Quick Start Instructions
Opt Diss

Power On

1. Power on main power
2. Power on Source and Detector
3. Power on PC and monitor

System Initialization

1. Log in to PC and software
2. Turn on UV lamp (if planning on doing a run)
    a. Select Tools | Lamp Control | Turn Lamp On
    b. Allow 20-30 minutes for equilibration
3. Initialize Camera and Temperature
    a. Select Tools | Initialize Camera
    b. Select Tools | Read CCD Temperature (wait for 5 minutes to reach CCD temperature)
    c. Temperature must be between -25°C to -35°C

File Set-Up

1. Creating a new file
    a. Category Structure
        i. Organize by product, user, month, etc.
    b. File Structure
        i. Name by product, date, user, etc.
2. Opening a File
    a. Open a file for date review
    b. Open a previously stored method
        i. When opening a method make sure to rename the file immediately
3. Saving a File or Method
    a. Save a File at the conclusion of the run
        i. Enter the password to save File
    b. Save a Method

Methods can be saved with method parameters and standard and blank data (if planning on performing a test be sure to rename the method as a file)

Software Overview

1. Views (Quick Buttons and View Menu)
    a. Report View
        i. Method Parameters
        ii. Standard Information
        iii. Absorbance Values
        iv. % Dissolved Results

b. Spectral View
    i. Wavelength Calibration File
    ii. Blank Spectra
        1. Intensity
    iii. Standard Spectra
        1. Absorbance
    iv. Sample Spectra
        1. Absorbance
    v. Spectra List
        1. List of all acquired and pending spectra
c. Dissolution Curve View
    i. Real-time plotting of dissolution results
d. Image View
    i. Color representation of intensity (Transmittance)
e. Event Log (View Menu only)
    i. Audit Trail to track method changes

Method Parameter Set-Up

1. General

a. Noted, Media Type informational
b. Volume critical to calculation
c. RPM critical if in bath control

2. Sample

a. Unit Dose (mg) for Ingredient A and B critical to calculation
b. Sample ID, Study Number, Storage Conditions informational

3. Run

a. Exposure Time
    i. Exposure Auto Set
        1. Place probes in blank media
        2. Select Exposure Auto Set
            a. System will systematically find optimal exposure time
            b. Optimal exposure time will populate exposure time field in method parameters
b. Pathlength (Informational Only)
c. Number of Scans (Signal Averaging)
    i. Scope
        1. Used to improve signal to noise ratio
        2. Will provide better representation of true concentration in vessel
    ii. Setting
        1. Traditional Application 3 to 4 scans
        2. Low Absorbing Application 10 plus scans
    iii. Precaution
        1. Selecting too many scans can freeze the computer if sampling interval is not long enough
        2. Rule of Thumb: Assume 2 – 3 seconds for every scan due to the need to collect background and process data
d. Phases (Timepoints)

i. Divide dissolution curve into relevant segments
    1. Disintegration or Capsule Burst Section
    2. Rate of Release section
    3. Plateau section
ii. Select interval relevant to requirement for characterization
    1. Early Timepoints
        a. 10 or 15 second interval for first 5 – 15 minutes
            i. More variability
            ii. Better define formulation
    2. Middle Timepoints
        a. 30 seconds to 1 minute for next 15 – 45 minutes
            i. Characterize rate of release
            ii. Identify potential production issues
                1. Content Uniformity
                2. Blending
                3. Compaction Pressure
                4. Etc.
    3. End Timepoints
        a. 1 minute to 15 minutes for remainder of test

4. Analytical

a. Calculation Type
    i. Single Component Analysis
        1. Analytical Wavelength (Single)
            a. Defines calculation wavelength
            b. Able to change before, during, and after run
    ii. Multi-Component Analysis
        1. Wavelength Region (Multi)
            a. Defines the portion of the spectrum used for data analysis
            b. Region should encompass spectral regions that include absorbance peaks for both analytes A and B
            c. Able to change before, during, and after run
b. Baseline Correction (Single Component Analysis)
    i. Scope
        1. Accounts for UNDISSOLVED PARTICULATES in solution (scattering effects)
    ii. Types
        1. Single Wavelength
            a. Reference Wavelength
        2. Double Wavelength
            a. Two Point Perpendicular Drop
        3. Average Over Range
            a. Define baseline by Range
        4. First Derivative
            a. Inflection points at peak maxima locations of original spectrum
            b. Analytical wavelength should be set to the largest positive or negative peak
            c. Used when there is no flat portion of spectrum available for reference wavelength
        5. Second Derivative

