SoRite Fentanyl DECON

FOR

Aseptic Health, LLC

d/b/a SoRite LLC

Mr. Blake Bernard
4721 Trousdale Drive, Suite 116
Nashville, Tennessee 37220

MRIGlobal Project No. 311985

July 14, 2025

Preface

MRIGlobal is pleased to submit this final report to Aseptic Health, LLC for SoRite Drug Decontamination as described in proposal/contract "SoRite Drug Decontamination (March 25, 2025, 839063)". This report includes the primary task related to decontamination efficacy testing for fentanyl hydrochloride. MRIGlobal has prepared this Report to summarize all activities involved during April 2025. The Report was written by Ms. Katelyn Koll and reviewed by Ms. Lindsey Schissel and Mr. Evan Durnal. All of the work was performed at the MRIGlobal facility in Kansas City, Missouri.

(U) This work was conducted in MRIGlobal's Integrated Defense Unit. Mr. Evan Durnal was the Program Manager and Ms. Katelyn Koll was the Principal Investigator for this work.

(U) MRIGLOBAL

Ms. Katelyn Koll
Principal Investigator

Approved:

Mr. Evan Durnal
Assistant Director-IDS Programs

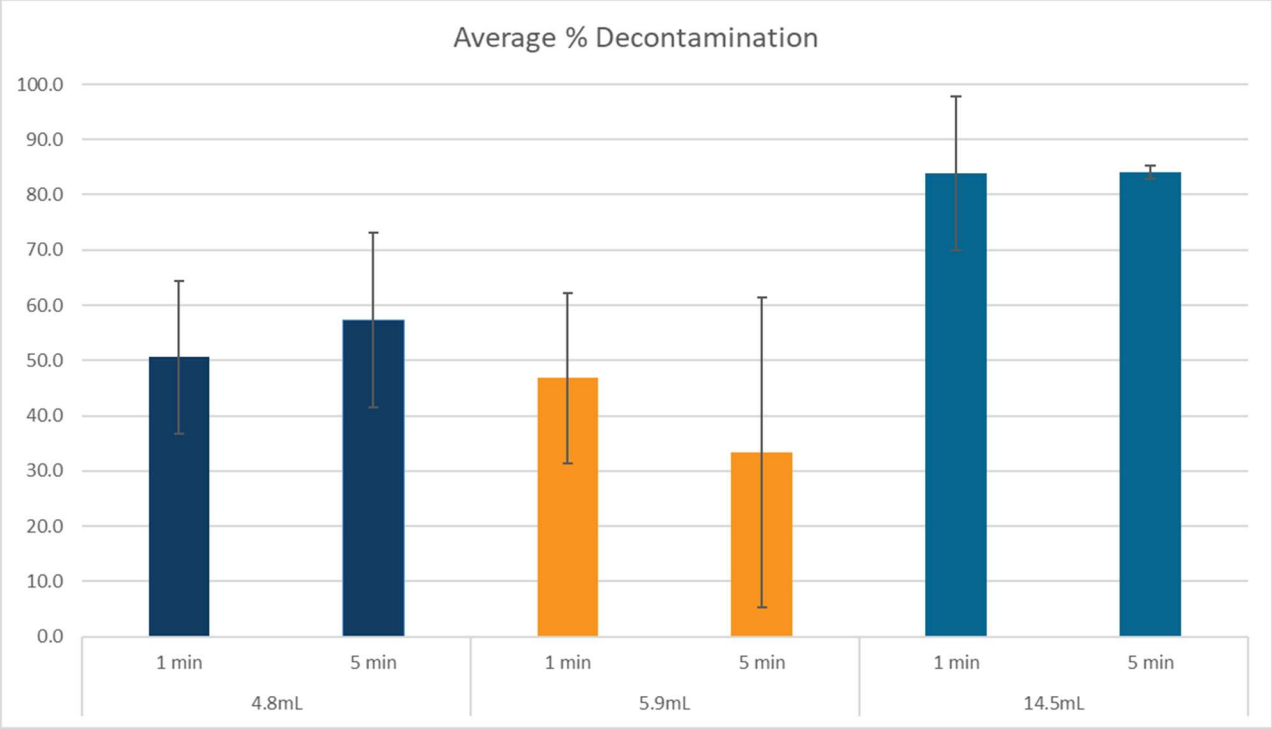
Executive Summary

The objective of this effort is to evaluate the efficacy of SoRite DECON to decontaminate fentanyl hydrochloride. Each condition was tested with three replicate trials to provide relevant results. Pure fentanyl hydrochloride was added to a reaction vessel and SoRite decontamination solution was sprayed into the reaction vessel, and the mixture was then allowed to react for an allotted time prior to decontamination evaluation. For the purposes of the included study, decontamination efficacy is defined as the chemical destruction via molecular disassembly of the target threat. The terms "mitigation" and "efficacy" are inclusive of these factors.

Overall Efficacy (Fentanyl Hydrochloride)

SoRite DECON solutions showed significant mitigation of fentanyl hydrochloride at 1mg target to 14.5mL (12 sprays) application ratio. The one-minute contact time averaged (n=3) 83.9±13.9% mitigation and the 5-minute contact time averaged (n=3) 84.0±1.23%.

The decon also showed some mitigation of fentanyl hydrochloride at lower application ratios. At 1mg target to 4.8mL (4 sprays) application ratio, the one-minute contact time averaged (n=3) 50.6±13.8% mitigation and the 5-minute contact time averaged (n=3) 57.3±15.8%. At 1mg target to 5.9mL (5 sprays) application ratio, the one-minute contact time averaged (n=3) 46.8±15.4% mitigation and the 5-minute contact time averaged (n=3) 33.3±28.1%.



Contents

Figures

Tables

Section 1.
Technical Approach

1.1 Objectives

The objective of this effort is to evaluate the efficacy of the SoRite Decontamination technology to decontaminate fentanyl. MRIGlobal staff utilized client provided, proprietary, decontamination products to decontaminate fentanyl hydrochloride over multiple time points (one and five minutes). Each condition was tested with three replicate trials to demonstrate reproducibility of results.

1.2 Overview

1.2.1 Method Validation & Range Finding

Analytical development was initially limited to standard preparation and calibration verifications. MRIGlobal used existing LC/MS/MS methods for fentanyl analysis.

Initial range finding experiments were performed to verify reaction quenching and determine appropriate dilution schemes. The following tables present the specific test analytes used and the overall test matrix inclusive of all conditions and test analytes.

Table 1. Test Analytes

Category	Chemical	CASRN	Purity
Opioid	Fentanyl Hydrochloride	1443-54-5	99.9%

Table 2. Planned Test Matrix

Sample/Extraction Type	Value
Application Ratio (1mg:5mL, 6mL, 14.5mL)	3
Target Analytes (Fentanyl HCl)	1
Temperature and humidity level (Ambient)	1
Timepoints (1, 5 minutes)	2
Formulations	1
Replicates	3
Total Test Samples	**18**
Positive Control (each time point, analyte, ratio)	6
Negative Controls (Blanks)	9
Total Control Samples	**15**
Total Trials (Test Samples + Controls)	**33**

1.3 Standard Preparation

Stock, intermediates, and calibration standards were prepared and analyzed for instrument analyses. The stock was prepared at ~ 1 mg/mL in methanol by gravimetrically adding pure target to a volumetric flask and adding solvent to volume. Intermediate standards were prepared at ~ 20,000 ng/mL and ~ 200ng/mL by adding an aliquot of stock standard or intermediate standard to a volumetric flask and diluting with solvent. Calibration cocktail standards were prepared at concentrations ranging from 0.0985 ng/mL to 9.85 ng/mL for fentanyl by adding an aliquot of intermediate standard to a volumetric flask and diluting with solvent.

1.4 Sample Preparation

1.4.1 Blank Controls

1.4.1.1 Method Blank

SoRite decon was added to an empty reaction vessel and allowed incubate for the allotted time. At the end time, 100µL was pipetted from the reaction vial into a vial containing 10mL methanol, capped, and inverted 10 times. Sample extracts were filtered with a 0.2µm PTFE filter and diluted into sample analysis vials.

