Hands on basic instructions

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PDA
Parenteral Drug Association

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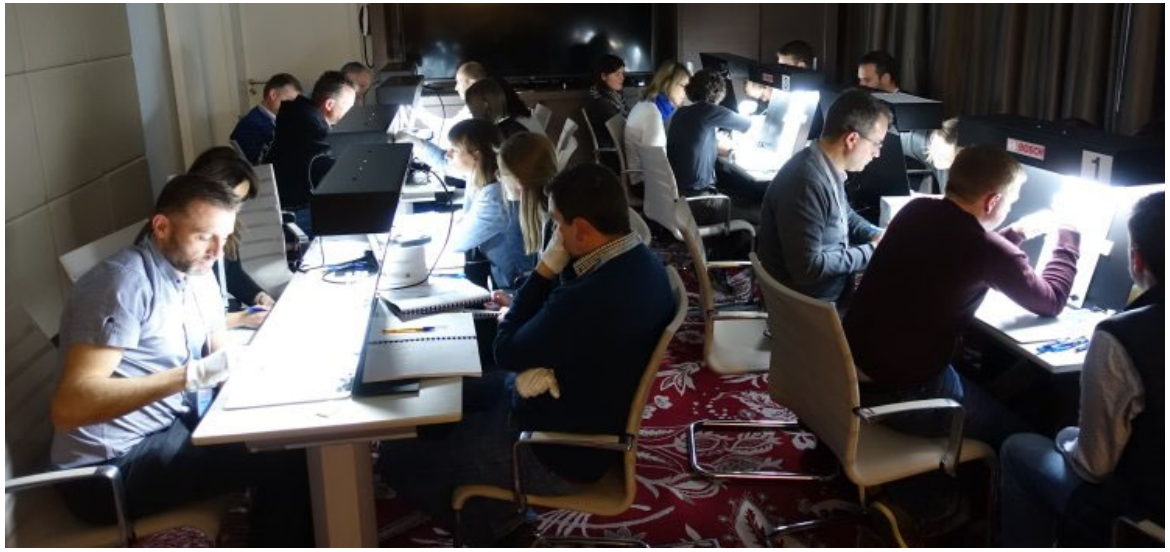
Goal of the Experiments

- Identify important parameters
- Recognize behavior of different particles
- It‘s hard to be an inspector even for half a day



Test Set

- Test set contains 28 vials
- Blanks and rejects
- Every Inspector has to inspect all 28 vials in each experiment
- Patiently wait until the class is ready to move on to the next experiment

Documentation

PARTICLE INSPECTION DATA SHEET #1: Normal Inspection

Inspector:_____ Test Set ID:_____

Inspection Station:_____ Illumination Intensity:_____lux

FULL Illumination Intensity **WITH** Agitation **5** Sec/Background

Vial Number	☑ Reject	Accept

- Write down your name on the data sheet
- Write down 3 digit number of the vial and your observation
- Write down Test set number
- Each inspector has to write down the inspection results for the entire set of 28 vials
- Write clearly

