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***Dry Concentrate Mixer Safe, Effective and Quality Operational  
Processes and Procedures***

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# Granuflo Concentrate Mixer Procedures

## Granuflo™ Batch Production Record

### Part 1

Granuflo™ Dry Acid Catalog Number \_\_\_\_\_  
Dissolution Tank Serial Number \_\_\_\_\_  
Facility Name \_\_\_\_\_  
Date & Time Mixed \_\_\_\_\_  
Operator \_\_\_\_\_  
Batch Size (Gallons) \_\_\_\_\_  
Number of Boxes to be used \_\_\_\_\_  
Acceptable Specific Gravity Range .....Low \_\_\_\_\_ High \_\_\_\_\_

*Note – Refer to manufacturer's table, "Granuflo™ Dry Acid Specific Gravity".*

### Part 2

#### Initials

1. \_\_\_\_\_ Area cleaned (No other Catalog/Formulation Numbers or empty packets from previous mixing procedures in area)
2. \_\_\_\_\_ 1 Micron Filter installed (replaced if transfer time has become excessive and during Disinfecting Granuflo™ Mixer procedure)
3. \_\_\_\_\_ Rinse performed YES/NO (circle) Date Completed \_\_\_\_\_
4. \_\_\_\_\_ Verify Tank is empty at start of dissolution cycle
5. \_\_\_\_\_ Verify Tank is approximately ½ full when the Granuflo™ "ADD GRANULES" begins to flash
6. \_\_\_\_\_ Granuflo™ Lot Number(s) (Lower right corner of boxes)  
Box #1 Lot Number \_\_\_\_\_ Box #2 Lot Number \_\_\_\_\_  
Box #3 Lot Number \_\_\_\_\_ Box #4 Lot Number \_\_\_\_\_  
Box #5 Lot Number \_\_\_\_\_ Box #6 Lot Number \_\_\_\_\_  
Box #7 Lot Number \_\_\_\_\_ Box #8 Lot Number \_\_\_\_\_  
Operator's Signature \_\_\_\_\_  
Licensed Nurse Signature \_\_\_\_\_
7. \_\_\_\_\_ Number of boxes added \_\_\_\_\_
8. \_\_\_\_\_ Label Tank with Date & Time, Catalog Number and Formula
9. \_\_\_\_\_ Dissolution Complete (visual check)
10. \_\_\_\_\_ Hydrometer Specific Gravity Check:  
Hydrometer Reading \_\_\_\_\_  
*Refer to Acceptable Specific Gravity Range in Part 1 above.*  
Operator's Signature \_\_\_\_\_  
Licensed Nurse Signature \_\_\_\_\_
11. \_\_\_\_\_ Transfer Line and Filter Housing rinsed to drain for 30 seconds with concentrate batch
12. \_\_\_\_\_ Catalog Number on Granuflo™ mixer and Batch Production Record matches  
Catalog Number on Storage Tank to be filled  
Operator's Signature \_\_\_\_\_  
Licensed Nurse Signature \_\_\_\_\_
13. \_\_\_\_\_ Date Granuflo™ batch transferred to Storage Tank \_\_\_\_\_

*Note – Batch must be transferred to Storage Tank within 14 days of mixing/preparation.*



# Concentrate Final Mix Validation

45X CitraPure Dry Acid								
Formula	Na+	K+	Ca++	Mg++	Citric	Dextrose	Hydrometer	
D4-Series	mEq/Lit	mEq/Lit	mEq/Lit	mEq/Lit	mEq/Lit	mg%	Lower Value	Upper Value
D4-103	100.00	2.00	2.25	1.00	2.40	100.00	1.183	1.207
D4-108	100.00	2.00	2.00	1.00	2.40	100.00	1.184	1.208
D4-109	100.00	3.00	2.25	1.00	2.40	100.00	1.186	1.210
D4-110	100.00	3.00	2.00	1.00	2.40	100.00	1.184	1.207
D4-114	100.00	1.00	2.50	1.00	2.40	100.00	1.183	1.206
D4-116	100.00	2.00	2.50	1.00	2.40	100.00	1.184	1.208
D4-117	100.00	3.00	2.50	1.00	2.40	100.00	1.186	1.210
D4-124	100.00	2.00	3.00	1.00	2.40	100.00	1.187	1.211
D4-126	100.00	3.00	3.00	1.00	2.40	100.00	1.188	1.212
D4-128	100.00	4.00	3.00	1.00	2.40	100.00	1.189	1.213

**NOTE:** When checking specific gravity, be aware that the addition of any substances, foreign or otherwise, may cause the present values to be different from the listed values.