1.4.1.2 Reagent Blank

A volume of methanol equivalent to that used for extractions was filtered using 0.2µm PTFE filters and aliquoted into sample analysis vials.

1.4.2 Positive Controls

1.4.2.1 Method Spike

Fentanyl was weighed into a reaction vessel, after which clean methanol was added to the reaction vessel utilizing a similar volume as SoRite decon spray. The mixture was allowed to react for the appropriate amount of time. At the end time, 100µL was pipetted from the reaction vial into a vial containing 10mL methanol, capped, and inverted 10 times. Sample extracts were filtered with a 0.2µm PTFE filter and diluted into sample analysis vials.

1.4.3 Target Samples

Fentanyl was weighed into a reaction vessel, after which SoRite decon was sprayed into the reaction vessel. The mixture was allowed to react for the appropriate amount of time. At the end time, 100µL was pipetted from the reaction vial into a vial containing 10mL methanol, capped, and inverted 10 times. Sample extracts were filtered with a 0.2µm PTFE filter and diluted into sample analysis vials. Figure 2 shows the sample preparation set up.

Application ratio was applied using number of sprays from a spray bottle. An average volume was obtained with a 5-6 replicate measurement to determine solution volume for calculations and reporting. 4 spray test is referred to as 4.8mL, 5 spray test is referred to as 5.9mL, and 12 sprays as 14.5mL.

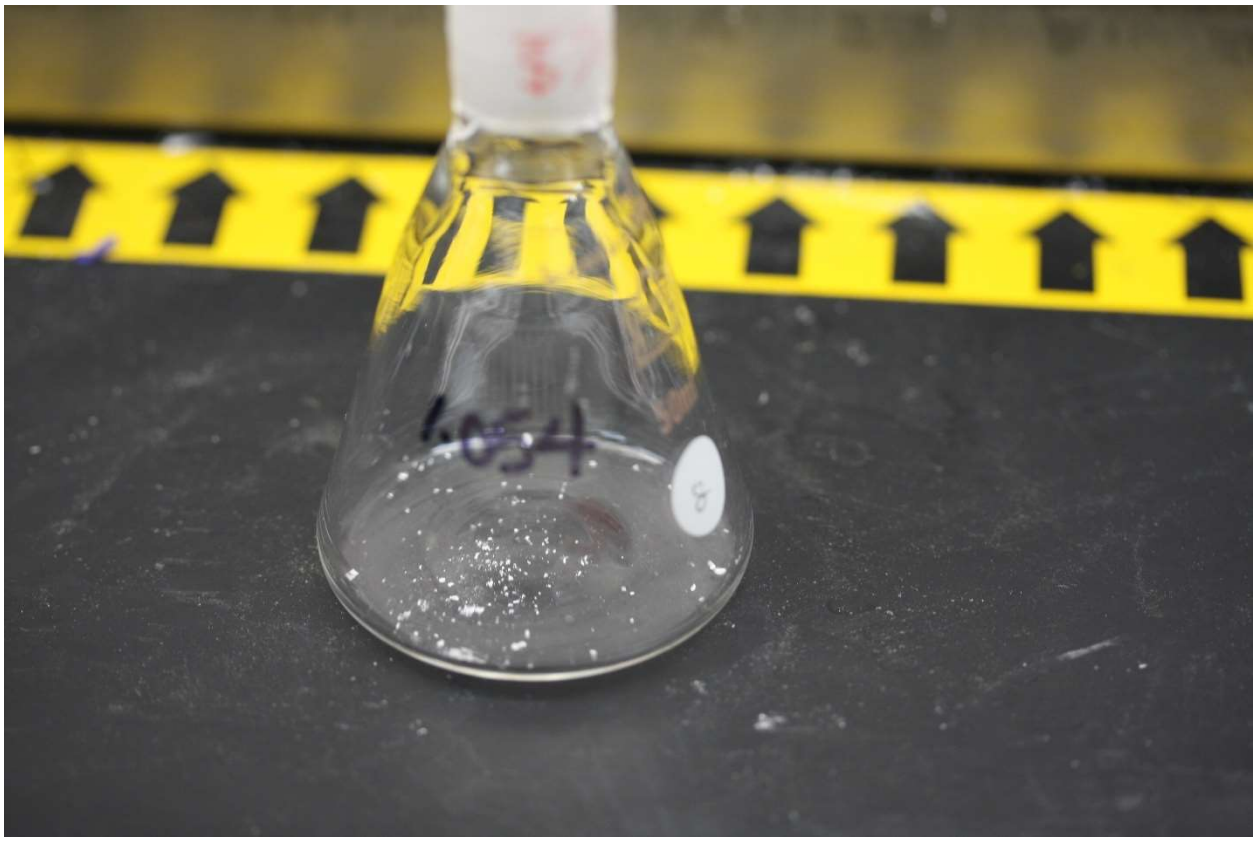


Figure 1. Reaction Vial Setup

1.5 Sample Analysis

Quantitative analysis of all samples was performed using Waters Acquity Premier Ultra Performance Liquid Chromatography (UPLC) coupled to a Waters TQ-Absolute Tandem Spectrometer (MS/MS). LC/MS/MS was chosen over conventional LC/MS and GC/MS for three primary reasons; 1) system sensitivity – ability to detect sub-nanogram levels of target compound, 2) system selectivity – the use of MS/MS decreases the possibility of mis-identification, and 3) the use of LC eliminates the need for added organic extraction and pH buffering steps that may artificially enhance/degrade the performance of the decontamination solutions of test.

The applied LC/MS/MS method used both known compound retention time (RT) and multiple reaction monitoring (MRM) transitions to provide an intrinsically orthogonal sample identification. It also allows us to easily recognize any potential RT shifting that may occur when sample matrix (decon) is introduced to the analytical column, as is commonly seen.

A salt correction factor was applied in order to obtain the most accurate quantitation possible. The factor considers molar ratio of the salt form to the freebase, which is generated the moment any salt is dissolved in aqueous or organic media. This factor is 0.902 for fentanyl hydrochloride. The calculation is given below.

Molar mass of Fentanyl Hydrochloride: 372.93 g/mol
Molar mass of freebase Fentanyl: 336.47 g/mol

*% Freebase: (336.47/372.93) * 100 = 90.2%*

Purity correction calculations were used for destruction efficacy results. Stock solutions were purity corrected at time of preparation for impurities and salt factors.

Calibration solutions were prepared as described in Section 1.3. Certified Reference Material of Fentanyl Hydrochloride was obtained from Cayman Chemical, Certificate of Analysis for which is attached.

A multi-point calibration curve was analyzed to provide accurate quantitation. Instrument blanks were analyzed periodically to reduce the chances of carryover. Matrix blanks (method blanks) and matrix spikes (method spikes) were prepared with each sample preparation batch to ensure process cleanliness and to monitor extraction efficiency for each target. Sensitivity verification standards (SVS) were analyzed at regular intervals (every 10 samples) to ensure sensitivity is maintained throughout the analytical sequence. Continuing calibration verification (CCV) standards were analyzed at regular intervals (every 10 samples) to ensure quantitative accuracy is maintained throughout the analytical sequence.

1.6 Quality Control

All work for this effort met the requirements specified in the MRIGlobal Corporate Quality Manual and its related policy and procedures and the requirements of ISO 9001:2015. The operations of MRIGlobal are certified to ISO 9001:2015 standards, with the most recent re-certification in May 2021.

All analytical sequences included positive and negative control standards used to verify the presence/absence of target each day. These control samples include the following and are also displayed in

Table 3:

- **System/Solvent/Instrument Blank**: A system blank is defined as an analysis in the absence of matrix. If the system fails the system blank, the system is examined for maintenance problems, corrective actions are taken as needed, and the test repeated. If the system continues to perform out of limit, the client is contacted for guidance.
- **Matrix Blank (Negative Control)**: A matrix blank is defined as an analysis of complete sample matrix in the absence of target. If the system fails the matrix blank, the system is examined for maintenance problems, corrective actions are taken as needed, and the test repeated. If the system continues to perform out of limit, the client is contacted for guidance.
- **Matrix Spike (Positive Control)**: A matrix spike is defined as an analysis with a spiked sample. If the system fails the matrix spike, the system is examined for maintenance problems, corrective actions are taken as needed, and the test repeated. If the system continues to perform out of limit, the client is contacted for guidance.
- **Multi-point calibration curve**: A calibration curve consisting of multiple known injections of target standards.

