# Near-Infrared (NIR) Spectroscopy

## Introduction

- **General information:**
  - Weight: 2.75 lb or 1.2 kg
  - Approximate cost: ~ 50 K (US $)
  - Calibration using USP <1119> with traceable wavelength standards
  - Measurement time: < 1 minute
  - Battery life: ~ 6 hours (rechargeable and interchangeable)

## How it works

- **Explain how the technology works:**
  - The technique employs Near-Infrared (NIR) light source to get chemical and physical fingerprint information (only between 1600 – 2400 nm, combination and first overtones)
  - Sampling mode: Diffused Reflectance
  - Optional adapters for liquids available

## Strengths

- **Include three strengths of the technology:**
  - Rapid analysis
  - Easy to transport
  - Non-destructive
  - Can provide quantitative information if proper calibration model is developed and validated

## Limitations

- **Include three limitations of the technology:**
  - A bit of steep learning curve to develop methods (PCA, PLS etc.)
  - Physical characteristics differences can influence the analysis
  - Generally not used for liquids
  - Unit is sensitive to shake during measurement
Why Portable?

- Take the laboratory to the crime scene
- No need to ship samples to a testing laboratory which means, no customs or FDA clearance needed
- Allow instant, remote detection of counterfeits
- Surveillance and monitoring of pharmacies, hospitals and manufacturing facilities and rapid screening of products
- Facilitate quicker identification and arrest of criminals
- Proactive approach and not reactive
- Save time and cost

Raman

NIR
Portable vs. Benchtop (NIR)

- Benchtop (Drug Product)
- Portable (Drug Product)
- Benchtop (API)

Absorbance vs. Wavenumber (cm\(^{-1}\))

- Absorbance range: 0.05 to 0.65
- Wavenumber range: 4170.00 to 6170.00 cm\(^{-1}\)

3

Securing Medical Product Quality Through the Supply Chain

U.S. Pharmacopeial Convention | March 28–31, 2017 | USA
NIR Analysis of Counterfeit Capsule A

Log 1/R or Abs vs WL (nm)

PC 2 vs PC 1
Counterfeit Capsule B

- Product supposed to contain two active ingredients
- Handheld NIR and Raman spectra revealed that it contained no active ingredients
- The spectral results matched with **calcium carbonate (chalk!!)**
- Runtime less than a minute!
NIR Analysis of Counterfeit Tablet

Counterfeit

Authentic

Log 1/R or Abs vs WL (nm)