# Working Instructions: Form 7 – Controlled Substance Use Form

Note: This form may be used to keep a running log of the controlled substance dispensed/administered as long as the drug name and concentration/strength is the same for all containers. **Disposition is no longer tracked on this form.** Use Form 4 to track the destruction of controlled substances.

# Definitions:

1. Controlled Substance - The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five schedules.  This placement is based on the substance’s medical use, potential for abuse, and safety or dependence liability.  More information can be found in [Title 21 United States Code (USC) Controlled Substances Act](https://uscode.house.gov/view.xhtml;jsessionid=2C85B8DEBFB1BB15A7D31E29A34C3DAA?req=granuleid%3AUSC-prelim-title21&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uODAx%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim) [Alphabetical List of Controlled Substances](https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf)
2. Registrant – A person licensed and registered with DEA to distribute, manufacture, administer, dispense, import, or export a Controlled Substance.
3. Stock Bottle – The container/bottle that was received from the supplier. The stock bottle has the original labels from the manufacturer.

# Header: Selecting a drug class

1. Select whether the drug is Schedule I-II or III-V. If unsure what schedule the drug is, please check the outside of the stock container. All controlled substance containers are required to have a drug class listed on the label (see image below). Noting the correct drug class is important because federal regulation 21 CFR 1304.04 requires that Schedule I-II records are kept separate from Schedule III-V records ([eCFR :: 21 CFR 1304.04 -- Maintenance of records and inventories.](https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR64b4002fc681198/section-1304.04))

# DEA Schedule Drugs from the Top 200 Drug List - PTCB Study Guide

# Box 1: Registration Information

1. Complete the Registrant’s Name, DEA #, and address in this section. The information must appear exactly (in its entirety), as it does on the Registrant’s DEA License.
2. This box is for the DEA Registrant information only and should not contain user information. If the user information is different from that of the DEA Registrant name, document the PI name or protocol in the “reason for use” section of Box 3.

# Box 2: Stock Bottle Information

1. Enter the Name of the Substance and Concentration/Strength, exactly as it appears on the stock bottle container. This form may be used continuously if the drug name and concentration/strength is the same for all containers. If the drug name and/or concentration/strength changes, then you must complete a new form. Please note that drug name must be the same exact drug name. For instance, fentanyl is not the same as fentanyl citrate raw powder or fentanyl base raw powder.

# Box 3: Controlled Substance Use Log

1. Document the drug name and concentration at the top of Box 3. Be sure to document the drug name and concentration on all subsequent pages, as well.
2. Record the date the drug was administered/dispensed. DO NOT document if remaining/expired drug was sent to destruction on this form. Use Form 4 to document destruction.
3. Record the Unique Bottle ID. Each Stock Bottle must be assigned a Unique Bottle ID. For instance, Ketamine Bottle #1 – KE01, MDMA HCL Container #4 – MDMA04. Similarly, you could use the date received and the abbreviated drug name as the Unique Bottle ID. For instance, if one container of Fentanyl citrate raw powder was received on 01-03-24, it could be documented as #FCP010324. When a new stock bottle with a different unique bottle ID is used on this form, you must start a new line. This is important to track the unique bottle ID because you are required to know how much drug is in each container at any given time.
4. Record the manufacturer’s expiration date for each unique bottle ID. Read the fine print – some containers have a puncture limit.
5. Record the starting volume/quantity, amount used, and remaining balance for each unique bottle ID.
6. Print the name of the person dispensing/administering. This person must be listed on Form 2: Controlled Substance Access and Key Log.
7. Optional reason for use: The document protocol number, PI name, the creation of a dilution noting the unique bottle ID of the working bottle, euthanasia, etc..
8. If additional pages are used, check the box at the bottom of the page.

# Sample Form 7: Controlled Substance Use Form

SCHEDULE I – II: \_\_\_\_\_\_\_\_\_\_ or SCHEDULE III – V: \_\_\_\_\_\_\_\_\_\_\_\_

**Note: This form is to be used to track the usage of all Schedule I – V controlled substance stock bottles. Select the drug schedule above.**

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| **Box 1: Registrant Information** |
| **Registrant’s Name:** Joe Smith | **DEA #:** RS1234567 | **Registered Address:** 123 Main Street, Room 123, Atlanta, GA, 30325 |

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| **Box 2: Stock Bottle Information** |
| **Name of Substance:** Fatal Plus | **Concentration/Strength:** 390mg/ml |

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of Controlled Substances. **Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must be promptly reported** using Form 5.

