

Computers as data analysis in Preclinical development

Chromatographic Data Analysis (CDS)

Introduction

- In preclinical development, before a drug is tested in humans, it is tested in laboratories to check:
 - Purity
 - Stability
 - Impurities
 - Degradation products
 - Drug concentration
- Chromatography is a laboratory technique used to separate chemical components in a mixture.
- Common chromatographic techniques:
 - HPLC (High Performance Liquid Chromatography)
 - GC (Gas Chromatography)
 - TLC (Thin Layer Chromatography)
- Computers are used to analyze chromatographic data. This computerized system is called Chromatographic Data System (CDS).

What is a Chromatographic Data System (CDS)?

- CDS is a computer software system used to:
 - Control chromatography instruments
 - Collect data from detectors
 - Process chromatographic signals
 - Analyze peaks
 - Generate reports
- It replaces manual calculations and paper-based recording.

How Chromatographic Analysis Works

- **Step 1:** Sample is injected into chromatographic instrument.
- **Step 2:** Components separate inside column.
- **Step 3:** Detector detects each component.
- **Step 4:** Detector sends signal to computer.

- **Step 5:** Computer generates chromatogram.

What is a Chromatogram?

- A chromatogram is a graph with:
 - X-axis: Time (Retention Time)
 - Y-axis: Signal Intensity
- Each peak represents a chemical component.
- **Example:**
 - Peak 1 → Impurity
 - Peak 2 → Active drug
 - Peak 3 → Degradation product

Role of Computer in CDS

1. Peak Detection

- Computer automatically:
 - Detects peaks
 - Calculates retention time
 - Measures peak area
 - Measures peak height
- Peak area is directly related to drug concentration.

2. Quantitative Analysis

- Using calibration curve:
- Computer calculates:
 - Exact drug concentration
 - % purity
 - % impurity

3. Qualitative Analysis

- Computers compare retention time with standard reference.
- Used to identify unknown compounds.

4. Data Storage

- All chromatograms are:
 - Stored electronically
 - Archived



FREE PREVIEW

[Click here to visit our website](#)

PHARMACY PREMIUM NOTES

Complete subject
and semesters are
available on
FirstHope app only.



[Scan or click here](#)

Click here to get the app



Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram



[Scan or click here](#)

@FirstHopeNotes

Instagram

@firsthope.official

[Click here to follow >](#)

YouTube channel

FirstHope-Pharmacy / Live streams

[Click here to watch >](#)

WhatsApp channel

Follow FirstHope on WhatsApp

[Click here to join >](#)

FirstHope website

firsthopenotes.com

[Click here to visit >](#)

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.