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An In-Depth Look at Dispensing and Dilution Forms

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Research Compliance
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In this presentation

In our previous webinar we covered the recent changes to the CS/DD forms, which included the move to continuous use forms and removing disposition from dispensing forms.

In this presentation, we will take an in-depth look at the dispensing and dilution forms. We will discuss the importance of proper recordkeeping and tracking your stock and working solutions.



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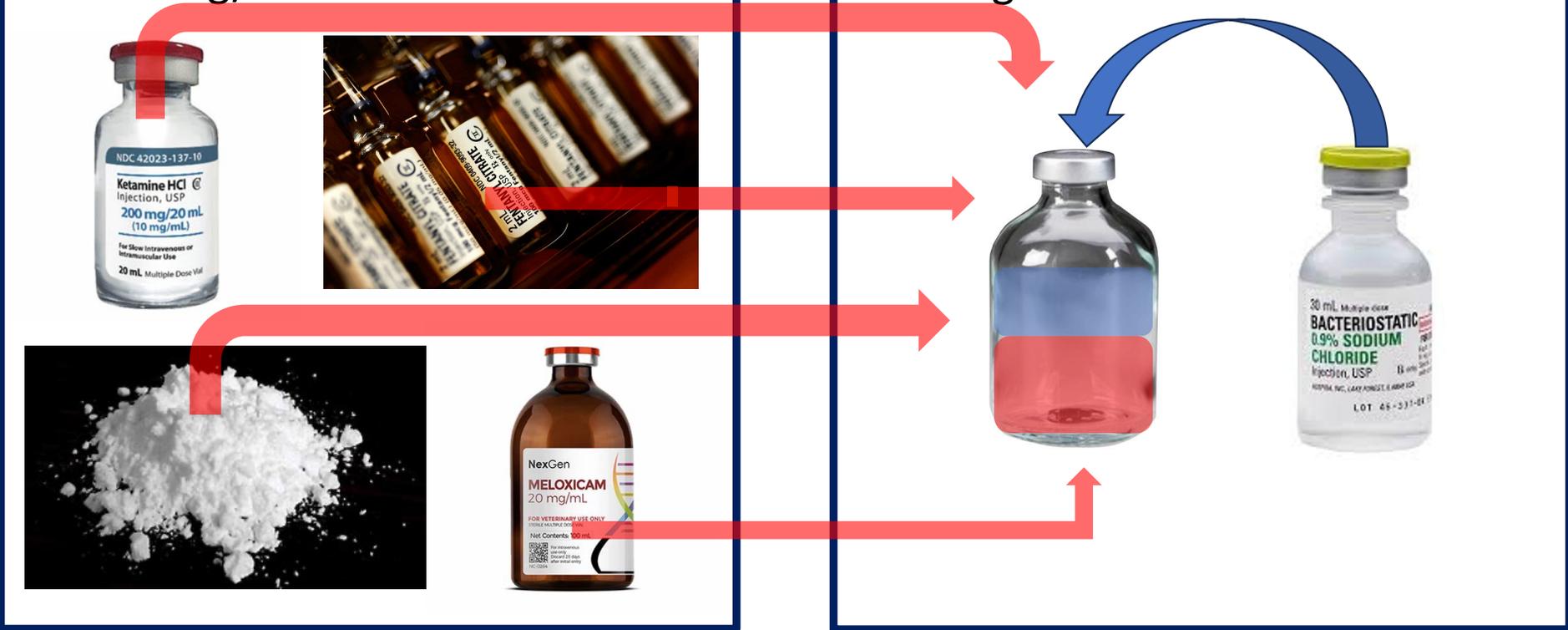
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What is a Stock and Working Solution?

Stock Drug/Solutions

Working Solutions



Defining Stock and Working Bottles

Stock Bottle – The container/bottle that was received from the supplier. The stock bottle has the original labels from the manufacturer.

Working Bottle- A chemical solution made for actual use in the lab, usually made from diluting or combining stock or standard solutions.

Recordkeeping for Stock Bottles

Emory Forms are optional, however, the information contained in them is required.

Controlled Substance (CS) Stock Bottle Dispensing Forms

Form 7 – CS Current Use Log

Form 13 – Use and Disposition Log Prescription (BUP ER, BAM)

Dangerous Drugs (DD) Stock Bottle Dispensing Forms

Form C – DD Use Log

Form D – Isoflurane Vaporize Use Log (only for use with a vaporizer)

Form G – Meloxicam Use Log (to help track punctures)

Sample Form 7-CONTROLLED SUBSTANCE CURRENT USE FORM

SCHEDULE I – II: _____ or SCHEDULE III – V: **X** _____

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

Box 1: Registrant Information

Registrant's Name: Joe Smith DEA #: RS1234567 Registered Address: 123 Main Street, Room 123, Atlanta, GA, 30325

Box 2: Stock Bottle Information

Name of Substance: Ketamine Concentration/Strength: 100 mg/ml

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of unit. 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.