- **Continuing Calibration Verification ("CCV")**: A mid-level (usually C2-C4) calibration standard periodically analyzed to verify system performance and recovery.
- **Sensitivity Verification Standard ("SVS")**: The lowest calibration standard periodically analyzed to verify system sensitivity.

Verification data are processed and analyzed per MRIGlobal SOPs. For an analysis to meet accuracy requirements, the criteria outlined in Table 3 must be met.

Table 3. Reporting Requirements for Analytical Method

Quality Control Measurement	Frequency	Data Quality Objective
Average relative error from standard curve	Each analyte daily	The average of the absolute values of the relative deviation across all calibration levels included in the curve must be less than 10%
Regression Fit	Each analyte Daily	The R^2 value associated with a calibration curve must be 0.98 at minimum. Values over 0.99 are preferred.
Single point relative error in curve	Each analyte Daily	No single calibration point can have a relative deviation greater than ± 30%.
Number of Calibration points	Each Curve	A minimum of four points must be used for linear regressions and five points for quadratic regressions. Removal of any point is allowable, when necessary, to meet the acceptance criteria or to improve linearity, provided the sample response remains bracketed by standards.
Quantitation Range	Each Sequence	It is acceptable to provide quantified results for samples within ± 25% of the calibrated range. Samples outside the calibrated range but within the 25% must be caveated.

Table 7 summarizes the data quality objectives for sample analysis; planned corrective actions are also listed.

Table 4. Data Quality Objectives

QC Analysis	Frequency	Data Quality Objective	Threshold	Corrective Action
Negative Control Sample	Each test day	Non-detection	< 10% of lowest standard	Consult with Client
Positive Control Sample	Each test day	100% recovery	Detected with > 50% recovery	Repeat analysis; consult with Client
Laboratory Control Blank	Each test day	Non-detection	< 10% of lowest standard	Consult with Client

Section 2.
Results

2.1 Environmental Conditions

Testing described in this proposal was performed at ambient lab temperatures, typically 23° ± 5°C and 40% ± 20% relative humidity (RH). Observed laboratory temperature and RH was documented, but not controlled. Sample preparation and extraction was completed in a certified, rated chemical fume hood.

2.2 Analytical Methods

2.2.1 LC/MS/MS Analytical Methods

The LC/MS/MS method is summarized below (Table 8). Final analysis method parameters can be found in Table 5 through

Table 7.

Table 5. LC Method Parameters

LC/MS/MS Method Parameter	Fentanyl/Carfentanil Method
Mobile Phase A	Water w/ 0.1% Formic Acid
Mobile Phase B	Acetonitrile w/ 0.1% Formic Acid
Sample Solvent	Methanol
Injection Volume	10µL
Flow Rate	0.3 mL/min
Ion Source	ES+
Column	Phenomenex Prodigy 3 µm ODS-3 100Å S/N: PRD-691380

Table 6. MS Method Parameters

Mass Spec Source	Electrospray, positive ion mode
Mass Spec Software	MassLynx 4.2
Desolvation, nebulizer gas	Nitrogen
Collision gas	Argon
Mass Resolution	Unit in Q1, Unit in Q3

Table 7. MS Analysis Parameters

Compound Name	Precursor (m/z)	Quantifier Ion (m/z)	Qualifier Ion (m/z)	Qualifier Ion (m/z)	Dwell (sec)
Fentanyl	337	188	105	--	0.05

The LOD and calibration levels for each target are shown in Table 8. The LOD is based on the lowest standard displaying 5:1 signal to noise ratio for both product ions. For fentanyl, the LOD is ~ 1.6 pg/mL based on the respective calibration curve. Graphical representations for the calibration curve is shown in the Appendix B.

Table 8. Calibation Levels

Target Analyte	LOD	C1	C2	C3	C4	C5	C6
		ng/mL					
Fentanyl	1.6 pg/mL	0.0985	0.197	0.492	0.985	2.46	9.85

Calibration parameters for each analyte can be found in Table 9.

Table 9. Calibration Curve Quality Assessment

Target Analyte	Calibration Date	No. of Points	Fit	R^2	Average Relative Error in Curve
Fentanyl	20250421	5	Linear ($1/x^2$ weight)	0.999746	1.08
Fentanyl	20250423	4	Linear ($1/x^2$ weight)	0.996726	3.25
Fentanyl	20250625	6	Linear ($1/x^2$ weight)	0.999876	0.73

Table 10 displays the CCV results across all sample analyses. All SVS and CCV injections met data quality objectives.

Table 10. CCV Results-Fentanyl

Analyte	Date	% Recovery
Fentanyl	20250421	95.8
		96.8
	20250423	96.0
		94.4
	20250625	87.2
		108

2.3 Quench Verification

In order to determine if the decontamination formulation had stopped reacting with the target analyte at the intended time point, a quench sample was analyzed. A single sample was selected, one for each application ratio, and analyzed immediately after sample preparation, and again at the end of the analysis sequence to verify the reaction was quenched via the solvent dilution.

The results of the quench testing with all application ratios demonstrate acceptable (< 10%) variance over the time associated with analysis, indicating the samples did not continue to degrade or otherwise react once prepared for analysis.

Table 11. Quench Sample Results

Collection Date	Target Analyte	Decon Volume	Time (min)	Percent Recovery	Time Between 1st and Last Injection	Variance
20250421	Fentanyl	4.8mL	1	50.7	3 hours	0.146%
				50.0		
20250423	Fentanyl	5.9mL	1	38.1	3.2 hours	2.05%
				35.2		
20250625	Fentanyl	14.5mL	1	30.9	3	1.55%
				33.4		

2.4 Sample Analysis

A total of 18 test samples were analyzed, with an associated 15 controls and 30 calibration standards, totaling over 63 analytical data points. Results are reported as ng/mL for each sample and converted to % decontamination based on the theoretical concentration of target in the sample prior to decontamination. Samples detected above the calibration curve were diluted appropriately then analyzed at a level within the range of the instrument calibration. The chromatograms shown include both the primary (top) and secondary (bottom) ion(s) transition monitored for fentanyl.

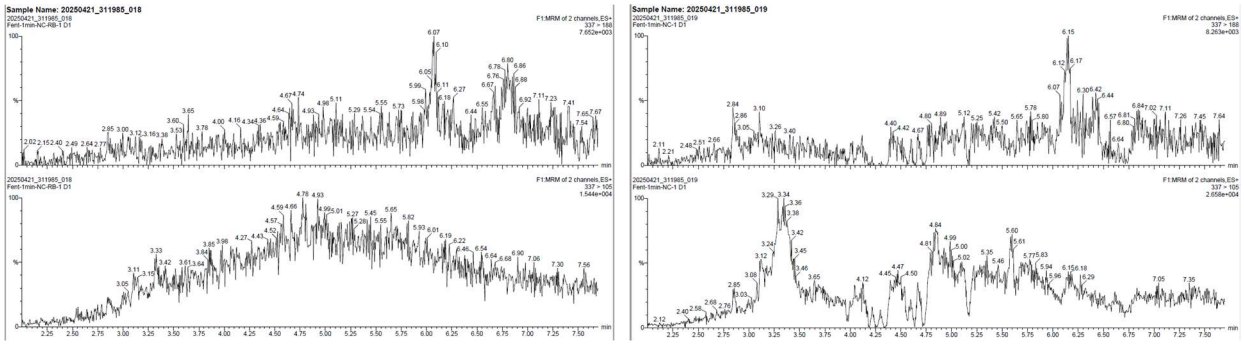


Figure 2. Solvent Blank (left) vs. Method Blank (right)