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| **Box 3: Controlled Substance Use Log** | **Drug Name/Concentration/Strength:** Fatal Plus 390mg/ml |
| **Date** | **Unique Bottle ID** | **Expiration Date of Unique Bottle ID** | **Starting Volume/Quantity** | **Amount Used** | **Balance Remaining** | **Printed Name of Person who Dispensed/Administered Drug** | **Reason for Use (optional)** |
| 02/11/23 | FP001 | 06/30/26 | 250 ml | 10ml | 240ml | Joe Smith | Euthanasia |
| 02/15/23 | FP001 | 06/30/26 | 240ml | 20ml | 220ml | JoAnn Taylor | Euthanasia  |
| 02/19/23 | FP001 | 06/30/26 | 220ml | 10ml | 210ml | Joe Smith | Dilution FPSA002 |
| 02/28/23 | FP001 | 06/30/26 | 210ml | 30ml | 180ml | Joe Smith | Euthanasia |
| 03/05/23 | FP001 | 06/30/26 | 180ml | 50mlSAMPLE | 130ml-------------------------New Bottle Started (per PI/protocol change)-------------------------------------------- | Joe Smith | Euthanasia |
|  |  |  |  |  |  |  |  |
| 03/10/23 | FP002 | 06/30/26 | 250ml | 40ml | 210ml | JoAnn Taylor | Dr. Claus |
| 03/11/23 | FP002 | 06/30/26 | 210ml | 10ml | 200ml | JoAnn Taylor | Protocol 12345677 |
|  |  |  |  | -------------------------Return to Bottle FP001 -------------------------------------------------------------------- |  |  |  |
| 03/15/23 | FP001 | 06/30/26 | 130ml | 30ml | 100ml | Joe Smith | Euthanasia |
| 03/17/23 | FP001 | 06/30/26 | 100ml | 30ml | 70ml | Joe Smith | Euthanasia |
| 03/18/23 | FP001 | 06/30/26 | 70ml | 50ml | 20ml | Joe Smith | Euthanasia |
| **Box 3: Controlled Substance Use Log Continued** | **Drug Name/Concentration/Strength:** Fatal Plus 390mg/ml |
| **Date** | **Unique Bottle ID** | **Expiration Date of Unique Bottle ID** | **Starting Volume/Quantity** | **Amount Used** | **Balance Remaining**  | **Printed Name of Person who Dispensed/Administered Drug** | **Reason for Use (optional)** |
| 03/20/23 | FP001 | 06/30/26 | 20ml | 15ml-------------------------FP001 sent to reverse distributor (Form 4) ---------------------------------------------- | 5ml | JoAnn Taylor | Euthanasia |
|  |  |  |  |  |  |  |  |
| 05/15/23 | FP002 | 06/30/26 | 200ml | 50ml | 150ml | JoAnn Taylor | Protocol 12345677 |
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# Form 7: Controlled Substance Use Form

SCHEDULE I – II: \_\_\_\_\_\_\_\_\_\_ or SCHEDULE III – V: \_\_\_\_\_\_\_\_\_\_\_\_

**Note: This form is to be used to track the usage of all Schedule I – V controlled substance stock bottles. Select the drug schedule above.**

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| **Box 1: Registrant Information** |
| **Registrant’s Name:**  | **DEA #:**  | **Registered Address:**  |

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| **Box 2: Stock Bottle Information** |
| **Name of Substance:**  | **Concentration/Strength:**  |

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of Controlled Substances. **Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must be promptly reported** using Form 5.

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| **Box 3: Current Controlled Substance Use Log** | **Drug Name/Concentration/Strength:**  |
| **Date** | **Unique Bottle ID** | **Expiration Date of Unique Bottle ID** | **Starting Volume/Quantity** | **Amount Used** | **Balance Remaining** | **Printed Name of Person who Dispensed/Administered Drug** | **Reason for Use (optional)** |
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| **Box 3: Current Controlled Substance Use Log Continued** | **Drug Name/Concentration/Strength:**  |
| **Date** | **Unique Bottle ID** | **Expiration Date of Unique Bottle ID** | **Starting Volume/Quantity** | **Amount Used** | **Balance Remaining** | **Printed Name of Person who Dispensed/Administered Drug** | **Reason for Use (optional)** |
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