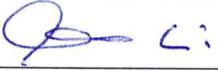


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| Owner                | Sijin Guo     | 20Mar2025 |  |
| Operation Management | Baozhong Zhao | 20Mar2025 |  |
| Quality Assurance    | Xibo Li       | 20Mar2025 |  |

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| ALL     | 1. New document    |                       |

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## 1. PURPOSE

The purpose of this document is to describe the procedure for spectral and quantitative analysis of an analyte (or analytes) using the Thermo-Scientific NanoDrop One UV-Vis Spectrophotometer.

## 2. SCOPE

This SOP encompasses the principles, use, maintenance, and troubleshooting of the Thermo-Scientific NanoDrop One UV-Vis Spectrophotometer.

## 3. INTERNAL REFERENCES

| Document ID | Title |
|-------------|-------|
|             |       |
|             |       |

## 4. EXTERNAL REFERENCES

| Document ID                     | Title  |
|---------------------------------|--|
| NanoDrop One Series User Manual | Uv-Vis Instruments NanoDrop One Series User Guide (©2016 Thermo Fisher Scientific Inc. – Revision B) |
| ICH Q7 (API)                    | Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients                           |
| ICH Q9                          | Quality Risk Management  |
| ICH Q10                         | Pharmaceutical Quality System  |

## 5. RESPONSIBILITIES

| Job Function and/or Department | Responsibility  |
|--------------------------------|---|
| Operational Employees          | Employees who are trained in the operation of the NanoDrop One UV/Vis spectrophotometer are responsible for adhering to this procedure. |
| Operational Management         | Responsible for training operational employees on the operation of the NanoDrop One UV/Vis spectrophotometer and ensuring               |

## 6. DEFINITION

| Term         | Definition  |
|--------------|---|
| NanoDrop One | Spectrophotometer system for measurement of absorbance. |

## 7. PROCEDURE

### 7.1. Sample Preparation and Disposition

- 7.1.1. Only 1-2 µL of solution (sample) is needed on the lower Pedestal. At Synoligo, most if not all of sample concentration measurement should read in **5-10 OD** to maintain the maximum consistence though the manufacturer suggest a higher concentration can be measured. Make a serial dilution if the measures concentration is outside this range. When making serial dilutions, avoid exceeding a 200-fold dilution at each step.
- 7.1.2. **DO NOT USE hydrofluoric acid (HF) or HF-containing sample on the pedestals.** Fluoride ions will permanently damage the quartz fiber optic cables.

### 7.2. Operation of the NanoDrop

- 7.2.1. **NOTE: NanoDrop must be rebooted every day. If this is the first time being used in the day, make sure reboot the system.**
- 7.2.2. Turn on the power switch on the back of the spectrophotometer. Wait for the system to initialize. The power indicator on the keypad stops blinking when initialization is complete.
- 7.2.3. Before taking pedestal measurements with the NanoDrop One instrument, lift the instrument arm and clean the upper and lower pedestals. At a minimum, wipe the pedestals with a new laboratory wipe.

FIGURE 1: INSTRUMENT



### 7.3. General Data Acquisition

- 7.3.1. From the main screen, select the appropriate application.
- 7.3.2. Specify a baseline correction if desired.
- 7.3.3. Pipette 1-2 uL blanking solution on the lower pedestal and lower the arm.
- 7.3.4. Tap Blank and wait for the measurement to complete. If Auto-Blank is On, the blank measurement starts automatically after you lower the arm.
- 7.3.5. Lift the arm and clean both pedestals with a new laboratory wipe.
- 7.3.6. **NOTE: Calibrate the system by measuring the standard sample. If the measured concentration falls into the range, proceed measuring the real sample. If not, notify management.**
- 7.3.7. Pipette 1-2 uL sample solution onto the pedestal and lower the arm.
- 7.3.8. Start the sample measurement. If Auto-Measure is On, lower arm; if Auto-Measure is Off, lower arm and tap Measure. When the sample measure is completed, the spectrum and reported values are displayed.
- 7.3.9. When you finished measuring samples, tap End Experiment.
- 7.3.10. Lift the arm and clean both pedestals with a new wipe.