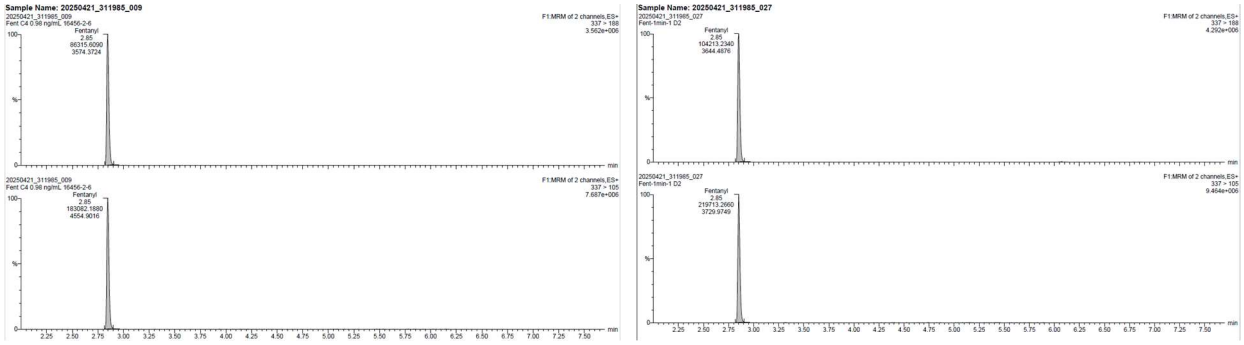


Figure 3. Fentanyl C4 Standard (left) vs. Fentanyl 4.8mL 1 minute Sample (right)

Table 12. Complete Fentanyl Results

Decon Volume	Time (min)	Sample ID	Neat Conc. (ng/mL)	% Decontamination	Average % Decontamination	Stdev
4.8mL	1	Fent-1min-1	1443.07	36.9	50.6	13.8
		Fent-1min-2	784.72	64.5		
		Fent-1min-3	1218.05	50.3		
	5	Fent-5min-1	1326.86	42.0	57.3	15.8
		Fent-5min-2	583.27	73.6		
		Fent-5min-3	1073.46	56.2		
5.9mL	1	Fent-1min-1	529.61	64.6	46.8	15.4
		Fent-1min-2	907.24	37.8		
		Fent-1min-3	1050.12	38.0		
	5	Fent-5min-1	601.58	59.8	33.3	28.1

		Fent-5min-2	1402.37	3.90		
		Fent-5min-3	1082.46	36.1		
14.5mL	1	Fent-1min-1	238.94	68.1	83.9	13.9
		Fent-1min-2 D2	93.18	89.2		
		Fent-1min-3 D2	58.37	94.3		
	5	Fent-5min-1 D2	108.92	85.4	84.0	1.23
		Fent-5min-2 D2	146.08	83.1		
		Fent-5min-3 D2	169.22	83.6		

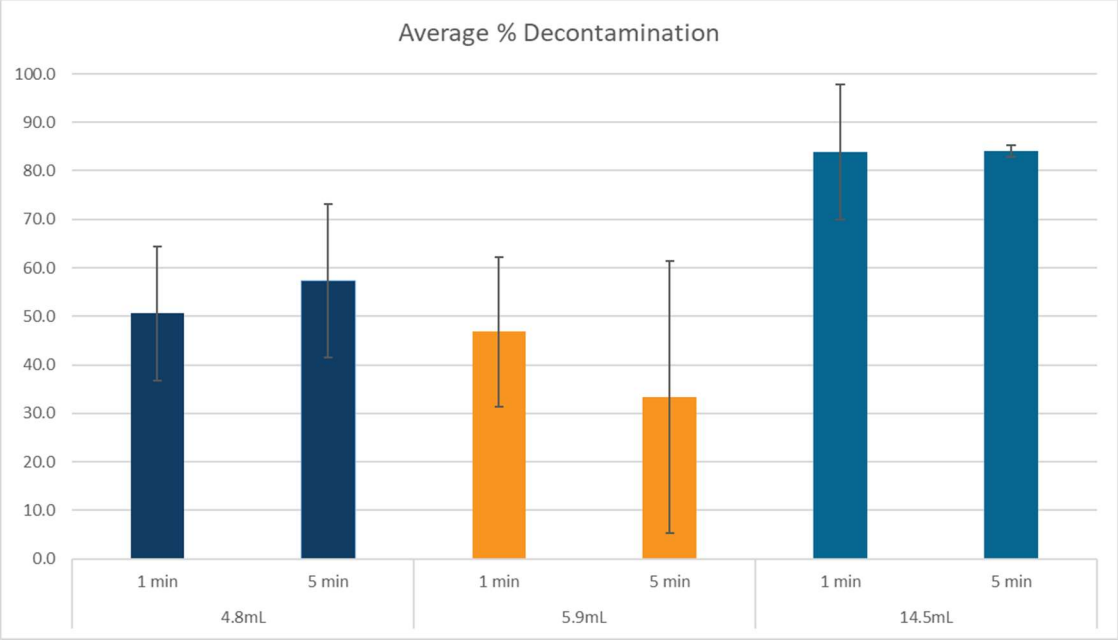


Figure 4. Fentanyl Results at 1 and 5 Minutes

2.4.1 Quality Control

Table 13 lists the positive control results associated with the sample analyses. These method spikes (MS) while targeting > 50% recovery, serve to establish a baseline expected recovery for non-mitigated samples rather than demonstrate the entire process creates acceptable extraction efficiencies. All of the positive controls were above the DQO target.

Table 13. Positive Control Results—Fentanyl

Analyte	Control Type	Time (min)	Sample ID	% Recovery
Fentanyl	Method Spike	1	Fent-1min-PC-1 D2	127
		5	Fent-5min-PC-1 D2	115
	Method Spike	1	Fent-1min-PC-1 D2	116
		5	Fent-5min-PC-1 D2	99.4
	Method Spike	1	Fent-1min-PC-1 D2	85.8
		5	Fent-5min-PC-1 D2	158

Table 14 lists the negative control results associated with the sample analysis. All samples not specified with recoveries in Table 18 were either free of analyte detections, or detections were below the lowest standard. Hits reported in Table 14 were above 10% area of the lowest standard. Minor contamination is noted in the negative controls associated with the 5.9mL test, positive detection in negative controls was less than 50% of the lowest calibration level. This could impact only the 5.9mL test samples by up to 3%, biasing the decontamination efficacy low. Test results for the 5.9mL test are not calculated with this potential impact.

Table 14. Negative Control Results

Analyte	Volume	Control Type	Time (min)	Sample ID	%C1
Fentanyl	4.8mL	Method Blank	1	Fent-1min-NC-1	ND
			5	Fent-5min-NC-1	ND
		Solvent Blank		Fent-1min-NC-RB-1	ND
	5.9mL	Method Blank	1	Fent-1min-NC-1	30.5
			5	Fent-5min-NC-1	46.1
		Solvent Blank		Fent-1min-NC-RB-2	30.2
	14.5mL	Method Blank	1	Fent-1min-NC-1	ND
			5	Fent-5min-NC-1	ND
		Solvent Blank		Fent-1min-NC-RB-1	ND

ND = nondetect, less than 10% lowest calibration level.

Section 3.
Conclusions

3.1 Fentanyl Efficacy (Fentanyl Hydrocloride)

SoRite DECON solutions showed significant mitigation of fentanyl hydrochloride at 1mg target to 14.5mL (12 sprays) application ratio. The one minute contact time averaged (n=3) 83.9±13.9% mitigation and the 5 minute contact time averaged (n=3) 84.0±1.23%.

