

# Precision, trueness, accuracy *guidelines*

## Validation guidelines

- ICH
- AOAC
- Eurachem
- IUPAC
- EMA
- FDA
- SANCO
- Nordtest Guide for measurement uncertainty

## Validation guidelines

- ICH
- AOAC – AOAC International
- Eurachem
- IUPAC – Union of Pure and Applied Chemists
- EMA
- FDA
- SANCO
- Nordtest Guide for measurement uncertainty

Single laboratory method  
validation guidelines

## Validation guidelines

- ICH
- AOAC
- Eurachem
- IUPAC
- EMA – European Medicines Agency
- FDA – The United States Food and Drug Administration
- SANCO
- Nordtest Guide for measurement uncertainty

Bioanalytical  
methods

## Validation guidelines

- ICH - International Conference on Harmonization
- AOAC
- Eurachem
- IUPAC
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- Nordtest Guide for measurement uncertainty

Registration of  
pharmaceuticals

## Validation guidelines

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Validation guideline for  
pesticide residue analysis in  
food and feed

## Validation guidelines

- ICH
- AOAC
- Eurachem – “The Fitness for Purpose of Analytical Methods”
- IUPAC
- EMA
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## Terminology - precision

- **Repeatability** = within-run precision (FDA, EMA)
- **Intermediate precision** = between-run precision (FDA, EMA)
  - = intra-lab reproducibility (Eurachem)
  - = within-laboratory reproducibility (Nordtest)

## Terminology

<b>Organization</b>	<b>Term</b>	<b>Meaning according to VIM</b>
Eurachem, AOAC, ISO	Accuracy Trueness	Accuracy Trueness
ICH, FDA, EMA	Accuracy	Trueness
IUPAC, NordVal	Trueness	Trueness

## Intermediate precision

- Time interval only specified in:
  - EMA – two different days
  - Nordtest\* – at least several months

### Recommendation

Ideal – several months

In practice – estimate with one month

## How many concentration levels?

- 2 – IUPAC
- 3 – FDA, NordVal
- 4 – EMA, AOAC
- Not specified in Eurachem
- ICH
  - 1 level if concentration doesn't vary
  - Can choose levels as long as 9 measurements in total

### Recommendation

Choose accordingly to concentration levels you are expecting!

## How many replicates?

- 5 replicates – NordVal, EMA, FDA, AOAC
- 3 replicates – ICH
- 6 replicates – ICH (1 concentration level)
- 6-15 replicates – Eurachem

### **Recommendation**

5 – 10 replicate measurements

Can reduce number of replicates if a long period intermediate precision.

## And for trueness?

- Most times done with precision measurements.

**BUT**

- If carried out separately from precision, a reduced design may be used (e.g., 2 replicates in five days).