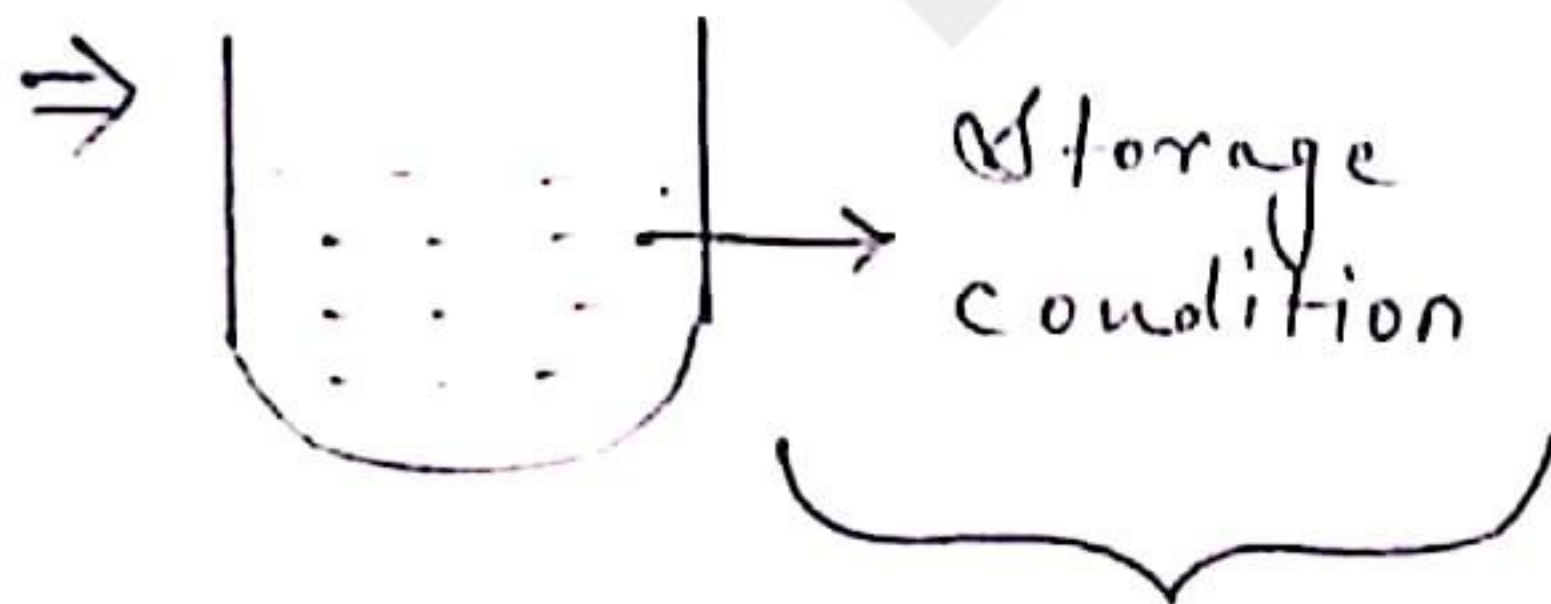


Accelerated stability testing in expiration dating of Pharmaceutical dosage forms :-

(Photolytic degradation & its prevention)

→ Predict stab. and shelf life formulation
By increasing temp., moisture, light

[DEPTH OF BIOLOGY]



Either it is satisfactory or not



Perform stability testing

[DEPTH OF BIOLOGY]

⇒ ICH & WHO Guidelines :-

Q.1.A. (R2) Stab. testing of new drug
Substance & Pdt.

Q.1.B. Photo Stab. testing of new drug
Substance & Pdt.