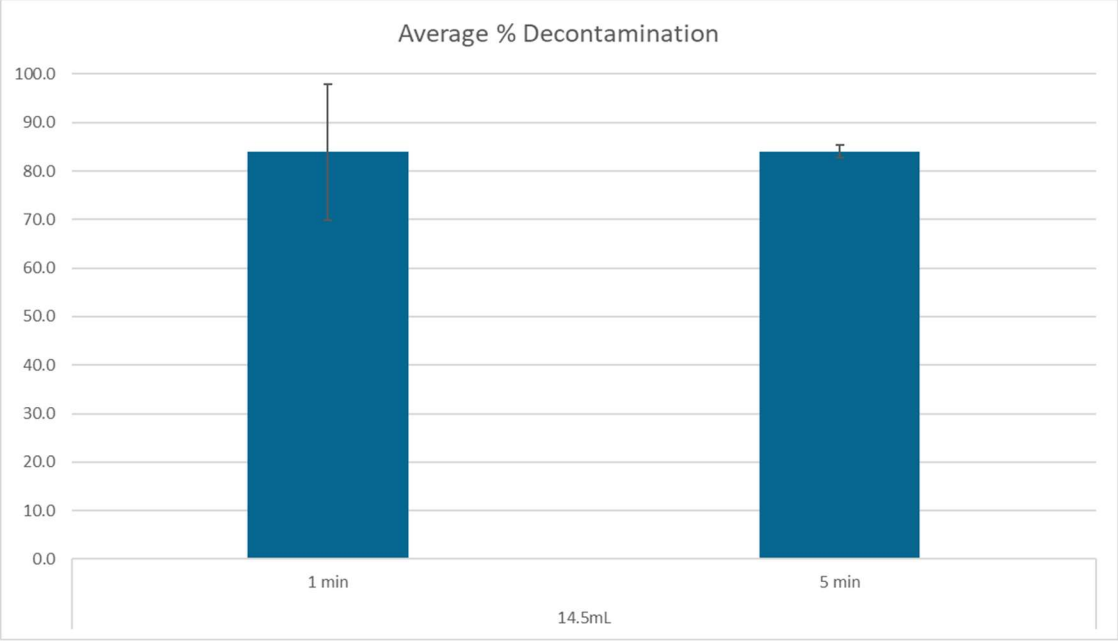


Figure 5. Fentanyl Results at 1 and 5 Minutes with 14.5mL

SoRite DECON solutions showed some mitigation of fentanyl hydrochloride at 1mg target to 5.9mL (5 sprays) application ratio. The one minute contact time averaged (n=3) 46.8±15.4% mitigation and the 5 minute contact time averaged (n=3) 33.3±28.1%.

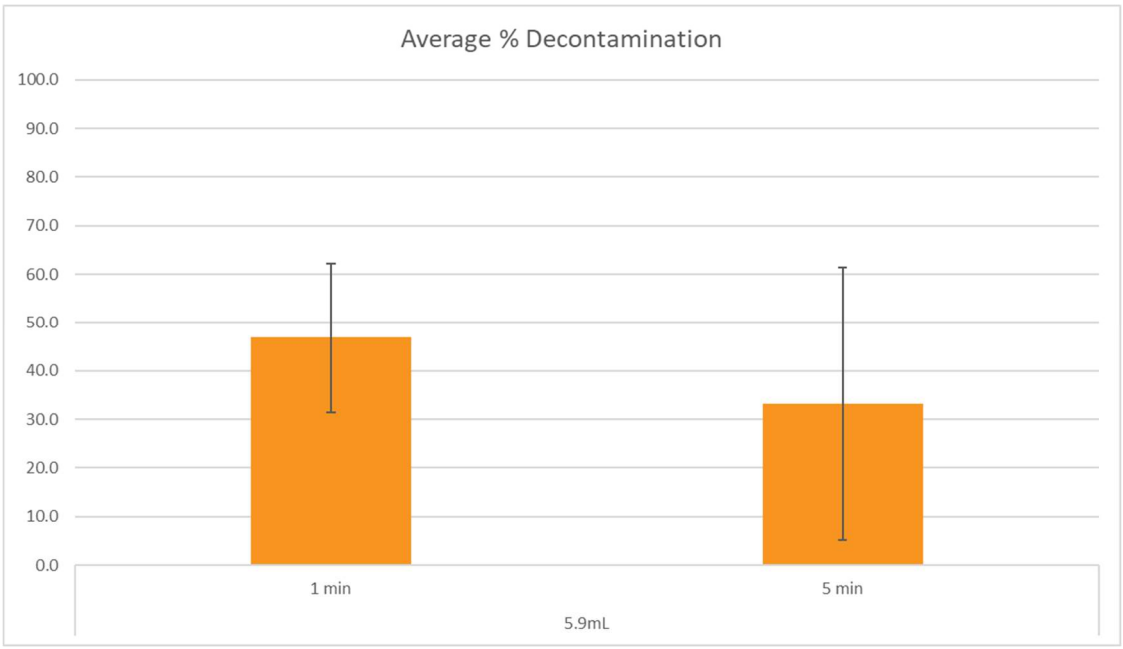


Figure 6. Fentanyl Results at 1 and 5 Minutes with 5.9mL

SoRite DECON solutions showed some mitigation of fentanyl hydrochloride at 1mg target to 4.8mL (4 sprays) application ratio. The one minute contact time averaged (n=3) 50.6±13.8% mitigation and the 5 minute contact time averaged (n=3) 57.3±15.8%.

