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# PHARMACEUTICAL BIOTECHNOLOGY

## UNIT 2

**TOPIC :**

- c) Application of r DNA technology and genetic engineering in the production of:
  - i) Interferon
  - ii) Vaccines- hepatitis- B
  - iii) Hormones-Insulin.



# Application of rDNA Technology And Genetic Engineering In Production of Interferon, Hepatitis-B Vaccine and Insulin

- Recombinant DNA (rDNA) technology and genetic engineering are important tools in biotechnology used to produce therapeutic proteins, vaccines, and hormones by introducing desired genes into host organisms.

Applications include:

1. Production of Interferons
2. Production of Hepatitis-B Vaccine
3. Production of Human Insulin

## i) PRODUCTION OF INTERFERON

- Interferons are glycoproteins produced naturally by body cells in response to viral infection. They help protect cells against viruses and regulate immune responses.

Types:

- Interferon- $\alpha$  (Alpha)
- Interferon- $\beta$  (Beta)
- Interferon- $\gamma$  (Gamma)

## Production of Interferon by rDNA Technology

### Step 1: Isolation of Interferon Gene

- Human cells producing interferon are selected.
- mRNA for interferon synthesis is isolated.

### Step 2: Formation of Complementary DNA (cDNA)

- Reverse transcriptase enzyme converts mRNA into cDNA.

### Step 3: Insertion into Vector

- Interferon gene is inserted into plasmid vector using:
  - Restriction endonucleases
  - DNA ligase

Recombinant plasmid is formed.

### Step 4: Transfer into Host Cell

- Recombinant plasmid is introduced into host cells.

Common hosts:

- *Escherichia coli* (*E. coli*)
- Yeast cells

### Step 5: Production and Purification

- Host cells multiply and produce interferon protein.
- Interferon is extracted and purified.

### Uses of Interferon

- Viral infections
- Hepatitis treatment
- Multiple sclerosis
- Certain cancers

## II) Production Of Hepatitis-B Vaccine By rDNA Technology

- Hepatitis-B is a viral liver disease caused by Hepatitis-B virus (HBV).
- Recombinant Hepatitis-B vaccine is prepared using genetic engineering methods.

### Production Process

#### Step 1: Isolation of HBsAg Gene

- Gene coding for Hepatitis-B surface antigen (HBsAg) is isolated.

HBsAg = Hepatitis-B Surface Antigen

#### Step 2: Insertion into Vector

- HBsAg gene is inserted into plasmid vector.

Enzymes used:

- Restriction endonuclease
- DNA ligase

#### Step 3: Introduction into Host Cell

Recombinant plasmid is transferred into yeast cells.

Common host:

- *Saccharomyces cerevisiae*

#### Step 4: Expression of Antigen

- Yeast cells produce Hepatitis-B surface antigen protein.

#### Step 5: Purification and Vaccine Preparation

- Antigen is purified.
- Purified antigen is formulated into vaccine.

# Advantages of Recombinant Hepatitis-B Vaccine

- Safe and highly pure
- No live virus used
- Reduced side effects
- Effective immune protection

## Uses

- Prevention of Hepatitis-B infection
- Prevention of liver cirrhosis
- Reduces risk of liver cancer

## III) Production Of Human Insulin By rDNA Technology

Insulin is a peptide hormone produced by  $\beta$ -cells of pancreas.

Function:

- Controls blood glucose level.

Human insulin produced by recombinant DNA technology is called recombinant human insulin.

## Production Process

### Step 1: Isolation of Human Insulin Gene

- Human insulin-producing gene is isolated.

### Step 2: Preparation of Recombinant Plasmid

- Plasmid vector and insulin gene are cut using restriction enzymes.
- DNA ligase joins insulin gene with plasmid.

Recombinant plasmid is formed.

### **Step 3: Transfer into Host Cell**

Recombinant plasmid is introduced into bacterial cells.

Common host:

- *Escherichia coli* (*E. coli*)

Sometimes yeast cells are also used.

### **Step 4: Multiplication of Host Cells**

- Bacteria multiply rapidly.
- Large quantities of insulin protein are produced.

### **Step 5: Purification**

- Insulin is extracted and purified.

Purified insulin is used for treatment.

## **Uses of Recombinant Human Insulin**

- Treatment of Diabetes mellitus
- Control of blood glucose level

## **Advantages of Recombinant Human Insulin**

- Highly pure
- Less allergic reaction
- Large-scale production
- Safer than animal insulin