# Form H: Working Instructions for Meloxicam\* Working Bottle Use

# Definitions:

1. Meloxicam\* – Meloxicam and any of its variants. The name of the substance must be recorded as it appears on the drug container.
2. Registrant – A person licensed and registered with the Georgia Board of Pharmacy (GBP) to distribute, manufacture, administer/dispense, store a dangerous drug.
3. Stock Bottle – The container/bottle that was received from the supplier. The stock bottle has the original labels from the manufacturer.
4. Working Bottle- A chemical solution made for actual use in the lab, usually made from diluting or combining stock or standard solutions.

# Box 1 Instructions: Registration Information

1. Complete the Registrant’s Name, Georgia Board of Pharmacy (GBP) Number, and address in this section. The information must appear exactly (in its entirety), as it does on the Registrant’s GBP License.

# Box 2: Calculating Concentration from Stock Bottles

1. In column 2a, enter the Drug Name exactly as it appears on the stock bottle container. (Meloxidyl ≠ Ositlox ≠ Loxicom. If these different brands are used they should be recorded on separate forms)
2. If mixing more than three 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.
3. 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.
4. 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.
5. In column 2d, record the total volume of solution created in the Working Bottle.
6. 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 a controlled substance 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. Meloxidyl/Saline)
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 Meloxidyl/Saline solution would be to combine the drug name and use the creation date e.g., MELSAL040123 . 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 MELSAL040123.
6. Document the Working Bottle's first puncture date and the date that is 180 days after the first puncture.
7. Record the date the solution was mixed and the initials of the person mixing.

# Box 4: Drug Usage for the Working Bottle

1. This form may be used continuously if the drug name and concentration remain the same.
2. Record the Name of the Substance and Concentration in the header of Box 4.
3. Record the puncture number. Each puncture should be recorded on a separate line, even if the punctures are made on the same day. This will aid the Registrant in tracking the number of punctures accurately.
4. Document the date of the dispensation.
5. Create and record the Unique Bottle ID from the Meloxicam\* stock bottle. Stock bottles may be identified by the drug name, date received. If more than one stock bottle is received on the same date, then the bottles must be numbered. Example: A stock bottle unique id # could be ME011515-1
6. Record the Manufacturer’s Expiration Date for the Meloxicam\* stock bottle associated with the Unique Bottle ID.
7. Record the first puncture date of the Meloxicam\* stock bottle with the associated Unique Bottle ID.
8. Calculate and record the 180th day after the first puncture date. You may use this website to determine 180 days after the puncture date. <https://timedatecalc.com/180-days-from-today> The expiration date of the Meloxicam\* stock bottle is 180 days after the first puncture or after 51 punctures of both the stock bottle and the working bottle, according to the manufacturer label. *Read the fine print.*
9. Document the initial/starting volume, the volume removed, total volume remaining, initials of the person administering
10. Optional: Record the reason for use. The Researcher may choose to document the PI who used the drug, protocol number, number of animals dosed, etc.
11. When using an additional page for the same bottle, mark the box “Continued on Additional Page”
12. On all additional pages, document the drug name and concentration in the header of Box 4.
13. DO NOT record the disposition on this form. If Meloxicam is destroyed, it should be documented on form I (Dangerous Drug Destruction Log). If this dilution is mixed with a controlled substance then the working bottle must be destroyed by a reverse distributor and the total drug remaining of the controlled substance must be reported on Form 4.

Sample Form H: Meloxicam\* Working Bottle Use

(see working instructions on how to complete this form)

*The purpose of this log is to help track the use of the drug and the number of punctures in the working bottle.*

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| **Box 1: Registrant Information** |
| **Registrant’s Name:** John Smith | **GA Board of Pharmacy #:** PHRS12345678 | **Registered Address:** 123 Main Street, Building Name, Room #, Atlanta, GA, 30325 |
| **Box 2: Calculating Concentrations from Stock Bottles** |
| **(2a)** | **(2b)** | **(2c)** | **(2d)** | **(2e)** |
| **Meloxicam\* Drug Name:** Meloxidyl | **Concentration (C):** 1.5mg/ml | **Volume Added (V):** 2ml | **Total Volume (TV):**10ml | **Conversion Factor (CF)\* (CF=C x V/TV):** 1.5mgx 2ml/10ml=0.3 |
| **Drug #2 Name:** bacteriostatic saline | **Concentration (C):** N/A=1 | **Volume Added (V):** 8ml | **Conversion Factor (CF)\*: (CF=C x V/TV):** 1 x 8ml/10ml=0.8SAMPLE |
| **Drug #3 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):** Meloxidyl/Saline | **Working Bottle 1st Puncture Date:** varied |
| **Concentration (Box 2):** 0.3mg/0.8mg/ml | **Working Bottle Expiration Date (180 days after puncture):** 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** |

