Precision, trueness, accuracy

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

Validation guidelines

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

Single laboratory method validation guidelines

Bioanalytical methods
Validation guidelines

• ICH - International Conference on Harmonization
• AOAC
• Eurachem
• IUPAC
• EMA
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• SANCO
• Nordtest Guide for measurement uncertainty
Validation guidelines

- ICH
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- Eurachem – “The Fitness for Purpose of Analytical Methods”
- IUPAC
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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)

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### Terminology

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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

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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).