a. Slope of the Slope
b. Attempting to decipher the effect of an active peak from a placebo
c. Poorly understood by regulatory

c. Component Selection (Multi-Component Analysis)
   i. Select Ingredient A for Component 1
   ii. Select Ingredient B for Component 2
   iii. Select Baseline Shift Type(s):
      1. Constant
         a. Spectrum shifts either up or down by a constant amount across UV spectrum
      2. Linear
         a. Spectrum shifts by an amount that varies in linear manner with respect to wavelength
      3. Light Scattering
         a. Curved baseline shift by Rayleigh scattering
      4. Custom
         a. Ad-hoc image of excipient/placebo solution
d. Standard Mixtures (Multi-Component Analysis)
   i. Scope
      1. Accounts for interactions between both ingredients
   ii. Select Ad-hoc images for mixtures
   iii. Input ingredient concentrations of the selected mixture

5. Report

a. Customize report format
b. Customize format of displayed values (decimal points)
c. Select channels of interest
   i. Running two different formulations
   ii. Running two different strengths
   iii. Running two different medias
d. Multi-Component
   i. Select which ingredient or both to display
   ii. Average Fit Error option
      1. To ensure proper wavelength region and baseline shift options that results with the lowest Average Fit Error
   iii. Display Observed vs. Calculated Plot option
      1. Select specific time point during dissolution run
      2. To ensure proper wavelength region and baseline shift options that results with Calculated Spectra matching Observed Spectra

6. Standards Information
    a. Enter name of standard A
    b. Enter name of standard B
    c. Enter relevant standard concentrations for Standard A and Standard B
    d. Lot Number, Purity, Std. Weight, Preparation Date – informational

7. Bath – for Distek baths only
    a. Select Enable Bath A and or B
    b. Set Temperature, RPM, Medium and Set Vol. (volume)
    c. Select Active Vessel Positions

Acquisition of Blanks and Standards

1. Standard Blanks
    a. Place probes in dissolution media or media used in preparation of standards
    d. Acquire Standard Blank A and or Standard Blank B by selecting each individually under the Acquire Tab
        i. The intensity of the lowest peak must be at least 40% of the highest peak
        ii. Select Spectral View
            1. Consistency: With all blank readings you are looking for consistency (If probe 3 is noticeably the strongest in intensity it should remain the strongest throughout all blank readings)
            2. Similar Shape: All probes, though different intensities, should have a similar shape (A strange shape is indicative of an air bubble)
2. Standards
    a. Move probes from tank with blank media into tank with standard media blotting dry with Kimwipe (If two standards are prepared pour standards into two separate tanks and label accordingly)
    b. Acquire Standard A and Standard B by selecting each individually under the Acquire tab
        i. The absorbance of the individual channels may differ slightly due to the slight differences in the true pathlengths
        ii. Select Spectral View
            1. Similar Shape: Each channel's absorbance plot should have similar shaped curves
        iii. Select Report View
            1. Verify the Response Factor ratio of the two standards is 1.00 plus or minus 0.02
3. Sample Blanks
    a. Non-mixture mode (and Single Component)
        i. Place probes into individual vessels using cover spacer for 900 mL test and direct into cover for 500 mL test
        ii. Acquire Sample Blank under Acquire tab
    b. Mixture mode
        i. Place probes in dissolution media or media used to prep standards
        ii. Acquire Sample Blank under Acquire tab
4. Standard Mixtures
        i. Place probes in tank with standard mixture
        ii. Acquire mixture spectra as Ad Hoc datasets using Acquire Image under Acquire tab

iii. Move probes to next mixture tank after blotting dry with Kimwipe and Acquire Image
iv. Repeat for all mixtures
v. Place probes in vessels either using cover spacer for 900 mL test or directly into the cover slot for 500 mL test

Starting a Run

1. Dissolution Unit Set-up
    a. Make sure dissolution unit is set up with correct RPM and run time if not in communication with Opt Diss
    b. Verify vessel temperatures have reached 37.0 degrees ± 0.5
2. Preparation of Dosage Forms
    a. Baskets
        i. Raise Drive Head
        ii. Place dosage form in basket
        iii. Attach basket to adapter
    b. Paddles
        i. Locate dosage forms as close to hole in vessel cover as possible
        ii. Stop rotation of the paddle blades
3. Starting the Opt Diss
    a. Start Run
        i. Select Start Run under Acquire Tab
        ii. Enter appropriate drop timer
4. Starting the Test
    a. Select OK from drop timer window
    b. Lower drive head for baskets
    c. Drop dosage forms for paddles
    d. Start rotation of stirring device