bacterial Endotoxin Tests[2,8].

Parenterals-Injectables (Dry powder Injection)

Appearance, Clarity after reconstitution, Weight, Average weight, Weight variation, Particulate matter,
Shape of container, Sealing quality of container, Leak testing of container[2,8].

II. CONCLUSION

Pharmaceutical industry make products with good quality and quantity. The production personnel play an important role in manufacturing process. Injectable manufacturing is a critical process so personnel working in injectable plant should aware about his job responsibilities.

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