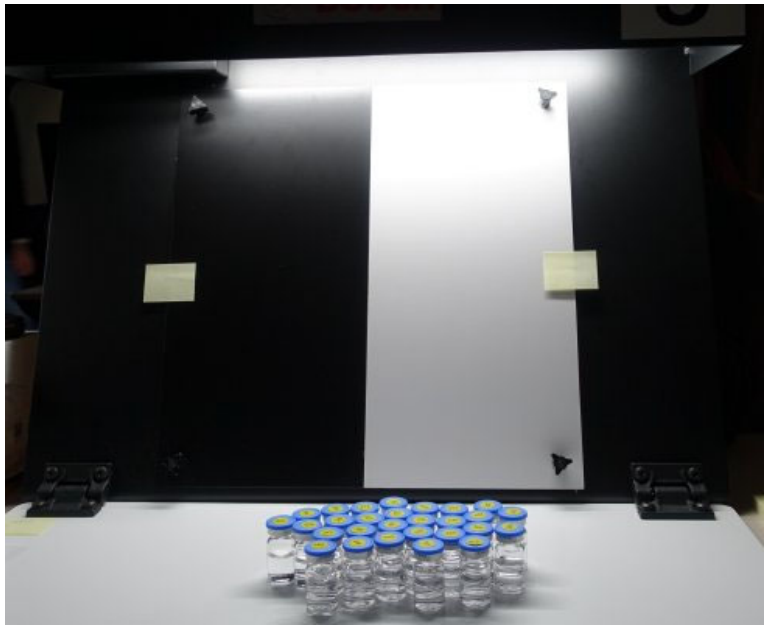
Setup of the instrument

Switch on both lamps

Measure light intensity. Mark a position at ~ 3000 Lux

Mark a position at ~ 3000 Lux

Tools



Tools

- Remove cover from sensor
- Select measurement range

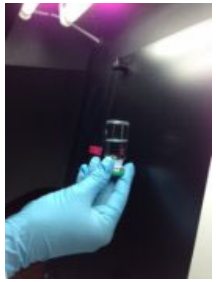
- Just listen to the metronome while inspecting to get the right timing

Inspection Technique

- Pick up vial holding at approximately a 30-degree angle
  - **bring to the black and then the white background** to inspect for any heavy particles on the lower portion of the vial bottom.
- Gently swirl to inspect for any fine sediment on the bottom of the vial in **both backgrounds**.
- **In front of the black background**, Fully invert to fully 'wash' the stopper area, return upright, and swirl the vial looking for particulate matter.
- **In front of the white background**, Fully invert, return upright, and swirl lookin for particulate matter.
- Record results on data sheet.

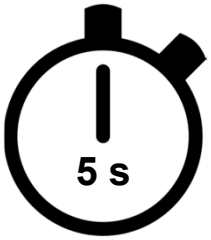
Training

- Two vials of each set (marked with a dot) contain easy to observe particles
- Make yourself familiar with swirling and inverting for a couple of minutes with these vials to practice the particle detection
- Try swirling and inverting

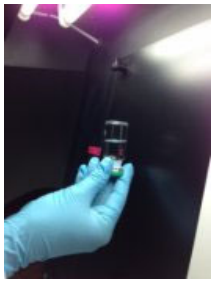


Exp. 1: Standard condition

Inspect at marked position



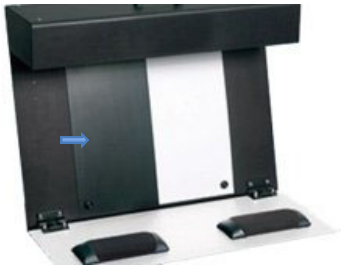
Inspection time 5s black, 5 s white background



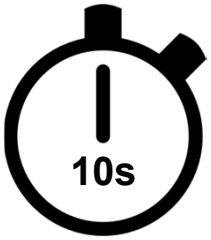
Swirl or invert

Record result

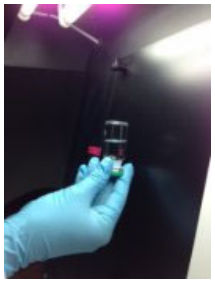
Exp.2: Elevated inspection time



Inspect at marked position



Inspection time 10s black, 10s white background



Swirl or invert

Record result

Exp.3: Reduced Light intensity - setup

Switch off one lamp

Measure light intensity

Mark a position at ~ 1500 Lux

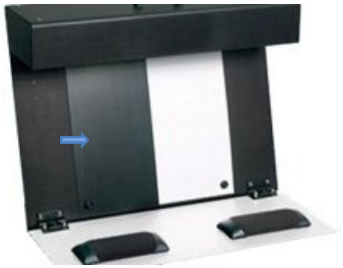
ML9

ML9

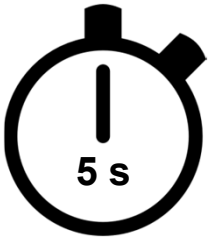
fehler

Markus Lankers; 04.04.2017

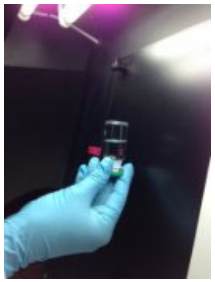
Exp.3: Reduced Light intensity



Inspect at marked position



Inspection time 5s black, 5 s white background

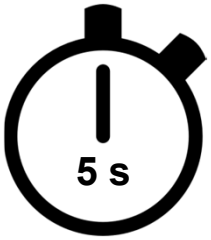


Swirl or invert

Record result

Exp.4: No agitation

Inspect at marked position



Inspection time 5s black, 5 s white background

No Swirling or inverting

Record result