# Working Instructions: Form F: Dangerous Drug Dilution and Use Form

# Definitions:

1. Dangerous Drug - A "dangerous drug" (DD) means any drug other than a drug contained in any schedule of Article 2 of this chapter, which, under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040 (1938)), 21 U.S.C. Section 301, et seq., as amended, may be dispensed only upon prescription. In addition to subsection (a) of this Code section, a "dangerous drug" means any other drug or substance declared by the General Assembly to be a dangerous drug; to include any of the following drugs, chemicals, or substances; salts, isomers, esters, ethers, or derivatives of such drugs, chemicals, or substances which have essentially the same pharmacological action; all other salts, isomers, esters, ethers, and compounds of such drugs, chemicals, or substances unless specifically exempted and the following devices, identified as "dangerous drugs".  See the complete list of dangerous drugs here. [Dangerous Drug List Link](https://law.justia.com/codes/georgia/2010/title-16/chapter-13/article-3/16-13-71/)
2. Drug – For the purpose of the form drug is defined as any 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 – 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, multiply the conversion factor by the total drug remaining in the container.

# Box 1: Registration Information

1. Complete the Registrant’s Name, Georgia Board of Pharmacy (GBP) #, and address in this section. The information must appear exactly (in its entirety), as it does on the Registrant’s GBP License. If the registrant is not the user 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](mailto: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 the bottle labels 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 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. 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](mailto: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](mailto: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. Xylazine/Saline or Tamoxifen/Saline).
3. Record the Concentration of the solution created. The Concentration should be recorded as (mg/ml). Concentration is the total concentration of the solution created (see box 2), not the dose per animal.
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 C. An example of a Unique ID for a Xylazine/Saline solution would be to combine the drug names from each stock bottle and add the creation date e.g. XYSA040123. If multiple vials are created then add a -01, -02, -03 to the end of the sequence. On the stock bottle form (form C), document that the drug went into solution XYSA040123.
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: 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 in the container, then the Total Volume Remaining is to be documented on Form I. DO NOT zero out a drug if it was sent to EHSO 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 F: Dangerous Drug Dilution and Use Form

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:** Joe Smith | | **GA Board of Pharmacy #:** PHRS12345678 | | **Registered Address:** 123 Main Street, Room #4567, Atlanta, GA, 30325 | | |
| **Box 2: Calculating Concentrations from Stock Bottles** | | | | | | |
| **(2a)** | **(2b)** | | **(2c)** | | **(2d)** | **(2d)** |
| **DD Drug Name :** Xylazine | **Concentration (C):** 1.5mg/ml | | **Volume Added (V):** 2ml | | **Total Volume (TV):**  10ml | **Conversion Factor (CF)\* (CF=C x V/TV):** (1.5mg x 2ml)/10ml = 0.3mg/ml |
| **Drug Name:** (diluent) Bacteriostatic Saline | **Concentration (C):** 1 | | **Volume Added (V):** 8ml  SAMPLE | | **Conversion Factor (CF)\*: (CF= V/TV):** (8ml/10ml) = 0.8ml |
| **Drug #3 Name(if applicable):** N/A | **Concentration (C):** N/A | | **Volume Added (V):** N/A | | **Conversion Factor (CF)\*** N/A |
| **Drug #4 Name(if applicable):**  N/A | **Concentration (C):** N/A | | **Volume Added (V):** N/A | | **Conversion Factor (CF)\*** N/A |

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| **Box 3: DD Dilution Working Bottle Information and Label** | **Working Bottle Unique ID:** varied |
| **Mixture Name:** Xylazine /Saline | **Working Bottle Expiration Date\*:** varied |
| **Concentration of Working Dilution\* (mg/ml):** 0.3mg/ml | **Working Bottle 1st Puncture Date:** varied |
| **Total Volume (TV) :** 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:** Xylazine/Saline 0.3mg/ml | | | | |
| **Date** | **Unique Bottle ID** | **Unique Bottle ID Expiration Date** | **Starting volume** | **Volume removed** | **Total volume remaining (TVR)** | **Initials of person administering** | | **Reason for Use** |
| 04/01/23 | XYSA040123 | 06/01/23 | 10ml | 1ml | 9ml | DB | | Protocol 21345 |
| 04/03/23 | XYSA040123 | 06/01/23 | 9ml | 2ml | 7ml | JS | | Protocol 21345 |
| 04/10/23 | XYSA040123 | 06/01/23 | 7ml | 1ml | 6ml | JS | | Protocol 21345 |
| 04/15/23 | XYSA040123 | 06/01/23 | 6ml | 1ml | 5ml | DB | | Protocol 21345 |
| 04/16/23 | XYSA040123 | 06/01/23 | 5ml | 2ml | 3ml | DB | | Protocol 21345 |
| **Box 6: Drug Usage for Working Bottle Cont’d:** | | | | **Drug Name and Concentration:** Xylazine/Saline 0.3mg/ml | | | | |
| **Date** | **Unique Bottle ID** | **Unique Bottle ID Expiration Date** | **Starting volume** | **Volume removed** | **Total volume remaining (TVR)** | **Initials of person administering** | **Reason for Use** | |
| 04/25/23 | XYSA040123 | 06/01/23 | 3ml | 1ml | 2ml | JS | Protocol 21345 | |
| 04/28/23 | XYSA040123 | 06/01/23 | 2ml | 1ml | 1ml | JS | Protocol 21345 | |
|  |  |  | -------------------New Bottle----------------------------------------------------------------------------------- |  |  |  |  | |
| 05/01/23 | XYSA050123 | 07/01/23 | 10ml | 3ml | 7ml | DB | Protocol 21345 | |
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# Form F: Dangerous Drug Dilution and Use Form

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:** | | **GA Board of Pharmacy #:** | | **Registered Address:** | | |
| **Box 2: Calculating Concentrations from Stock Bottles** | | | | | | |
| **(2a)** | **(2b)** | | **(2c)** | | **(2d)** | **(2d)** |
| **DD Drug Name :** | **Concentration (C):** | | **Volume Added (V):** | | **Total Volume (TV):** | **Conversion Factor (CF)\*** |
| **Drug 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: DD Dilution Working Bottle Information and Label** | **Working Bottle Unique ID:** varied |
| **Mixture Name:** | **Working Bottle Expiration Date\*:** varied |
| **Concentration of Working Dilution\* (mg/ml):** | **Working Bottle 1st Puncture Date:** varied |
| **Total Volume (TV) :** | **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** | **Volume removed** | **Total volume remaining (TVR)** | **Initials of person administering** | **Reason for Use** | |
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| **Box 6: Drug Usage for Working Bottle Cont’d:** | | | | **Drug Name and Concentration:** | | | | |
| **Date** | **Unique Bottle ID** | **Unique Bottle ID Expiration Date** | **Starting volume** | **Volume removed** | **Total volume remaining (TVR)** | **Initials of person administering** | | **Reason for Use** |
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