# Granuflo Concentrate Mixer Procedures

## **TITLE: GRANUFLO® CONCENTRATE DISSOLUTION UNIT (132 GALLON) MIXING PROCEDURE**

### **Materials required:**

- Eight (8) boxes of desired formula/catalog number of Granuflo® Concentrate for a 132 gallon tank
- Granuflo® Batch Production Record
- Clean Soft Cloth
- One (1) hydrometer with graduated cylinder
- Digital pocket thermometer with the following minimum specifications:
  - a. Range: 25°C (+/- 5°C); 68° to 86°F
  - b. Accuracy: +/- 1°C; 3.6°F
- Transfer Nozzle (if dispensing directly into individual containers)
- Appropriately labeled Residual Acid Concentrate Bucket
- PPE-personal protective equipment (face protection, gloves, fluid resistant/fluid impervious barrier garment)

### **NOTES:**

- Specific gravity and temperature tests are performed in the sample located in the collection cylinder. DO NOT place hydrometers or temperature probe in the acid concentrate mixer.

Procedure		Rationale	
<b>A-Dissolution Unit Preparation</b> <i>The steps below will be verified prior to starting any rinse, batch preparation or disinfection operation.</i>			
1.	Verify the Granuflo® power cord is connected to a 115 VAC, single phase, 20 Amp, GFI-protected power supply.	1.	Verifies the Granuflo® has an adequate and safe power supply.
2.	Verify that the Dissolution Unit Drain Hose is connected to a floor drain and secondary drain line valve is open.	2.	Subsequent rinsing steps will require flow into a floor drain.  Note: Some Drain hose lines are hard plumbed.





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3.	Verify dialysis quality water valve that supplies the Granuflo® is turned "on".	3.	Subsequent rinsing and dissolution steps require the use of dialysis quality water.
4.	Verify Transfer Line is connected to the top of Dissolution Unit Tank.	4.	Closes open end of Transfer Line and prevents inadvertent contamination.
5.	Verify Power Switch is in the ON position.	5.	Subsequent steps require the Power Switch be ON in order to operate the Granuflo®.
<p style="text-align: center;"><b>B-Rinse Cycle</b></p> <p><i>A Rinse Cycle must be performed:</i></p> <ul style="list-style-type: none"> <li>• <i>Following any Disinfection Cycle (Disinfection Cycle is described in a separate procedure)</i></li> <li>• <i>Immediately before preparing a batch of acid concentrate having a different formulation than the preceding batch.</i></li> <li>• <i>To avoid bacterial growth in the Granuflo® and 1 micron filter, a Dissolution Cycle will immediately follow a Rinse Cycle.</i></li> </ul>			
1.	Verify the Tank Access Port Lid is closed.	1.	Prevents inadvertent leakage/spraying during rinse cycle operations.
2.	Press the rinse START or HOLD button.	2.	This step initiates the Rinse Cycle.
3.	While the RECIRCULATE lamp is lit, remove the Small Access Port and check the Spray Ball for rotation.	3.	The Spray Ball must rotate in order to adequately rinse the interior of the Dissolution Unit Tank.
4.	If the Spray Ball is rotating, replace the Small Access Port and allow the cycle to continue.	4.	After verifying Spray Ball rotation, the Small Access Port must be replaced to prevent inadvertent leakage/spraying during rinse cycle operations.
5.	If the Spray Ball is stationary, push the PAUSE or STOP button and contact Biomedical Services.	5.	Biomedical Services will need to replace or repair Spray Ball to provide appropriate rinsing.
6.	Once the recirculation cycle is complete, the system will automatically go to DRAIN.	6.	This is normally a ten (10) minute time cycle.