Box 3: Current Controlled Substance Use Log

Drug Name/Concentration/Strength: Ketamine 100mg/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	KET001	06/30/26	10 ml	1ml	9ml	Joe Smith	Protocol 12345677
02/15/23	KET001	06/30/26	9ml	0.5ml	8.5ml	JoAnn Taylor	Protocol 12345677
02/19/23	KET001	06/30/26	8.5ml	2ml	6.5ml	Joe Smith	Dilution KXS021923
02/28/23	KET001	06/30/26	6.5ml	1ml	5.5ml	Joe Smith	Protocol 12345677
03/05/23	KET001	06/30/26	5.5ml	0.5ml	5ml	Joe Smith	Protocol 12345677
03/10/23	KET001	06/30/26	5ml	2ml	3ml	JoAnn Taylor	Dilution KXS031023
03/11/23	KET001	06/30/26	3ml	2ml	1ml	JoAnn Taylor	Dilution KXS031123
03/15/23	KET001	06/30/26	1ml	0.75ml	0.25ml	Joe Smith	Protocol 12345677
03/17/23	KET002	06/30/26	10ml	0.5ml	9.5ml	Joe Smith	Protocol 12345677
03/18/23	KET002	06/30/26	9.5ml	1ml	8.5ml	Joe Smith	Protocol 12345677
03/20/23	KET002	06/30/26	8.5ml	1ml	7.5ml	JoAnn Taylor	Protocol 12345677
04/01/23	KET002	06/30/26	7.5ml	2ml	5.5ml	Joe Smith	Dilution KXS040123

0.25 Ketamine 100mg/ml sent for destruction using Form 4.

Recordkeeping for Working Bottles

Controlled Substance (CS) Working Bottle Dispensing Forms

Form 11 – CS Dilution Log

Dangerous Drugs (DD) Working Bottle Dispensing Forms

Form F – DD Dilution Log

Form H – Meloxicam Dilution Log

Sample 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.

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

Box 3: Working Bottle Information and Label	Working Bottle Unique ID*: <i>varied</i>
Drug Name (Box 2): <i>Ketamine/Xylazine/Saline</i>	Working Bottle Expiration Date*: <i>varied</i>
Concentration (Box 2): <i>20mg/30mg/0.5ml per ml</i>	Working Bottle 1st Puncture Date: <i>varied</i>
Total Volume Created : <i>10ml</i>	Date Mixed and Initials of person Mixing: <i>varied</i>
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

Box 4: Drug Usage for Working Bottle				Drug Name and Concentration: <i>Ketamine/Xylazine/Saline 20mg/30mg/0.5ml per ml</i>			
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)
<i>02/19/23</i>	<i>KXS021923</i>	<i>03/19/23</i>	<i>10ml</i>	<i>10ml</i>	<i>0ml</i>	<i>DB</i>	<i>Protocol #1245677</i>
<i>03/10/23</i>	<i>KXS031023</i>	<i>4/10/23</i>	<i>10ml</i>	<i>10ml</i>	<i>0ml</i>	<i>DB</i>	<i>Protocol #1245677</i>
<i>03/11/23</i>	<i>KXS031123</i>	<i>04/11/23</i>	<i>10ml</i>	<i>10ml</i>	<i>0ml</i>	<i>JS</i>	<i>Protocol #1245677</i>
<i>04/01/23</i>	<i>KXS040123</i>	<i>05/01/23</i>	<i>10ml</i>	<i>10ml</i>	<i>0ml</i>	<i>DB</i>	<i>Protocol #1245677</i>

Buprenorphine ER

If you already have a DEA license you can obtain BUP ER directly from Wedgewood Village Pharmacy in Emory Express. Please contact our office for the guidance document on setting up an account and ordering.

After you received your order you will document the receipt on Form 9 and keep all packing slips. You will then use Form 7 to dispense and Form 4 to dispose with a reverse distributor.

For those who do not have a DEA license, you will use Form 13.

Sample Form 13: Current Use and Disposition Form for Prescription Controlled Substances (BUP SR/ER)

Note: This form is only to be used when a Researcher obtains a controlled substance through a prescription for the clinical care of animals. One form needs to be used every new bottle received.

Box 1: Registrant/PI Information		
Registrant/PI Name: <i>Joe Smith</i>	DEA # (if applicable): <i>RS1234567</i>	Address: <i>123 Main Street, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information						
Name of Substance: <i>Buprenorphine SR</i>	Concentration/ Strength: <i>0.05mg/ml</i>	Starting Volume/ Quantity: <i>10ml</i>	Expiration Date: <i>08/30/2026</i>	Date added to inventory: <i>02/10/23</i>	Prescription #: <i>RX123546790</i>	Unique Bottle ID: <i>BPSR0023</i>

Box 3: Stock Bottle Disposition Information				
Name of Substance: <i>Buprenorphine SR</i>	Concentration/Strength: <i>0.05.mg/ml</i>	Total Volume/Quantity Disposed: <i>0.5 ml</i>	Method of Destruction: <i>EHSO RX Destroyer</i>	Disposition Date: <i>06/10/23</i>
Research Staff Printed Name: <i>Joe Smith</i>	Signature: <i>Joe Smith</i>		Date: <i>06/10/23</i>	
Research Staff Printed Name: <i>JoAnn Taylor</i>	Signature: <i>JoAnn Taylor</i>		Date: <i>06/10/23</i>	

Box 4: Current Prescription Controlled Substance Use Log					Unique Bottle ID: <i>BPSR0023</i>
Date	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who Dispensed/Administered Drug	Reason for Use
<i>02/11/23</i>	<i>10ml</i>	<i>0.5ml</i>	<i>9.5ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>
<i>02/15/23</i>	<i>9.5ml</i>	<i>0.5ml</i>	<i>9.0ml</i>	<i>JoAnn Taylor</i>	<i>Pain Management</i>
<i>02/19/23</i>	<i>9.0ml</i>	<i>1ml</i>	<i>8ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>
<i>02/28/23</i>	<i>8ml</i>	<i>2ml</i>	<i>6ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>
<i>03/05/23</i>	<i>6ml</i>	<i>0.5ml</i>	<i>5.5ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>
<i>03/10/23</i>	<i>5.5ml</i>	<i>2ml</i>	<i>3.5ml</i>	<i>JoAnn Taylor</i>	<i>Pain Management</i>

Questions?



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