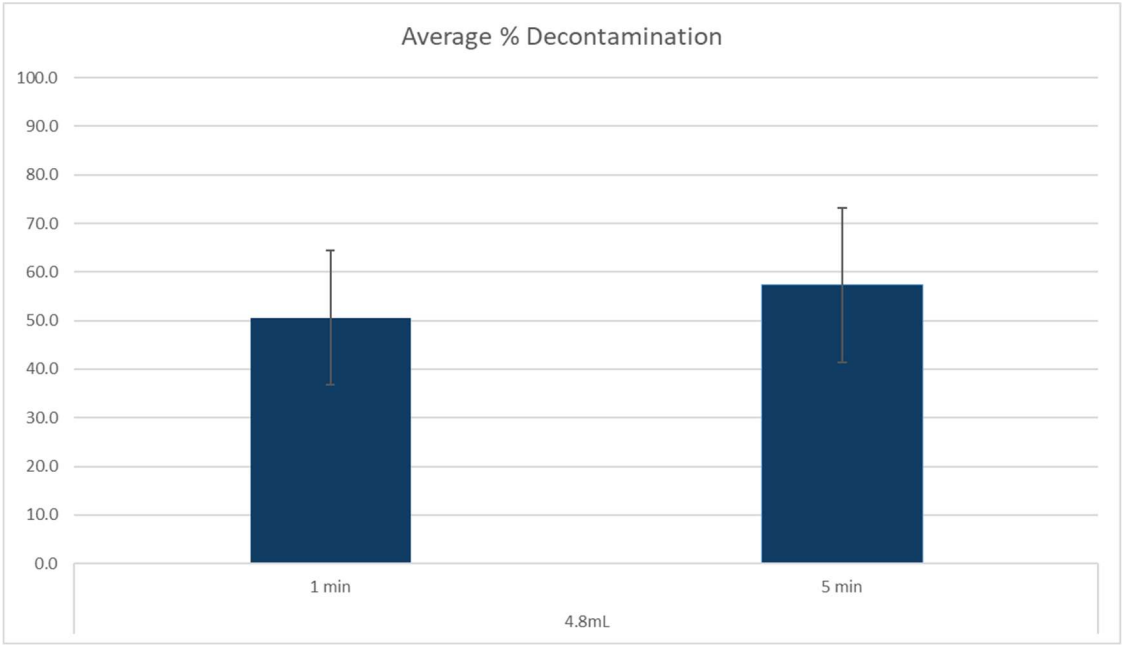


Figure 7. Fentanyl Results at 1 and 5 Minutes with 4.8mL

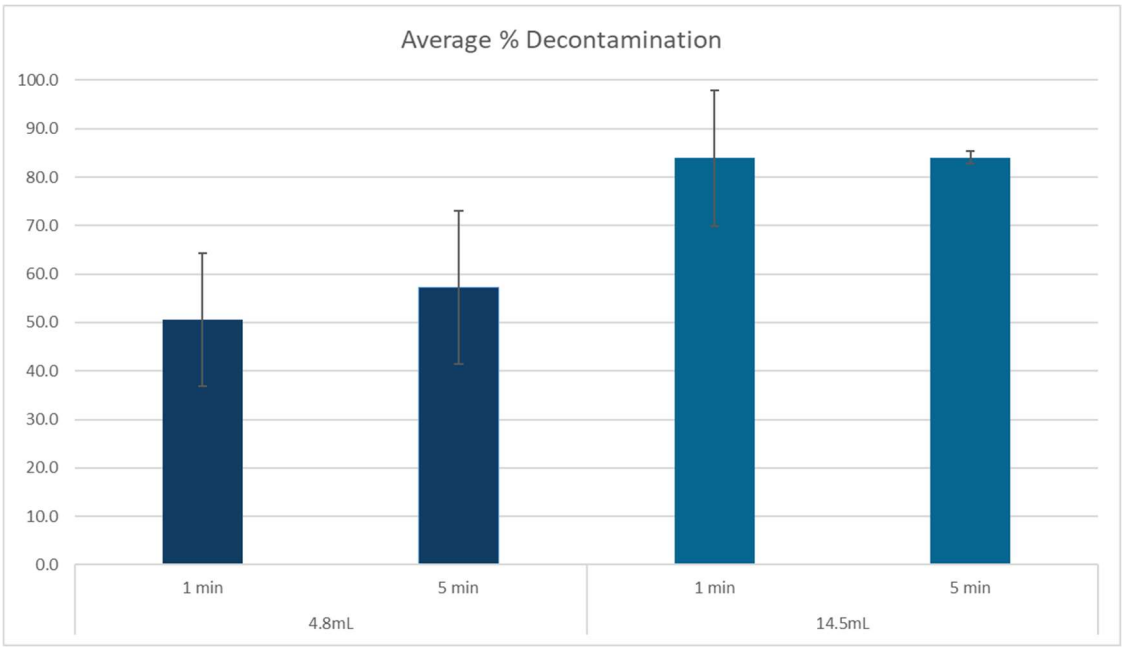


Figure 8. Fentanyl Results at 1 and 5 Minutes with 4.8mL and 14.5mL

3.2 Overall Recommendations

SoRite DECON showed promise in the decontamination of fentanyl hydrochloride at the conditions tested herein. These results should not be taken as final operational guidance but rather a step toward determining the most effective steps for SoRite to be used properly in the field.

We recommend:

1. Testing additional target to product ratios
2. Additional reaction time testing
3. Target solubility testing

Appendix A.
Challenge Chemical Certifications

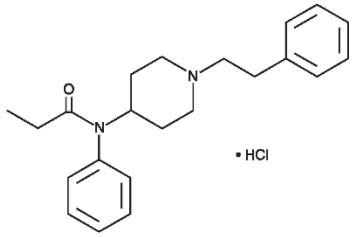
MRIGlobal

CONFIRMATION of ANALYSIS

Cayman CHEMICAL
ACCREDITED
ISO 17034 #AR-1774

Fentanyl (hydrochloride)

Reference Material



Item No.:	14719
Batch No.:	0616220
CAS Registry No.:	1443-54-5
Molecular Formula:	$C_{22}H_{28}N_2O$ • HCl
Formula Weight:	372.90 amu
UV λ_{max}:	205 nm
Expiry Date:	09AUG2036 (valid from date of certification)
Supplied as:	A neat solid
Storage:	Unopened at -20°C ± 10°C
Safety:	Refer to Safety Data Sheet
Intended Use:	For analytical testing purposes only, not intended for human or animal use.
Instructions for Use:	Store reference materials away from light, away from sources of heat, and in dry conditions. Once opened this material should be minimally exposed to ambient conditions and returned to recommended storage conditions immediately after use. Ongoing stability testing supports a negligible decrease in purity over a series of thaw-refreeze cycles. It is recommended that laboratories perform periodic testing to verify the material remains fit for the intended use.

Approval: Roxanne Franckowski

Title: Senior Manager of ISO Quality ***Confirmation Date:*** 09AUG2021

Cayman Chemical certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date when stored unopened as recommended.

ilac-MRA ANAB ANSI National Accreditation Board ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

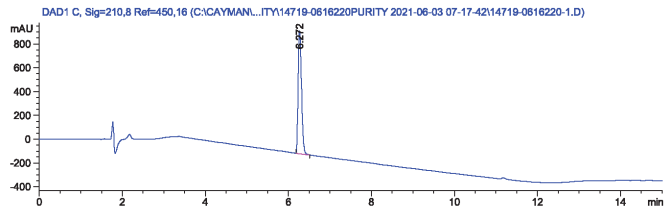
CONFIRMATION of ANALYSIS

Qualifier	Method	Result
Appearance	Visual inspection	White solid
Chromatographic Purity, HPLC	Cayman Method TST SD132	>99.90%
Identity, LC-MS	Cayman Method TST SD13, +ESI	337.2 amu
Identity, GC-MS	Cayman Method TST SD12	Conforms
Identity, FTIR	Cayman Method TST SD03	Conforms
% LOD	Cayman Method TST SD24	0.43%
% ROI	Cayman Method TST SD06	<0.10%
Identity, NMR	^{1}H NMR	Conforms

Appearance, NMR and optical rotation (if applicable) are provided as supplemental information but are not within scope of ISO accreditation.

Supplemental Data (Neat Material)

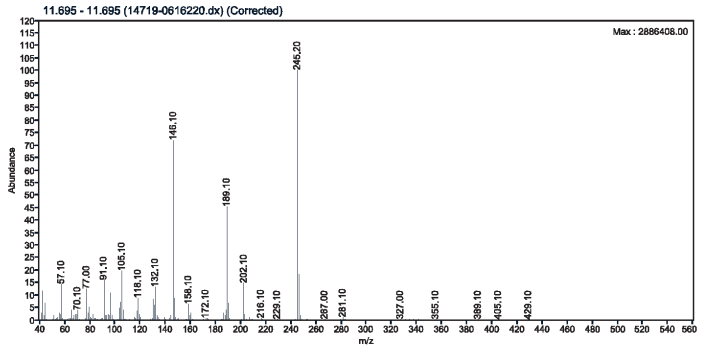
HPLC-UV



Conditions	
Instrument	Agilent 1100/1200 Series
Column	4.6 x 150 mm, 5 µm Luna Phenyl-Hexyl
Mobile Phase	A: 0.1% Trifluoroacetic Acid in Water B: Acetonitrile
Gradient	*Time (min)* *%B* 0-10 20-95% 10-13 95% 13.1-20 20%
Flow Rate	1 ml/min
Column Temp	30˚C
Wavelength	UV monitored at 210 nm

CONFIRMATION of ANALYSIS

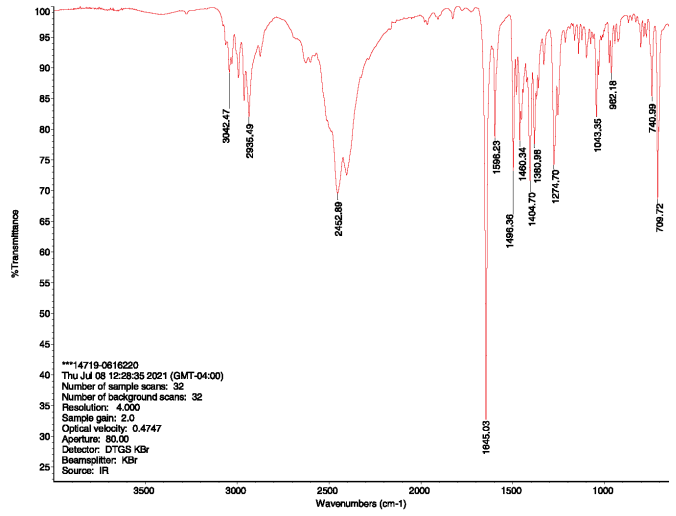
GC-MS



Conditions	
Instrument	Agilent GC MSD
Column	30 m x 0.32 mm, 0.5 µm Rtx-5MS
Carrier Gas	He
Flow Rate	2 ml/min
Inlet Temp	300˚C
Split Ratio	15:1
Oven Program	50˚C hold for 1 min, ramp to 300˚C at 30˚C per min, hold at 300˚C to 15 min
Transfer Line Temp	300˚C
Voltage	70eV EI MS
Scan Range	40-650 m/z
Tune File	atune (custom)