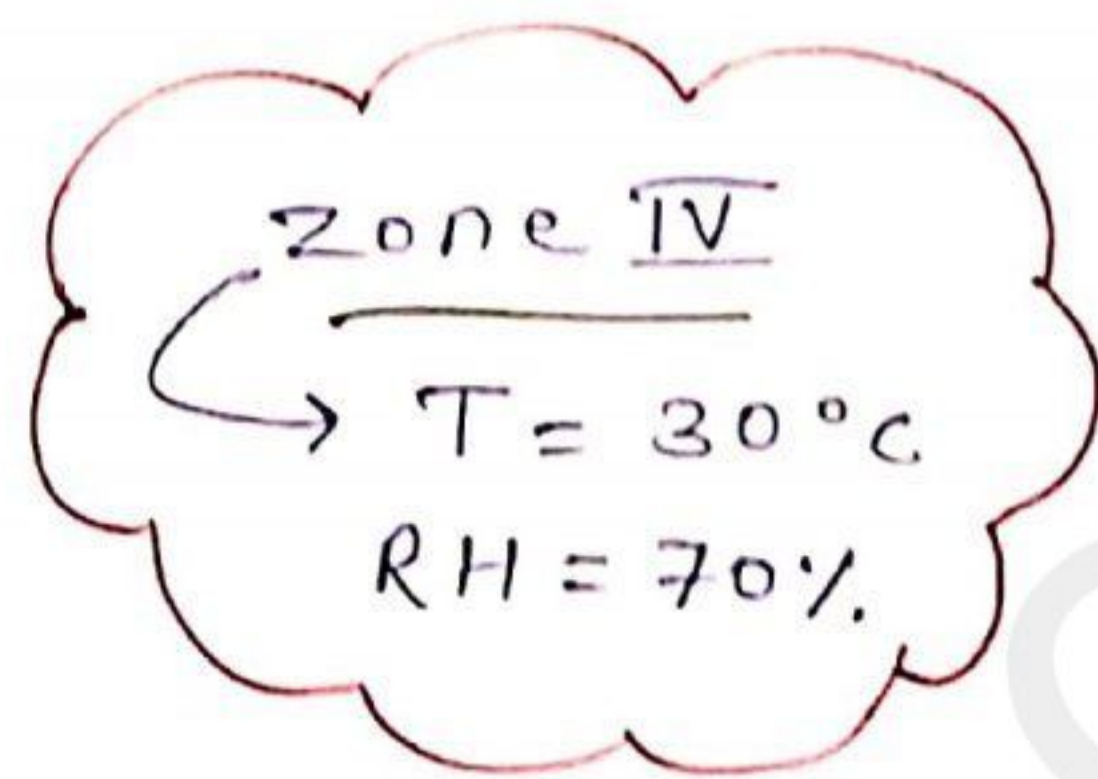
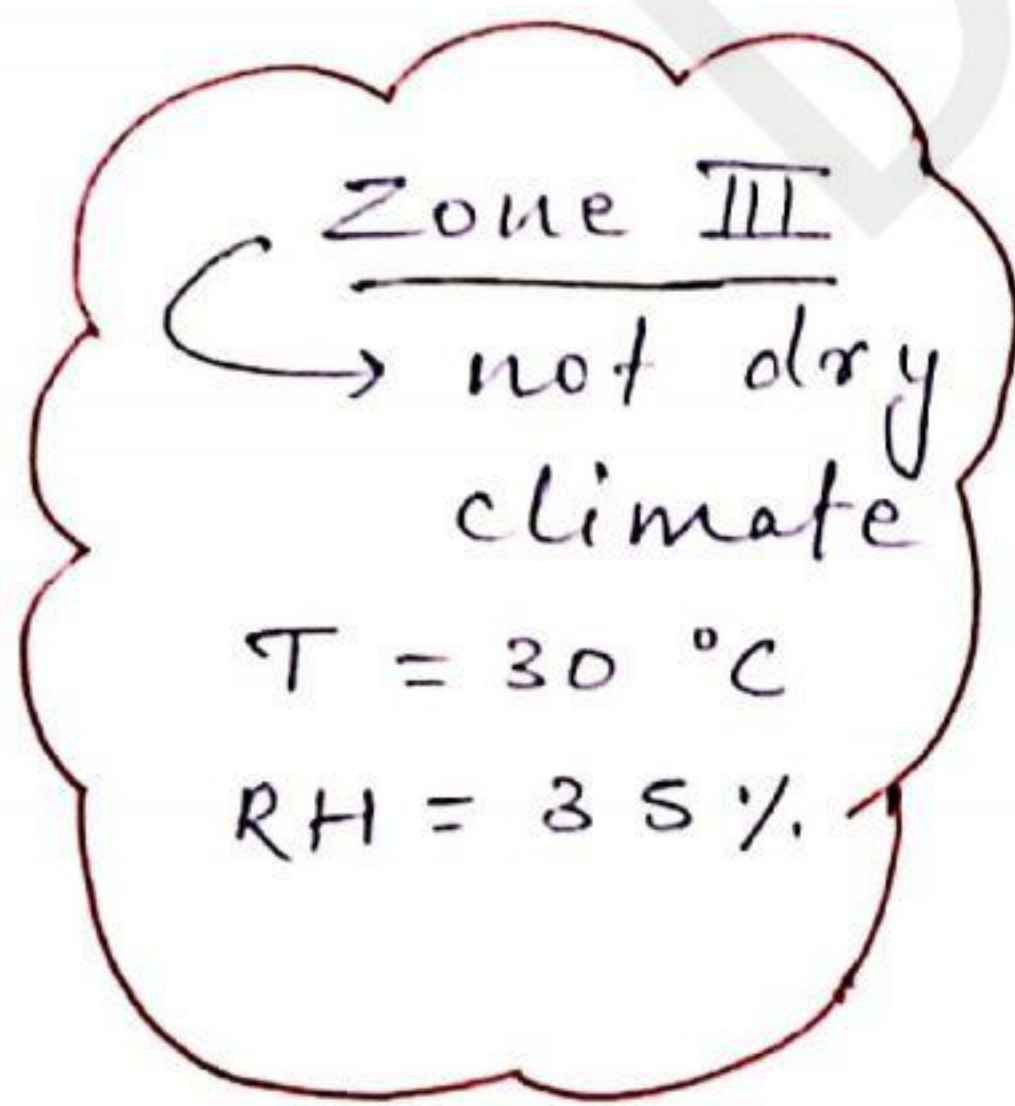
[DEPTH OF BIOLOGY]

