




5. WEEK

DISSOLUTION RATE

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- ❖ Under standardized conditions, the amount of active substance which is dissolved from solid dosage form and passed to dissolution medium in per unit time is called the "Dissolution Rate".
The unit is expressed in mg/min.

- ❖ The Intrinsic Dissolution Rate is the amount of substance dissolved from the unit surface in per unit time. The unit is $\text{mg}/\text{min}/\text{cm}^2$.
- ❖ Active substances with an intrinsic dissolution rate lower than $1 \text{ mg}/\text{dk}/\text{cm}^2$ show severe absorption and bioavailability problems in vivo.

- ❖ The dissolution rate of a solid in a liquid is defined by the Noyes-Whitney Equation.
- ❖ Noyes-Whitney Equation describes the formation of a very thin saturated film layer on the dissolved solid surface. The dissolution rate of the active substance is achieved by diffusion between this saturated layer and the unsaturated liquid.

$$dc/dt = K.(C_s - C)$$

❖ In this equation;

dc/dt : Dissolution rate (mg/sn)

C_s : The saturation solubility of the active substance in that environment (mg/ml)

C : The solubility of the active substance in that environment (mg/ml)

$$dc/dt = K.(C_s - C)$$

❖ In Noyes-Whitney's law; K is the "Intrinsic Dissolution Rate Constant" and is defined

as: $K = D.A / V.h$

D: Diffusion coefficient(cm^2/sn)


A: Surface area(cm^2)

V: Liquid volume (ml)

h: Diffused film layer thickness(cm)



- ❖ There are a variety of officinal and non-official methods to determine the dissolution rate of the active substance that is released from a dosage form.
- ❖ In determining the intrinsic dissolution rate, the most commonly used method is the "Rotating Disk" method.



❖ In this assay method, the pure active substance is pressed into the disk and the dissolution rate is fixed to the shaft portion of the device and placed in the dissolution rate environment.

❖ The dissolution rate test is carried out at high rotational speeds (300-1000 rpm).