# Working Instructions: Form 11: Controlled Substance Formulation/Dilution Use Form

# 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. Drug – For the purpose of the form, drug is defined as any Controlled Substance, Dangerous Drug, or diluent.
3. Registrant – A person licensed and registered with DEA to distribute, manufacture, administer, dispense, import, or export a Controlled Substance.
4. Stock Bottle – The container/bottle that was received from the supplier. The stock bottle has the original labels from the manufacturer.
5. Working Bottle- A chemical solution made for actual use in the lab, usually made from diluting or combining stock or standard solutions.
6. Conversion Factor – Is the number obtained while calculating the drugs concentration. The conversion factor is used to determine the total drug remaining in a drug formulation/dilution at any given time. To determine the total amount of controlled substance in a drug at any given time you multiple the conversion factor by the total drug remaining in the container.

# Box 1: Registrant 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. If another user’s name needs to be documented on this form, then you may note that in the “Reason for Use” section in Box 4.

#  Box 2: Calculating Concentration from Stock Bottles

1. In column 2a, enter the Drug Name exactly as it appears on the stock bottle container. If mixing more than four drugs, please contact ORIC@emory.edu for an updated form. This drug name must remain the same to use this form continuously. Before creating the formulation/dilution, check form 7 or C to ensure that none of the stock bottles have expired.
2. In column 2b, enter the stock bottles concentration/strength from the manufacturer’s label. This concentration must remain the same to use this form continuously.
3. In column 2c, record the Volume (V) of the stock drug added to the Working Bottle. This volume must remain the same to use this form continuously. If adding microliters (ul) to a solution, convert from ul to ml (ul/1000=ml). If adding grams to a solution, convert to mg (g x1000=mg). Keep units consistent.
4. In column 2d, record the total volume of solution created in the Working Bottle.
5. In column 2e, the Conversion Factors (CF) needs to be identified to help determine the concentration of the solution and to identify the total drug amount per ml in the Working Bottle at any time. Under certain circumstances it is required to determine the total drug remaining in a solution. For instance, some reverse distributors would only be concerned with the total amount of Ketamine remaining in the solution on the sample page below. The Conversion Factor (CF) for each drug will be multiplied by the Total Volume Remaining (TVR) in the Working Bottle to obtain the Total Drug Remaining (TDR). Below is a table for common Conversion Factors used in the creation of solutions. If you require additional conversion formulas or need further explanation, please contact ORIC@Emory.edu for assistance.

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| **Common Conversion Formulas (CF)** |
| Liquid drug (Concentration = total mg of drug in the liquid) | CF= (Drug Strength in mg x Volume ml Added to the Working Bottle)/Total Volume of ml in the Working Bottle | **CF = (C x V)/TV** |
| Diluent | CF= Volume of (ml) added / Total Volume of ml in the Working Bottle | **CF = V/TV** |
| Powder, tablets, capsules, patches, any other form of C/S | Contact ORIC for Conversion Formulas ORIC@Emory.edu | **variable** |

# Box 3: Working Bottle Information and Label

1. All the information in this section should be present on each Working Bottle. The drug name, concentration, and total volume should always remain the same. The unique bottle id, working bottle expiration date, working bottle puncture date, initials of person and date created will vary with each new bottle created.
2. The Drug Name is the combined name of the drugs (e.g. Ketamine/Xylazine/Saline or Euthasol/Saline or Testosterone/Beta-Cyclo Dextrin).
3. Record the Concentration of the solution created. The Concentration should be recorded as (mg/ml). Concentration is not the dose per animal. It is the total concentration of the solution created (see box 2).
4. Record the Total Volume created from box 2d.
5. The Working Bottle Unique ID can be any unique identifier that easily matches this form to the bottle and can link the stock bottle to Form 7 or C. An example of a Unique ID for a Ketamine/Xylazine/Saline solution would be to combine the drug name and use the creation date e.g., KXS011524. . If multiple vials are created then add a -01, -02, -03 to the end of the sequence. On the stock bottle form (form 7 or C), it should be documented that the drug went into solution KXS011524.
6. Document the Working Bottle's expiration date, which is the earliest date of all the combined drugs.
7. Record the date the solution was mixed and the initials of the person mixing.

# Box 4: Drug Usage for the Working Bottle

1. Record the drug name and concentration on the header for the first page and each subsequent page.
2. Document the date the drug is administered/dispensed.
3. Record the Unique Bottle ID for the Working Bottle. If a new Working Bottle is used, you may separate the lines to delineate between two bottles but that is optional.
4. Record the Unique Bottle IDs expiration date from each bottle’s label.
5. Document the starting volume, how much volume was removed, and the Total Volume Remaining.
6. Record the initials of the person who administered/dispensed the drug.
7. Optional: Document the reason for use. The number of animals dosed, protocol number, PI, or reason for using the drug may be documented here.
8. DO NOT record that a drug was destroyed on this form. If there is drug remaining on the container, then the Total Drug Remaining (TDR) is to be documented on Form 4. DO NOT zero out a drug if it was sent to a reverse distributor or destroyed onsite. Contact ORIC for further explanation.
9. If using additional pages, do not forget to check the box at the bottom of the page.

# Sample Form 11: Controlled Substance Formulation/Dilution Use

SAMPLE

Note: This form may only be used if the drug name, concentration, and total volume, created remains the same. A new form must be used if the concentration changes.