Q. 1. C. Stab. testing of new dosage form.

Q. 1. D. Bracketing & matrixing design for Stab. testing of new dosage form.

Q. 1. E. Evaluation of stability data.

Q. 1. F. Stab. data for climatic zone III & IV.



[DEPTH OF BIOLOGY]

Objective :-

① In a series of similar formulation we select best formulation with the help of Acc. Stab. Analysis.

② Predict Shelf life of Pdt.

[DEPTH OF BIOLOGY]

③ Rapid quality control.

Temp. $\uparrow$
degradation $\uparrow$

[DEPTH OF BIOLOGY]

Moisture
or
Humidity $\uparrow$
Hydrolysis of
Pdt.

Light
we check
effect of
sunlight

Physical and chemical factors influencing the chemical degradation of Pharmaceutical products :-

① Temperature :-

Generally, Speed of many rxn increased 2-3 times with each increase of 10°C in temperature.

Stability Study Life :-

(1) Long term. Stab. Studies.

(2) Intermed. Stab. Studies

$\rightarrow$ Duration = 6-month

$\rightarrow$ Temp. = $30 \pm 2^{\circ}\text{C}$

$\rightarrow$ RH = $65 \pm 5\%$

[DEPTH OF BIOLOGY]

(3) Accelerated stab. studies

↳ Duration = 6 m

↳ Temp = $40 \pm 2^\circ\text{C}$

[DEPTH OF BIOLOGY]

↳ RH = $75 \pm 5\%$

Storage Condition :-

Duration = 5 years

Temp = $25 \pm 2^\circ\text{C}$

RH = $60 \pm 5\%$

Prediction of Shelf Life :-

(i) Arrhenius equation :-

↳ $10^\circ\text{C} \uparrow$

↳ 2-3 x of rate

$$\log k = \log A - \frac{E_a}{2.303 RT}$$

[DEPTH OF BIOLOGY]

Steps involved in Acc. stab. Testing :-

(1) Pharm. Prep stored at different temperature (40, 50, 60)

(2) Conc. of reactant at each elevated temp. is determined.

③ Sample are withdrawn at different time interval.

④ ROR is determined by plotting the curve betⁿ concentration of reactant & time (Linear relationship).