*This form may be used continuously if the drug name and concentration remain the same. Each working bottle must have a unique identification. DO NOT record destructions on this form, use Form I.*

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| **Box 4: Working Bottle Drug Usage** | **Drug Name and Concentration:** Meloxidyl/Saline 0.3mg/ml |
| **Working bottle puncture #**  | **Date** | **Unique Bottle ID No:** | **Manufacturer Expiration Date:** | **1st Puncture Date:** | **180 days after 1st Puncture date:** | **Initial volume (ml)** | **Volume removed (ml)** | **Total volume remaining (ml)** | **Initials of person administering** | **Optional: Reason for Use** **(species & number of animals dosed)** |
| 1 | 04/01/23 | MELSAL001 | 05/30/24 | 04/01/23 | 09/28/23 | 10ml | 1ml | 9ml | db | Protocol #1234 |
| 2 | 05/10/23 | MELSAL001 | 05/30/24 | 04/01/23 | 09/28/23 | 9ml | 2ml | 7ml | md | 5 mice dosed |
| 3 | 05/20/23 | MELSAL001 | 05/30/24 | 04/01/23 | 09/28/23 | 7ml | 1ml | 6ml | db | Dr. Lee |
| 4 | 05/21/23 | MELSAL001 | 05/30/24 | 04/01/23 | 09/28/23 | 6ml | 1ml | 5ml | md | Protocol #1234 |

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| **Box 4: Working Bottle Drug Usage Continued** | **Drug Name and Concentration:** Meloxidyl/Saline 0.3mg/ml |
| **Working bottle puncture #**  | **Date** | **Unique Bottle ID No:** | **Manufacturer Expiration Date:** | **1st Puncture Date:** | **180 days after 1st Puncture date:**----------------------New Bottle------------------------------------------------------------------------------------------- | **Initial volume (ml)** | **Volume removed (ml)** | **Total volume remaining (ml)** | **Initials of person administering** | **Optional: Reason for Use (species & number of animals dosed)** |
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| 1 | 07/01/23 | MELSAL002 | 05/30/24 | 07/01/23 | 12/09/23 | 10ml | 5ml | 5ml | JS | Protocol #12345 |
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Form H: Meloxicam\* Working Bottle Use

(see working instructions on how to complete this form)

*The purpose of this log is to help track the use of the drug and the number of punctures in the working bottle.*

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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)** | **(2e)** |
| **Meloxicam\* Drug Name:**  | **Concentration (C):**  | **Volume Added (V):**  | **Total Volume (TV):** | **Conversion Factor (CF)\* (CF=C x V/TV):**  |
| **Drug #2 Name:**  | **Concentration (C):**  | **Volume Added (V):**  | **Conversion Factor (CF)\*: (CF=C x V/TV):**  |
| **Drug #3 Name(if applicable):** | **Concentration (C):**  | **Volume Added (V):**  | **Conversion Factor (CF)\* (CF=C x V/TV):**  |

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| **Box 3: Working Bottle Information and Label**  | **Working Bottle Unique ID:**  varied |
| **Drug Name (Box 2):**  | **Working Bottle 1st Puncture Date:** varied |
| **Concentration (Box 2):**  | **Working Bottle Expiration Date (180 days after puncture):** 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** |

*This form may be used continuously if the drug name and concentration remain the same. Each working bottle must have a unique identification. DO NOT record destructions on this form, use Form I.*

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| **Box 4: Working Bottle Drug Usage** | **Drug Name and Concentration:**  |
| **Working bottle puncture #**  | **Date** | **Unique Bottle ID No:** | **Manufacturer Expiration Date:** | **1st Puncture Date:** | **180 days after 1st Puncture date:** | **Initial volume (ml)** | **Volume removed (ml)** | **Total volume remaining (ml)** | **Initials of person administering** | **Optional: Reason for Use (species & number of animals dosed)** |
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| **Box 4: Working Bottle Drug Usage Continued** | **Drug Name and Concentration:**  |
| **Working bottle puncture #**  | **Date** | **Unique Bottle ID No:** | **Manufacturer Expiration Date:** | **1st Puncture Date:** | **180 days after 1st Puncture date:** | **Initial volume (ml)** | **Volume removed (ml)** | **Total volume remaining (ml)** | **Initials of person administering** | **Optional: Reason for Use (species & number of animals dosed)** |
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