

Biopharmaceutics and pharmacokinetics

Biopharmacy Lab 1

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The practical course will cover the following experiments!!

- Exp .1 Construction of calibration curve of Salicylic acid with the application of statistics
- EXP .2 In vitro evaluation of antacid
- EXP .3 In vitro evaluation of bulk forming laxatives
- EXP .4 Hydrolysis of acetyl salicylic acid solution in Sorensen phosphate buffer at pH 8
- Exp.5 pH and solvent effect on drug solubility
- EXP.6 In vitro dissolution of per-oral tablet

Introduction Biopharmaceutics and Pharmacokinetics

- **Biopharmaceutics** : the study of influence of formulation on the therapeutic activity of drug products
- **Pharmacokinetics** : deal with the mathematical description of biological processes which affect the time course of absorption and fate of drug in the body and which are themselves affected by drugs.

By kinetic we learn about :

- **Rate of absorption**
- **Rate of elimination of a drug and can**
- **Calculate the half life of a drug in the body**

So we can predict what will be the duration of correct dosage regimen for maintaining a therapeutic level

- During the practical course certain dosage form will be evaluated **in vitro** (means outside the body in the lab)
- **In vivo** (means inside the body)

Lab 1 :Preparation of calibration curve of salicylic acid with the application of statistics

Calibration curve is a curve which is prepared from a series of standard solutions to use it as a reference curve to obtain the concentration of an unknown sample of the same drug.

Curve fitting: To fit a straight line among scattered points to represent the linear trend of the points, one can use:

- 1- *Eye fitting*: often it is possible to fit the data points by eye to a straight line, but this method is not reliable.
- 2- *Least square fitting*: a commonly preferred method for obtaining estimates of parameters used in curve fitting, is the method of least square.

The least square method is based on the equation which minimizes the sum of the squares of the deviations of the observed values from the line $[\sum (y - \bar{y})^2]$, where y is the observed value and \bar{y} is the calculated value. In other words, the line of best fit is obtained when the sum of the squares of the vertical distances from the points to the line is a minimum. Such a line is called the linear regression line of y on x , based on the principle of least squares as in Fig. 1.

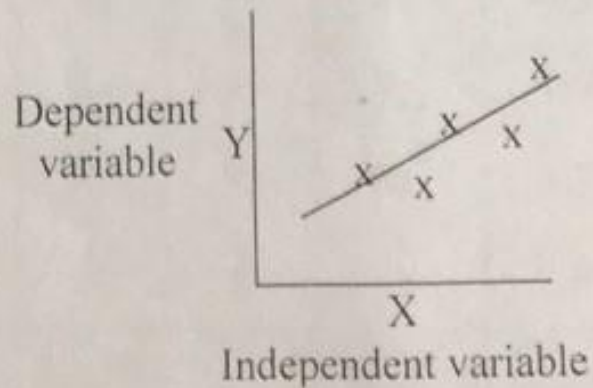
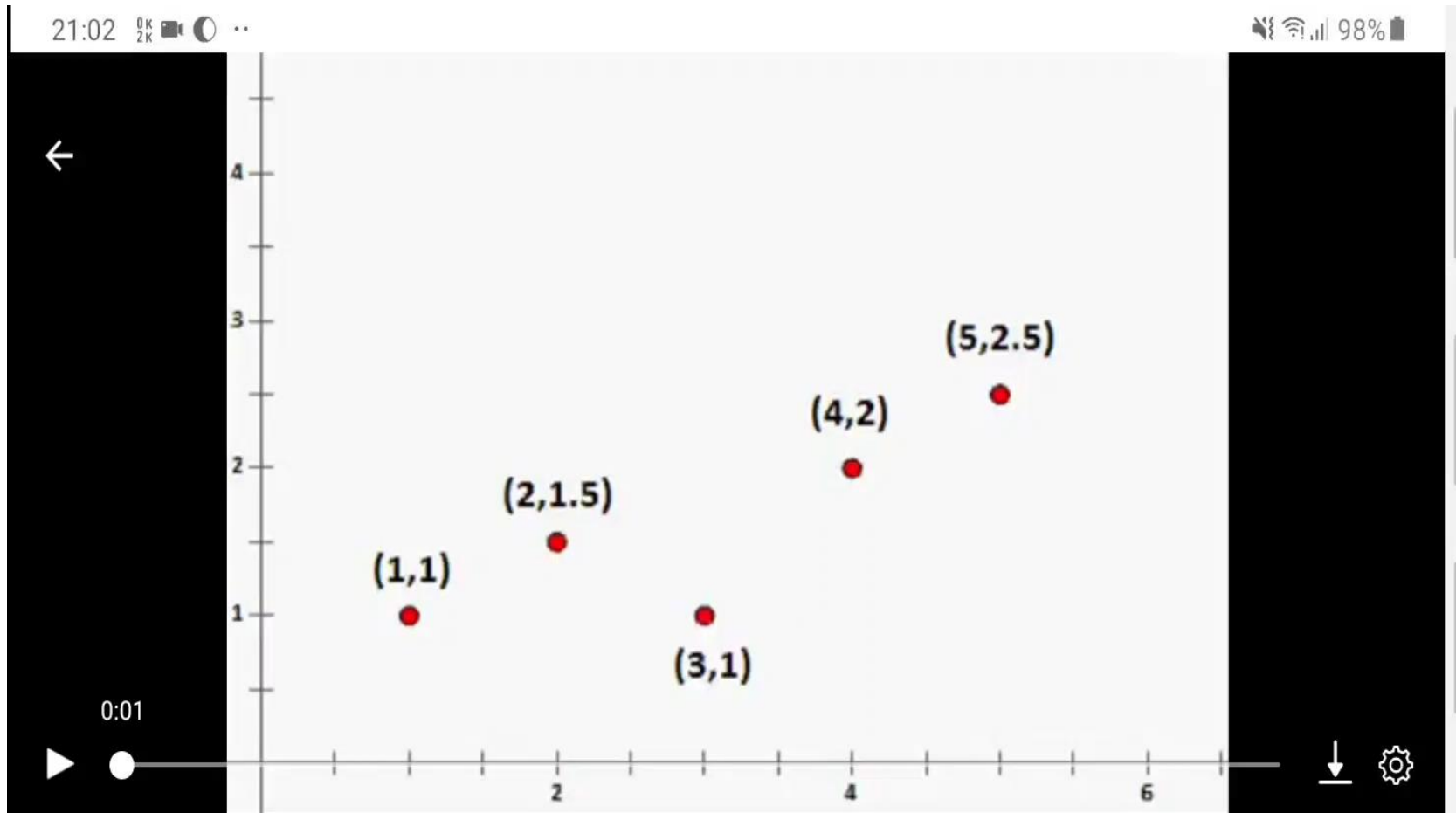


