

Good Practices in Pharmaceutical Industry

By
Anshuman Panda

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HIRA

It is a systematic risk assessment tool that can be used to assess the risks of various hazards.

HIRA or Hazard Identification and Risk Assessment assists emergency managers in answering these questions.

Purpose of HIRA

It offers the systematic approach assess hazards and their associated risks that may offer an objective measure of an identified hazard as well as provide a technique to manage the risk.

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Steps of HIRA

- 1) Look for Hazards
- 2) Decide who might be harmed and how
- 3) Evaluate the risks and decide if current precautions are adequate or need improvement.
- 4) Record your findings.
- 5) Review your assessment and revise it if necessary.

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Advantages

- 1) It helps in recognising and controlling hazards in your workplace.
- 2) Creating awareness among employees and using it as training tool.
- 3) Setting risk management standards based on acceptable safe practices.

Disadvantages

- 1) Unmanaged losses
- 2) Ambiguity
- 3) Depends on external entities

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Importance of HIRA

It is a risk assessment tool that can be used to assess which hazards pose the greatest risks in terms of how likely they are to occur and how great their potential impact may be.

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Good Practices in Production

- There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, purity, they purport or are represented to possess.
- Written and in-process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance.
- Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality and purity.

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- 1) The batch shall be formulated with the intent to provide not less than 100% of the labeled or established amount of active ingredient.
- 2) Components for drug product manufacturing shall be weighed, measured, as appropriate.
 - a) Component name or item code
 - b) Receiving or Control number
 - c) Weight or measure in drug product container
 - d) Batch for which component was dispensed, including its product, strength, and lot number.
- 3) Weighing, measuring, or subdividing operations for components shall be adequately

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4) Each component shall be added to the batch by one person and verified by a second person.

5) Calculation of Yield

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging of the drug product.

6) Equipment Identification

All compounding and storage containers, processing lines, and major equipment

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used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents.

Major equipment shall be identified by a distinct identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product.

7) Sampling and Testing of In-process Materials and Drug Products

- a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed, which describe the in-process controls, and tests to be conducted.

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Such control procedures shall be include, but are not limited, the following, where appropriate:

Tablet or capsule weight variation

Disintegration Time

Adequacy of mixing to assure uniformity and homogeneity

Dissolution time and rate

Clarity, completeness, pH of solutions

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Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process.

In process materials shall be tested for identity, strength, quality, and purity as appropriate and approved by the quality control unit.

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8) Time Limitations on Production

When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product.

9) Control of Microbiological contamination

Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.