

Chemical Quality Control

Lab 3

**Stability-indicating assay of
nicotinamide content in Supratorn
H[®] capsules via degradation.**



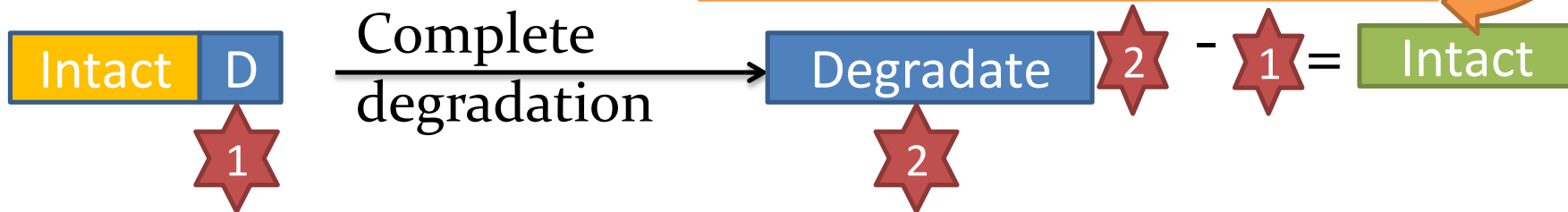
Stability Indicating Assay Methods (SIAM)

It is a method that determine the concentration of the intact drug in presence of it's degradation products.

Types: (4)

Development of **highly selective method for the intact drug** where the degradation products don't interfere.

Development of **highly selective method for the assay of the degradation product**, where the intact drug is determined via its degradation in subsequent step.



Types (continue):

Development of stability indicating method which **separate and quantify** both the drug and the degradation product.

Development of stability indicating method which **separate the drug** away from the degradation product.

Forced degradation is done to assess stability studies as

- 1- Hydrolysis (alkaline/acid).
- 2- Oxidation.
- 3- Humidity.
- 4- Photodegradation.
- 5- Heat.

Components of stability studies:

Two major components:

The tests to be performed

This section of the protocol is a list of tests that monitor the **quality, purity, potency and identity** to be performed on samples stored in the various environmental conditions.

Tests may be :

Assay

Degradation products

Dissolution

Appearance

the schedule of testing

It is **a series of stability test intervals** at which time all or some of the stability tests will be run on a sample in the study under a group of environmental conditions.

Supratorn H[®] capsules

✓ Nicotinamide is a water soluble vitamin of the B complex.

USES:

1. In human and animal nutrition to enrich various foods, drinks or feed.
2. As dietary supplement in tablets and capsules.

Deficiency:

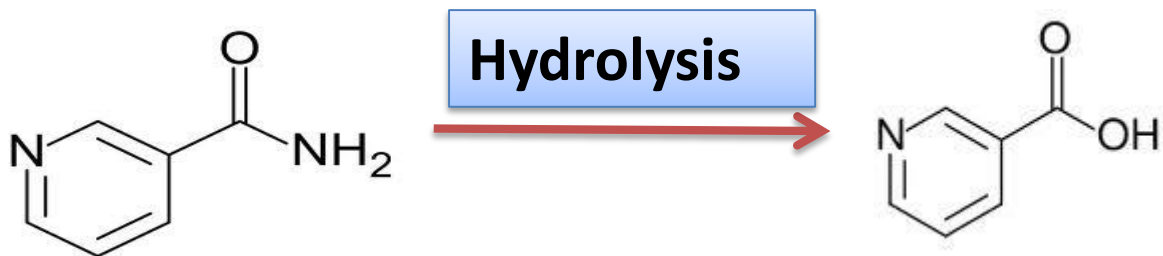
Leads initially to non-specific symptoms like lassitude, anorexia, weakness, indigestion and irritability.

Supraton H[®] capsules

PRINCIPLE:

✓ Degradation:

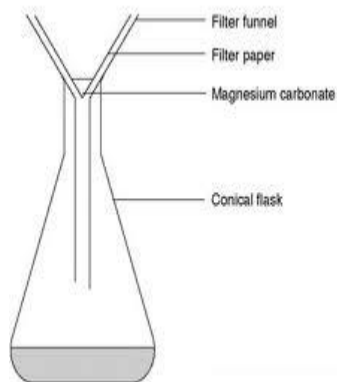
Being amide, nicotinamide is hydrolyzed into **nicotinic acid** which can be determined using **acid-base titration**.



Procedure:



1. In a 100 ml volumetric flask , weight an accurate amount from the powdered content of Supratoron H[®] equivalent to one capsule(**0.34g**).
2. Add 50 ml distilled H₂O, shake well for 5 min. for complete extraction, complete to the mark with H₂O, mix and filter.



3. Discard first 5 ml of the filtrate
4. Take 10 ml into conical flask + 10 dps ph.ph indicator.
5. Titrate with 0.001 N NaOH till first pink color. **mls 1**





5. **In new flask**, take 10 ml of the completely degraded sample of nicotinamide (**equivalent to one degraded capsule**) + 10 dps ph.ph indicator.

6. Titrate with 0.001 N NaOH till first pink color. **mls 2**

7. Calculate the **amount & recovery** of intact nicotinamide in Supraton H[®] capsules.



Calculation:

Each 1 ml of 0.001 N NaOH equivalent to 0.000122 g = 0.122 mg

$$\begin{aligned}\text{Found amount of nicotinamide (in 1 capsule)} &= \frac{\text{mls } 3 * f * F * 100}{10} \\ &= \dots\dots\dots\text{mg}\end{aligned}$$

Claimed amount of nicotinamide in one capsule is 15 mg

$$\begin{aligned}\text{Recovery \%} &= \frac{\text{found}}{\text{claimed}} * 100 \\ &= \frac{\text{Found amount}}{15} * 100 = \dots\dots\dots\%\end{aligned}$$

(if less than 90%, so it is an expired batch)

Thank you very much for your
attention