Fig. 1: Schematic plot of curve fitting by least square method.

Let us watch the following scientific video



Using the values obtained in Table (1) the constants b and c are then calculated using eq. (4) and eq. (5) which are the solutions to eq. (2) and eq. (3).

$$b = \frac{(\sum x \cdot y) - (\sum x)(\sum y)}{n(\sum x^2) - (\sum x)^2} \dots\dots\dots \text{Eq. (4)}$$

$$c = \frac{(\sum y) - b(\sum x)}{n} \dots\dots\dots \text{Eq. (5)}$$

b: is the slope of the least square line.

c: is the intercept of the least square line with the ordinate.

The constants b and c are then substituted into eq. (1) in order to obtain the calculated value of $[\bar{y}]$ for any given value of (x).

To explain how the linear regression line may be found let us assume we have " n " pairs of data $(x_1, y_1), (x_2, y_2), \dots, (x_n, y_n)$.

The predicting or estimating equation used to represent the experimental data is:

$$\bar{y} = c + b \cdot x \dots\dots\dots \text{Eq. (1)}$$

\bar{y} = Calculated value.

c = Intercept of the least square line with the ordinate.

b = slope of the least square line.

Thus, for each value of x, we have both an observed and a calculated value for y.

The calculated or predicted value \bar{y} is determined by substituting the approximate x value into equation (1) once values of b and c are known.

The least square criterion requires one to find the numerical value of the constants b and c in equation (1), for which the sum of the squares $\left[\sum (y - \bar{y})^2 \right]$ is as small as possible.

Table (1): Necessary calculation for the least square equation.

<u>Number</u>	<u>x</u>	<u>y</u>	<u>x²</u>	<u>x.y</u>
1	x ₁	y ₁	x ₁ ²	x ₁ y ₁
2	x ₂	y ₂	x ₂ ²	x ₂ y ₂
3	x ₃	y ₃	x ₃ ²	x ₃ y ₃
<u>↓</u>	<u>↓</u>	<u>↓</u>	<u>↓</u>	<u>↓</u>
n	($\sum x$)	($\sum y$)	($\sum x^2$)	($\sum x.y$)

Thank You