Apex spectrum – background (1 min window in front of peak)

FTIR



Conditions	
Instrument	Thermo Nicolet iS10 FTIR / Diamond SmartATR (single bounce)
Scans	32 scans / 32 background scans
Range	650-4,000 cm^{-1}
Resolution	4.000

ATR and background corrected

CONFIRMATION of ANALYSIS

ESI-MS

Conditions

Instrument	Agilent HPLC MSD
Mobile Phase	50:50:0.1 Methanol/Water/Acetic Acid
Flow Rate	0.5 ml/min
Ionization Mode	+ESI
Mass Range	100-1,000 m/z
Nebulizer	60 psi
Desolvation Gas	13 L/min
Desolvation Temp	350˚C
Electrospray Voltage	4kV

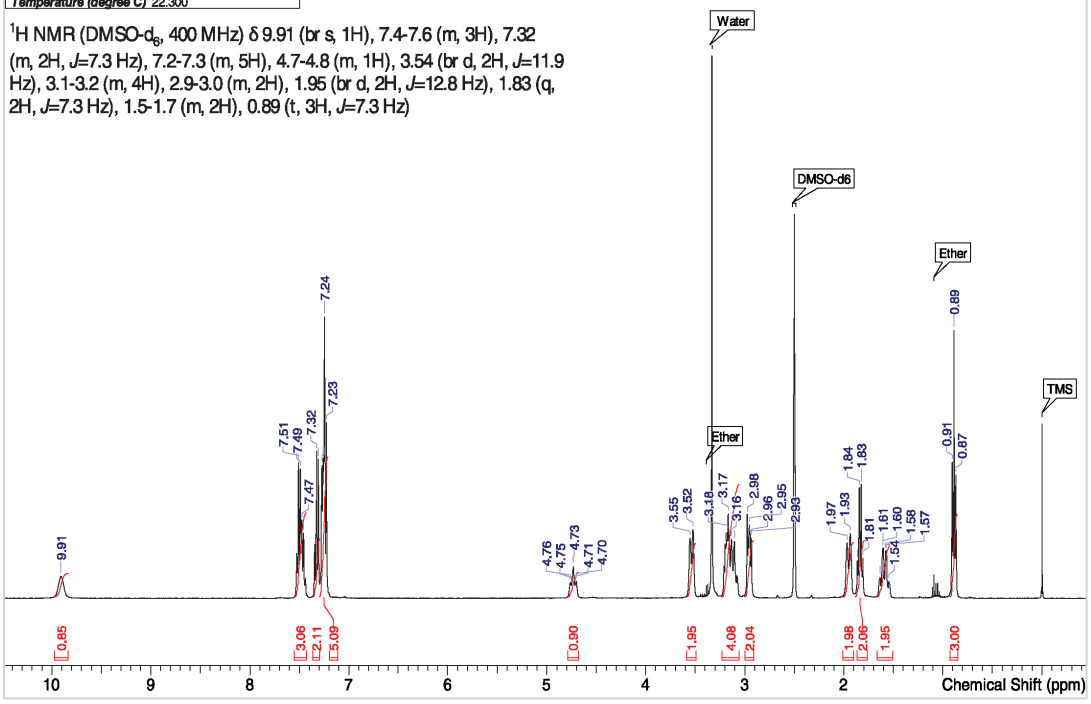
MS collected across peak width at half height

CONFIRMATION of ANALYSIS

NMR *(not within scope of ISO accreditation)*

File Name	\\sulfur\private\nmrdata\JEOL_2021\14719-0616220\14719-0616220_PROTON_17-May-2021-1-1.jdf				
Date	17 May 2021 13:21:23	***Nucleus***	1H	***Frequency (MHz)***	399.7822
Solvent	DMSO-d6	***Number of Transients***	16	***Origin***	JEOL ECZ400S Ca v601
Temperature (degree C)	22.300				

^{1}H NMR (DMSO-d_6, 400 MHz) δ 9.91 (br s, 1H), 7.4-7.6 (m, 3H), 7.32 (m, 2H, *J*=7.3 Hz), 7.2-7.3 (m, 5H), 4.7-4.8 (m, 1H), 3.54 (br d, 2H, *J*=11.9 Hz), 3.1-3.2 (m, 4H), 2.9-3.0 (m, 2H), 1.95 (br d, 2H, *J*=12.8 Hz), 1.83 (q, 2H, *J*=7.3 Hz), 1.5-1.7 (m, 2H), 0.89 (t, 3H, *J*=7.3 Hz)



Conditions	
Instrument	JEOL ECZ 400S
Scans	16 scans

Homogeneity

A minimum sample size of 2.0 µg was used to determine homogeneity of the bulk solid. The recommended minimum quantity for use is 2.0 µg. Quantities below this have not been evaluated.

Short-Term Stability

No decrease in the purity was observed at ambient or 60˚C after two weeks. This data supports shipping of this product at ambient temperature.

Long-Term Stability

Long-term stability data predicts 15 years stability at the -20˚C storage temperature. Long-term stability studies are ongoing and the Certificate of Analysis will be updated upon study completion.

CONFIRMATION of ANALYSIS

Quality Standard Documentation

The manufacturer of this Reference Material is accredited under ISO 17034:2016 accreditation issued by ANAB. Refer to ANAB certificate and scope of accreditation AR-1774.

The manufacturer of this Reference Material is accredited under ISO/IEC 17025:2017 accreditation issued by ANAB. Refer to the ANAB certificate and scope of accreditation AT-1773.

Revision History

Revision No.	Date	Reason for Revision
01	09AUG2021	Initial version
02	08JUL2022	Expiry date extension
03	21JUL2023	Updated format to version 5.0 and expiry date

Disclaimers

Material Safety Data
This material should be considered hazardous until information to the contrary becomes available. Do not ingest, swallow, or inhale. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. This information contains some but not all of the information required for the safe and proper use of this material. Before use, review the complete Safety Data Sheet, which has been sent *via* email to your institution.

Warranty and Limitation of Remedy
Cayman Chemical Company makes no warranty or guarantee of any kind, whether written or oral, expressed or implied, including without limitation, any warranty of fitness for a particular purpose, suitability and merchantability, which extends beyond the description of the chemicals hereof. Cayman warrants only to the original customer that the material will meet our specifications at the time of delivery.

Cayman will carry out its delivery obligations with due care and skill. Thus, in no event will Cayman have any obligation or liability, whether in tort (including negligence) or in contract, for any direct, indirect, incidental or consequential damages, even if Cayman is informed about their possible existence.

This limitation of liability does not apply in the case of intentional acts or negligence of Cayman, its directors or its employees.

Buyer's exclusive remedy and Cayman's sole liability hereunder shall be limited to a refund of the purchase price, or at Cayman's option, the replacement, at no cost to Buyer, of all material that does not meet our specification.

Said refund or replacement is conditioned on Buyer giving written notice to Cayman within thirty (30) days after arrival of the material at its destination. Failure of Buyer to give said notice within thirty (30) days shall constitute a waiver of Buyer of all claims hereunder with respect to said material.

For further details, please refer to our Warranty and Limitations of Remedy located on our website and in our catalog.