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7.	System will automatically repeat the Rinse Process. When the second Rinse Cycle is finished, the rinse CYCLE COMPLETE light will turn on and the Drain Valve will remain open, allowing any residual rinse water to go down the drain.	7.	
<b>C-Dissolution Cycle</b> <b>Prior to a Dissolution Cycle:</b> <ul style="list-style-type: none"> <li>Verify Rinse Cycle has been performed if preparing a batch of acid concentrate having a different formulation than the preceding batch.</li> </ul>			
1.	Complete PART 1 of Granuflo® Batch Production Record.	1.	Initiates appropriate documentation process for the batch that is due to be mixed.
2.	Verify and document on PART 2 of the Granuflo® Batch Production Record that all empty Granuflo® packets from previous mixing procedures have been properly discarded (clear of the Dissolution Tank).	2.	Verifies that information from the packets used for previous batches is not inadvertently transferred to the Granuflo® Batch Production Record.  This step and subsequent documentation will be made on PART 2 of the Granuflo® Production Record.
<b>NOTE:</b> Verify and document the 1 micron filter is in place.			
3.	Document whether a Rinse Cycle was done and if yes, the date the rinse cycle was performed.	3.	A Rinse Cycle must be performed following any Disinfection Cycle or when the formulation being mixed is different than the preceding batch.
4.	Verify the Dissolution Tank is empty then CLOSE the secondary drain line valve.	4.	The Dissolution Tank must be empty at the start of the Dissolution Cycle.
5.	Press the Granuflo® Mixer START or HOLD Button.	5.	Begins the initial fill cycle.
6.	While tank fills, obtain eight (8) boxes of Granuflo® powder. <b>CAUTION:</b> Be certain the same <b>Catalog Number</b> is on all eight (8) boxes. Document the Granuflo® Catalog powder lot numbers.	6.	Verifies the correct formulation of the concentrate batch being mixed.



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7.	Operator and Licensed Nurse must compare Catalog Number on Granuflo® boxes to verify they are the same and then document on the Granuflo® Batch Production Record where indicated.	7.	Verifies and documents that the type and formulation numbers are correct on all boxes before proceeding.
8.	Label Dissolution Tank with type of concentrate to be prepared.	8.	Identifies solution being mixed in tank.
9.	When the ADD GRANULES indicator flashes, verify that the Dissolution Tank is approximately half full of water.	9.	Verifies that initial filling provides the appropriate volume of water for dissolving the Granuflo® Dry Acid Powder.
10.	Wash hands and then put on PPE.	10.	PPE are needed for protection from dust and dry acid in Granuflo® powder.
11.	Remove lid and add the Granuflo® Dry Acid Powder to the Dissolution Tank.	11.	Starts the initial mixing cycle for Dry Acid.
12.	Carefully dry Upper Level Sensor with a clean soft cloth.	12.	Verifies that the final Upper Level Fill Control operates appropriately.
13.	Replace lid and press the START or CONTINUE/STEP button.	13.	Prevents inadvertent leakage/spraying during subsequent steps.
14.	The mix operation will continue automatically for approximately 35 minutes. At cycle completion, the TRANSFER light will flash.	14.	System automatically proceeds through a timed series of steps until it reaches the TRANSFER light flashes. Refer to Operator's Manual for complete listing of steps.
15.	Open the Tank Access Port Lid and visually confirm that all powder has been dissolved, the mixer will be in idle mode with the transfer light flashing or you will need to press STOP. Document dissolution is complete.	15.	A visual check is needed to positively confirm that all powder has been dissolved.
16.	Disconnect the Transfer Line from the top of the Dissolution Tank and hold over the Residual Solution Bucket.	16.	The Transfer Line and Filter Housing are not rinsed during the RINSE CYCLE. This step fills the transfer line and filter housing with prepared solution.