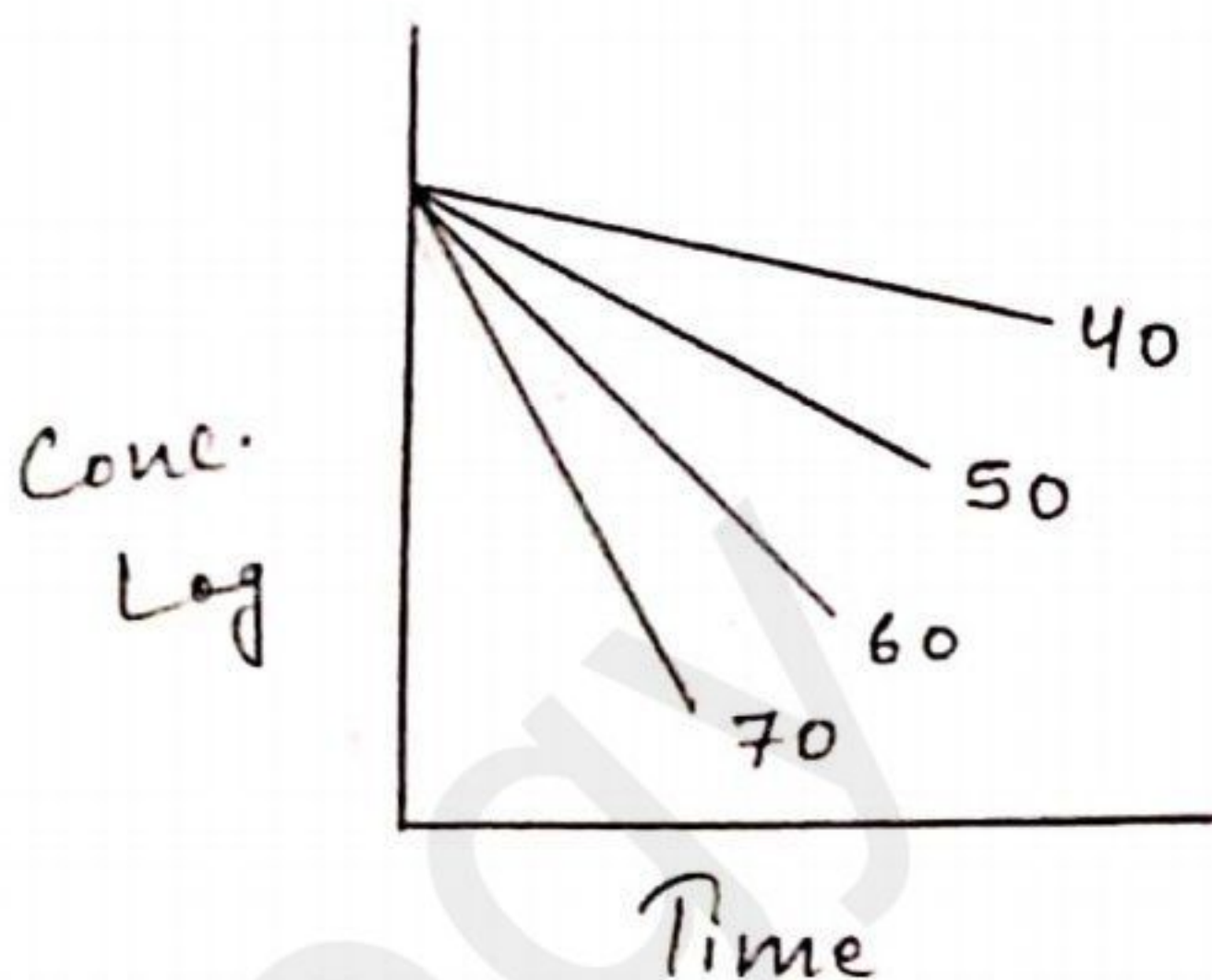
[DEPTH OF BIOLOGY]

⑤ With the help of this curve we can easily identify K value.

