Performance Monitoring Protocol (QA/QC) for the UV-Vis Spectrophotometer

1 Scope

This document addresses the performance monitoring (QA/QC) of the UV-Vis Spectrophotometer. This document applies to personnel using the associated instrument(s)/equipment in Quantico, VA in the following disciplines/categories of testing: Drug chemistry, toxicology, and Chemistry Unit general physical and chemical analysis.

2 Principle

The UV-Vis Spectrophotometer is used to measure the absorbance of light in the ultraviolet and visible regions of the electromagnetic spectrum. All identifications of spectral regions are based on absorption band positions which are given in wavelength (nm). Definitions and guidelines for following this protocol are outlined in the "General Instrument Maintenance Protocol."

3 Equipment/Materials/Reagents

a. Instrumentation – Thermo-Fisher Evolution 220 UV-Vis Spectrophotometer with Insight 2 software (or equivalent)

b. 1.0 cm quartz cuvette cell (or equivalent)

c. Caffeine (USP grade or equivalent)

d. Analytical Balance (Mettler or equivalent)

e. 1000 mL Volumetric Flask

f. Deionized Water, 18.2 MΩ·cm (Milli-Q or equivalent)

4 Standards and Controls

4.1 Testmix

The Testmix is used to assess daily operating performance and continued integrity of the system. The Testmix for the UV-Vis is a 10 ppm standard solution of caffeine in water. To prepare, weigh 10 mg caffeine. Dilute to 1000 mL with deionized water in a volumetric flask. Label the solution with the preparation date, initials, and expiration date. Store the solution at room temperature. It has a shelf-life of 5 years.

5 Sampling or Sample Selection

Not applicable.

6 Procedures

6.1 Daily Checks

The following steps will be performed daily. Enter the appropriate information in the QA/QC log to indicate completion.

a. Allow the spectrophotometer to warm up for at least 20 minutes.

b. Record the remaining disk space on the hard drive. Use Windows Explorer program to verify that the hard disk has at least 100 MB of free disk space. Do not use if less than 100 MB remain.

c. Perform an analysis of the Testmix. Verify use of the parameters as listed in the 'Instrumental Conditions' section of this protocol. Fill a cuvette with the Testmix. Start the analysis.

d. Use 'Find Peaks and Valleys' to label max and min. Evaluate the results using the 'Decision Criteria' section of this protocol. If the results are acceptable, print the absorbance spectrum of the Testmix with the y-axis scale ranging from 0-1 Absorbance Units.

e. If all requirements are within specification, prepare the documentation as outlined in the "General Instrument Maintenance Protocol." If any requirements fail, contact appropriate instrument support personnel.

7 Instrumental Conditions

7.1 UV-Vis Spectrophotometer

Start:	360 nm
End:	220 nm
Data Interval:	0.5 nm
Scan Speed:	120.00 nm/min
Band Width:	1.0000 nm

8 Decision Criteria

8.1 Testmix

Compare the daily Testmix to a previous analysis. The spectrum should be consistent with the previous analysis.

The absorbance spectrum is acceptable if the following are within a ±1 window of the expected Absorbance unit.

- Max = 272 nm
- Min = 245 nm

8.2 Performance Verification Standards

All tests performed during the performance verification must pass. If they do not, contact appropriate instrument support personnel.

9 Calculations

Not applicable.

10 Measurement Uncertainty

Not applicable.

11 Limitations

Only properly trained personnel will perform duties involved in the operation, maintenance, or troubleshooting of this instrument.

12 Safety

Take standard precautions for the handling of all chemicals, reagents, and standards. Refer to the *FBI Laboratory Safety Manual* for the proper handling and disposal of all chemicals. Personal protective equipment should be used when handling any chemical and when performing any type of analysis.

13 References

Manufacturer's Instrument Manuals for the specific models and accessories used.

"General Instrument Maintenance Protocol" (Inst 001) *Instrument Operation and Systems*

Support SOP Manual.

FBI Laboratory Safety Manual.

Rev. #	Issue Date	History
0	06/21/06	New document which replaces original titled "Performance Monitoring Protocol (QA/QC) for the Perkin Elmer Lambda 40 UV-VIS Spectrophotometer."
1	09/21/09	Removed model number from sections 1 and 2. Added explanation of UV-Vis in section 2. Updated model number in section 3a. Added statement about documentation in section 4.1. Clarified performance verification in section 4.2. Added reference to 'Instrumental Conditions' in section 7.1c. Added section 7.1d for labeling and reference to 'Decision Criteria.' Changed wording of statement in section 7.2f to be consistent with other SOPs. Updated section 7.2 to indicate 'as needed.' Updated sections 7.2c, d and f to reflect terminology used in new software. Updated conditions in section 8.1 based on new instrument methodology. Clarified section 9.1 with more specific decision criteria.
2	10/04/18	Removed Perkin Elmer from the title. Updated Section 1 Scope to include applicable disciplines/categories of testing. Removed Perkin Elmer from Section 2. Changed Perkin Elmer to Thermo-Fisher and added new instrument model to Section 3 a. Updated grade of caffeine in Section 3 c. Removed Section 3 b. Removed Section 4.2. Deleted Calibration section and updated heading in Section 5. Added “and Valleys” to Section 7.1 d. Removed Section 7.2. Removed Ordinate Mode and changed slit width to band width in Section 8.1. Added ‘appropriate instrument support personnel’ to Sections 7.1 e and 9.2. Updated ‘Instrument Operation and Systems Support’ in Section 14 and header.

Approval

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Drug Chemistry/
General Chemistry
Technical Leader: Date: 09/28/2018

Toxicology
Technical Leader: Date: 09/28/2018

IOSS Manager: Date: 09/28/2018

Chemistry Unit Chief: Date: 09/28/2018

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QA Approval

Quality Manager: Date: 09/28/2018