Quick Start Instructions
Opt-Diss 405

Power On

1. Power on Opt Diss Detector
2. Power on Controller (if available)
3. Power on Monitor
4. Power on PC's CPU

System Initialization

1. Turn on UV lamp (if planning on doing a run)
    a. Yellow light should illuminate
    b. Light should turn red after 5-15 seconds
    c. Allow 20-30 minutes for equilibration
2. Log into computer operating system
3. Load Symphony (If Software Version 1.14 or earlier)
    a. Acknowledge solid green lights on Controller
    b. If light does not go green, power down Controller and CPU and reboot
4. Open Opt Diss Software and Log In
5. Initialize Camera (under Tools on the menu bar)
    a. Verify temperature gets to -65 for CCD3000 and -30 for CCD4000 (under Tools on menu bar select Read Temperature)

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) critical to calculation
    b. Sample ID, Study Number, Storage Conditions informational
3. Analytical
    a. Wavelength
        i. Defines calculation wavelength
        ii. Able to change before, during and after run
    b. Baseline Correction
        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. 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
4. Run
    a. Exposure Time
        i. Manual Setting (Software version 1.14 or earlier)
            1. Scope

a. Optimize amount of light getting to sample based on pathlength while probes in blank media of DI water
2. Determining Optimal Exposure Time
a. Spectral View (Intensity versus Wavelength)
i. Under-saturated peaks look very noisy (Less than 50,000 light intensity units (LIU))
ii. Over-saturated peaks look flat at top of peak (Greater than 250,000 LIU)
b. Image View (Color representation of intensity)
i. Under-saturation is represented by dark blue to light blue channel image
ii. Over-saturation is represented by brick red channel image
3. Recommendations (may vary depending on CCD detector and lamp life):

a. 0.25, 0.50, and 1.0 mm	3 to 10 ms
b. 2.0 mm	10 to 25 ms
c. 5.0 mm	25 to 45 ms
d. 10.0 mm	80 ms and up

ii. Auto Setting (Software 1.16 or later)
1. Place probes in blank media or DI water
2. Under Tools select AutoSet Exposure Time
a. System will systematically find optimal exposure time by trial and error
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

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
6. Standards
   a. Enter name of standard A (i.e. Working Standard)
   b. Enter name of standard B (i.e. Check Standard)
   c. Enter relevant standard concentrations (If only one standard is prepared, must read as both A and B and so name and concentration will be entered in duplicate as both A and B)
7. Bath
   a. Select Active Vessel Positions and Active Baths

Acquisition of Blanks and Standards

1. Standard Blanks
   a. Place probes in dissolution media or media used in preparation of standards
   b. Acquire Standard Blank A and 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. Place probes into individual vessels using cover spacer for 900 ml test and direct into cover for 500 ml test
    b. Acquire Sample Blank under Acquire tab

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