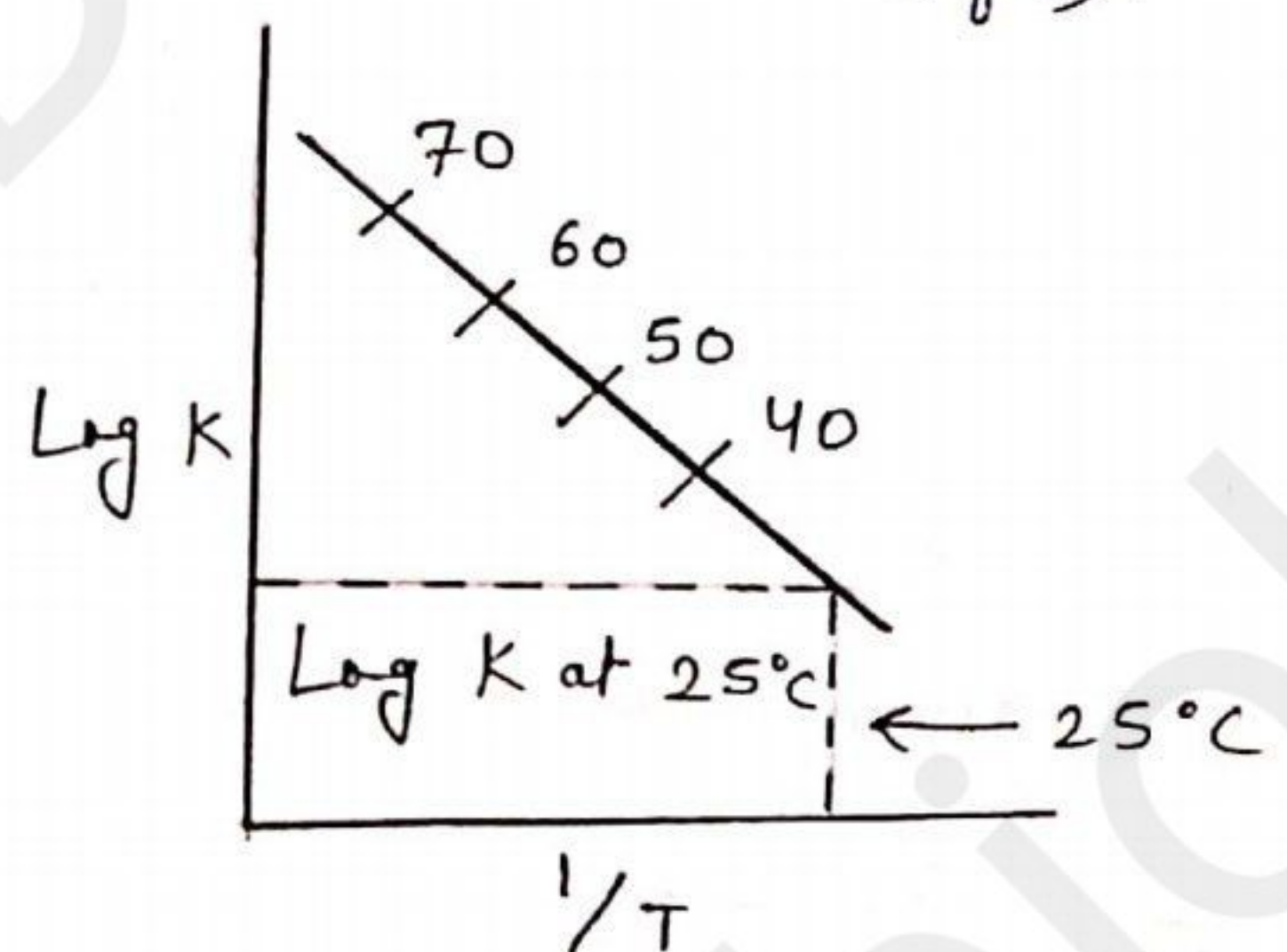
⑥ Dosage form (room temp.) $\rightarrow 25^{\circ}\text{C}$

$0^{\circ}\text{C} \leftarrow \text{K value} \leftarrow \text{Graph}$

⑦ 25°C K value substitute with already determine order (to determine shelf life).



[DEPTH OF BIOLOGY]



Limitation of Accelerated & stab. Analysis:-

① Not used in case of complex rxn.

② E_a = Activation energy
 $\rightarrow 10 - 30 \text{ Kcal/mol}$] Limitation

[DEPTH OF BIOLOGY]

③ Microb. Contam., freezing, excess agitation
this (is) not applicable for degradation.

④ This method is not suitable when
order change at high temperature.