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| **Box 1: Registrant Information** |
| **Registrant’s Name:** John Smith | **DEA #:** RS1234567 | **Registered Address:** 123 Main Street, Room #4567, Atlanta, GA, 30325 |
| **Box 2: Calculating Concentrations from Stock Bottles** |
| **(2a)** | **(2b)** | **(2c)** | **(2d)** | **(2e)** |
| **C/S Drug #1 name:** ketamine | **Concentration (C):** 100mg/ml | **Volume Added (V):** 2ml | **Total Volume (TV):**10ml | **Conversion Factor (CF)\* (CF=C x V/TV):** 100mgx 2ml/10ml=20 |
| **Drug #2 Name:** xylazine | **Concentration (C):** 100mg/ml | **Volume Added (V):** 3ml | **Conversion Factor (CF)\*: (CF=C x V/TV):** 100mg x 3ml/10ml=30 |
| **Drug #3 Name(if applicable):** bacteriostatic saline | **Concentration (C):** n/a = 1 | **Volume Added (V):** 5ml | **Conversion Factor (CF)\* (CF=C x V/TV):** 1 x 5ml/10ml=0.5 |
| **Drug #4 Name(if applicable):**N/A | **Concentration (C):** N/A | **Volume Added (V):** N/A | **Conversion Factor (CF)\* (CF=C x V/TV):** N/A |

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| **Box 3: Working Bottle Information and Label**  | **Working Bottle Unique ID\*:**  varied |
| **Drug Name (Box 2):** Ketamine/Xylazine/Saline | **Working Bottle Expiration Date\*:** varied |
| **Concentration (Box 2):** 20mg/30mg/0.5ml per ml | **Working Bottle 1st Puncture Date:** varied |
| **Total Volume Created :** 10ml | **Date Mixed and Initials of person Mixing:** varied |
| **Fill in this side of Box 3. This info must be on the working bottle** | **This side of Box 3 varies per bottle but must be on the working bottle** |

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| **Box 4: Drug Usage for Working Bottle** | **Drug Name and Concentration:** Ketamine/Xylazine/Saline 20mg/30mg/0.5ml per ml |
| **Date** | **Unique Bottle ID** | **Unique Bottle ID Expiration Date** | **Starting Volume (ml)** | **Volume removed (ml)** | **Total Volume Remaining (TVR) (ml)** | **Initials of person dispensing/ administering** | **Reason for Use (optional)** |
| **01/01/24** | KXS010124 | 03/01/24 | 10ml | 1ml | 9ml | DB | Protocol #12456 |
| **01/05/24** | KXS010124 | 03/01/24 | 9ml | 5ml | 4ml | DB | Protocol #12456 |
| **01/06/24** | KXS010124 | 03/01/24 | 4ml-------------------------------------New Bottle created----------------------------------------------------------- | 3ml | 1ml | JS | Protocol #12456 |
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| **Box 4: Drug Usage for Working Bottle Continued**  | **Drug Name and Concentration:** Ketamine/Xylazine/Saline 20mg/30mg/0.5ml per ml |
| **Date** | **Unique Bottle ID\*** | **Unique Bottle ID Expiration Date** | **Starting Volume (ml)** | **Volume removed (ml)** | **Total Volume Remaining (TVR) (ml)** | **Initials of person dispensing/ administering** | **Reason for Use (optional)** |
| **01/10/24** | KXS011024 | 03/10/24 | 10ml | 5ml | 5ml | JS | Protocol #45678 |
| **01/15/24** | KXS011024 | 03/10/24 | 5ml | 5ml | 0ml | JS | Protocol #45678 |
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# Form 11: Controlled Substance Formulation/Dilution Use

Note: This form may only be used if the drug name, concentration, and total volume, created remains the same. A new form must be used if the concentration changes.

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| **Box 1: Registrant Information** |
| **Registrant’s Name:**  | **DEA #:**  | **Registered Address:**  |
| **Box 2: Calculating Concentrations from Stock Bottles** |
| **(2a)** | **(2b)** | **(2c)** | **(2d)** | **(2e)** |
| **C/S Drug #1 name:**  | **Concentration (C):**  | **Volume Added (V):**  | **Total Volume (TV):** | **Conversion Factor (CF)\***  |
| **Drug #2 Name:**  | **Concentration (C):**  | **Volume Added (V):**  | **Conversion Factor (CF)\*:**  |
| **Drug #3 Name(if applicable):**  | **Concentration (C):**  | **Volume Added (V):**  | **Conversion Factor (CF)\***  |
| **Drug #4 Name(if applicable):** | **Concentration (C):**  | **Volume Added (V):**  | **Conversion Factor (CF)\***  |

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| **Box 3: Working Bottle Information and Label**  | **Working Bottle Unique ID\*:**  varied |
| **Drug Name (Box 2):**  | **Working Bottle Expiration Date\*:** varied |
| **Concentration (Box 2):**  | **Working Bottle 1st Puncture Date:** varied |
| **Total Volume Created :**  | **Date Mixed and Initials of person Mixing:** varied |
| **Fill in this side of Box 3. This info must be on the working bottle** | **This side of Box 3 varies per bottle but must be on the working bottle** |

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| **Box 4: Drug Usage for Working Bottle** | **Drug Name and Concentration:**  |
| **Date** | **Unique Bottle ID** | **Unique Bottle ID Expiration Date** | **Starting Volume (ml)** | **Volume removed (ml)** | **Total Volume Remaining (TVR) (ml)** | **Initials of person dispensing/ administering** | **Reason for Use (optional)** |
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| **Box 4: Drug Usage for Working Bottle Continued**  | **Drug Name and Concentration:**  |
| **Date** | **Unique Bottle ID\*** | **Unique Bottle ID Expiration Date** | **Starting Volume (ml)** | **Volume removed (ml)** | **Total Volume Remaining (TVR) (ml)** | **Initials of person dispensing/ administering** | **Reason for Use (optional)** |
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