ISO CRT SD01 v 5.0

CAYMAN CHEMICAL
1180 EAST ELLSWORTH RD
ANN ARBOR, MI 48108 · USA
PHONE: [800] 364-9897
[734] 971-3335
FAX: [734] 971-3640
crmquality@caymanchem.com
www.caymanchem.com

Appendix B.
Calibration Curves

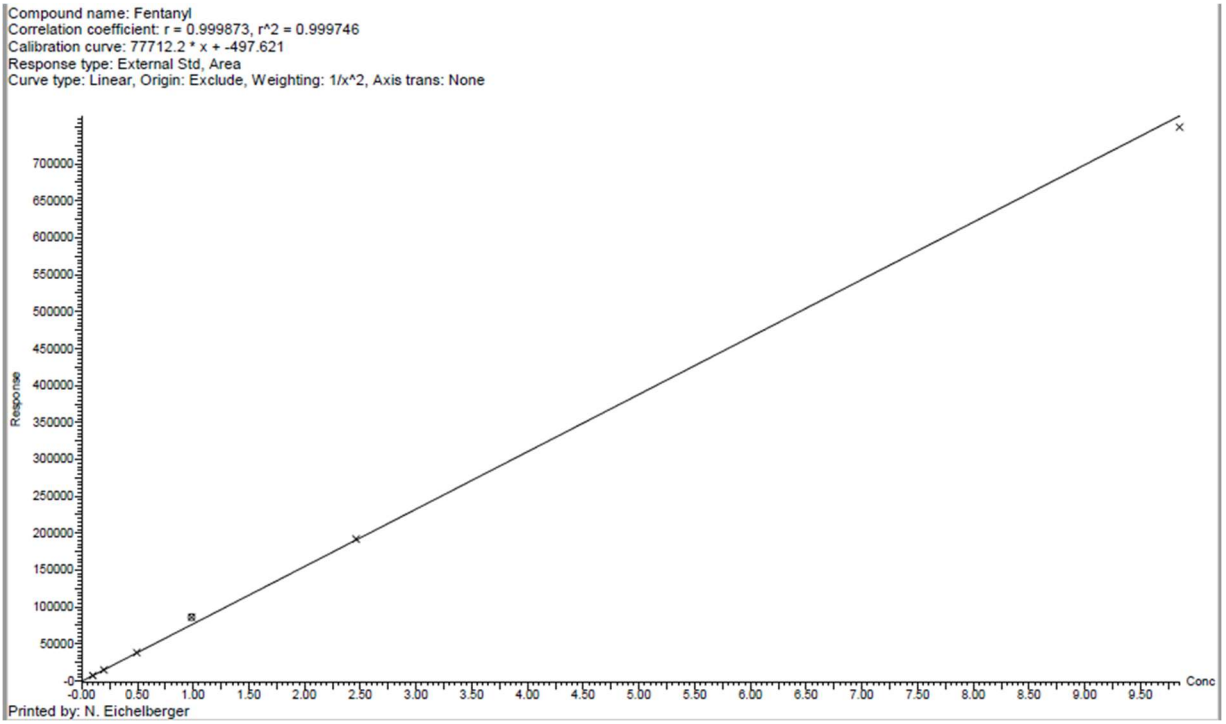


Figure 9. Fentanyl Calibration Curve 20250421

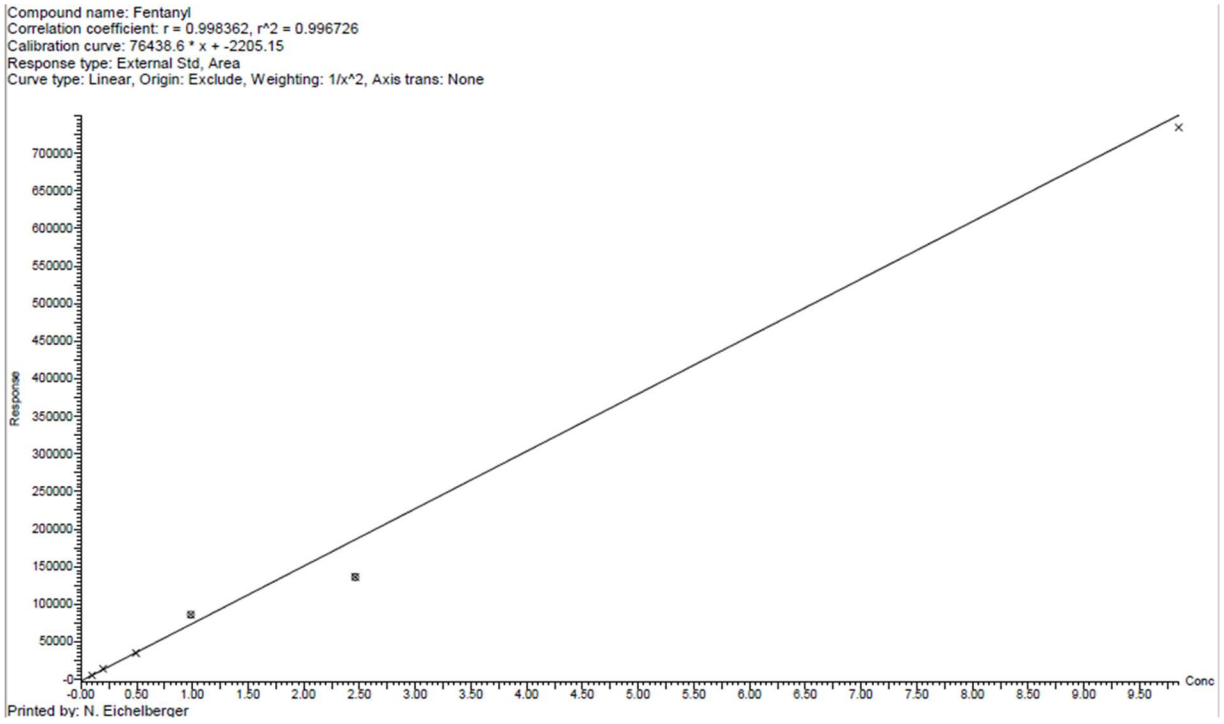


Figure 10. Fentanyl Calibration Curve 20250423

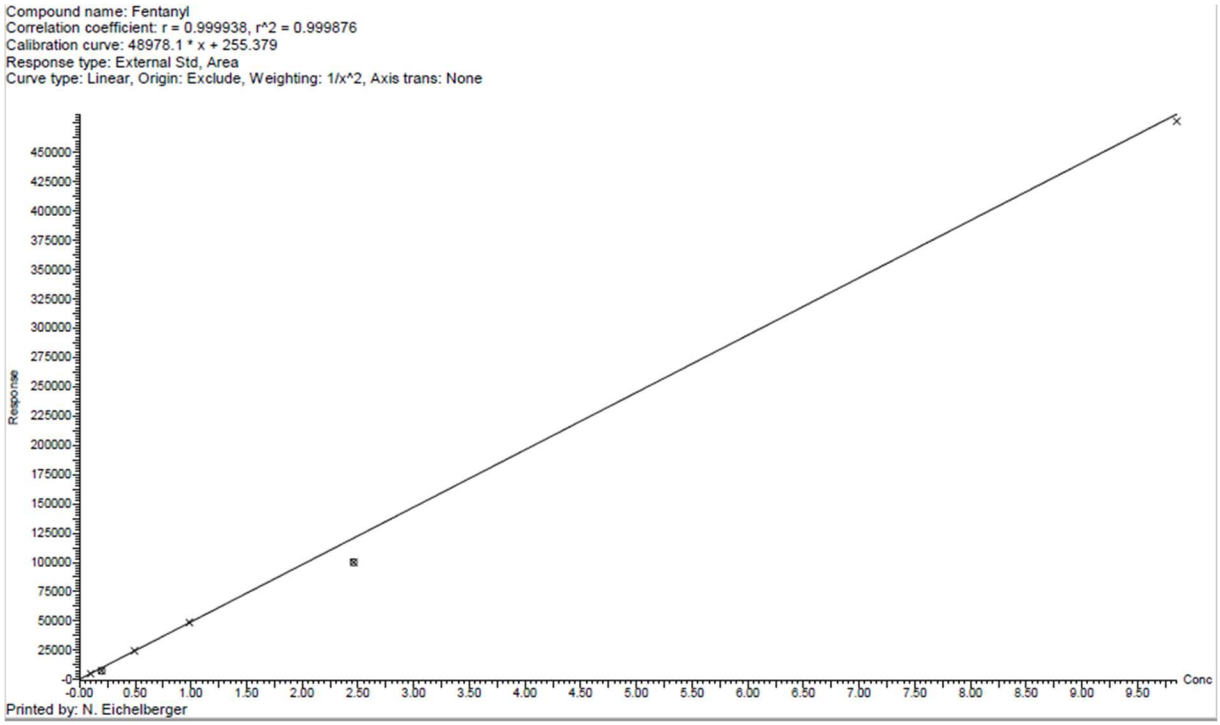


Figure 11. Fentanyl Calibration Curve 20250625