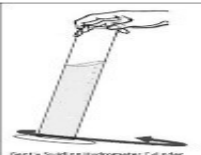
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17.	Rotate ball valve located on the side or toward the back of filter housing $\frac{1}{4}$ turn clockwise to rinse transfer line.	17.	Opening the valve allows solution to flow through the transfer line.
18.	Press the START button.	18.	Pressing the START button initiates the Solution Transfer operation.
19.	Flush approximately 3.5 gallons of solution to the Residual Solution Bucket., then press PAUSE or STOP button and close ball valve. Do not dispose of the solution in the Residual Solution Bucket. Hold this solution for neutralization. Refer to <i>Acid Concentrate Neutralization and Disposal Procedure – Small Batch</i> .	19.	Replaces any solution from previous procedures with freshly mixed solution and collects the appropriate volume of rinse solution for proper disposal.





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20.	<p>With Licensed Nurse present, collect a sample of the mixed concentrate solution from the transfer hose. Place the transfer hose in the graduated cylinder slowly opening the TRANSFER NOZZLE valve and allowing the solution to flow down the side of the cylinder to minimize bubbles by gently swirling the cylinder. <i>See figure 1.</i></p> <p>Place the thermometer probe into the graduated cylinder containing the concentrate solution to be tested and observe the temperature reading. Place a hydrometer in the graduated cylinder and observe the specific gravity reading.</p> <p><b>IMPORTANT – DO NOT PLACE A HYDROMETER IN THE DISSOLUTION TANK AT ANY TIME.</b></p>	20.	<p>Allows for the appropriate personnel to verify that proper steps are followed. <i>Figure 1.</i></p>  <p>The value observed on the scale of the hydrometer is the specific gravity of the solution measured within a specific temperature range. The 'hydrometer reading' is the specific gravity of the solution being checked.</p> <p>The hydrometer contains lead and, if broken, will contaminate the Dissolution Tank.</p>
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# Granuflo Concentrate Mixer Procedures

Specific Gravity Ranges 1:44 PROPORTIONING							
Catalog Number		17°C to 21°C		22°C to 26°C		27°C to 31°C	
		Low	High	Low	High	Low	High
1K	OFD1251-3B	1.191	1.203	1.188	1.200	1.186	1.198
	OFD2201-3B	1.191	1.203	1.189	1.201	1.187	1.199
2K	OFD2231-3B	1.192	1.204	1.190	1.202	1.187	1.199
	OFD2251-3B	1.192	1.204	1.190	1.202	1.188	1.200
3K	OFD2301-3B	1.193	1.205	1.191	1.203	1.189	1.201
	OFD3201-3B	1.193	1.205	1.191	1.203	1.188	1.200
	OFD3231-3B	1.194	1.206	1.191	1.203	1.189	1.201
	OFD3251-3B	1.194	1.206	1.192	1.204	1.189	1.201
	OFD3301-3B	1.195	1.207	1.193	1.205	1.190	1.202

Minimum Thermometer Specifications: Temperature range 25° C +/- 5°C (68° to 86° F) and accuracy +/- 1°C (3.6 °F)

Note: When using the new GranuFlo® Dry Acid Specific Gravity Tables and a thermometer that measures a temperature to the nearest 0.1°C, use the following table to determine the correct acceptance criteria (column):

If the Indicated/Measured Temperature falls between:	16.5°C and 21.4°C	21.5°C and 26.4°C	26.5°C and 31.4°C
Use the following column in the Specific Gravity table:	*17°C to 21°C*	*22°C to 26°C*	*27°C to 31°C*



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21.	Using the chart provided review the acceptable limits for the specific gravity based on formulation and temperature of the concentrate. Document the hydrometer and temperature reading on the Granuflo® Batch Production Record where indicated. Be certain that the Licensed Nurse has observed both of the tests, documentation of tests result and the specific gravity acceptable limits.	21.	The appropriate personnel verify that proper procedures were performed and that the appropriate results were accurately documented.
22.	After completing documentation of the hydrometer and temperature reading, both the Operator and Licensed Nurse must sign the Granuflo® Batch Production Record where indicated.	22.	By signing the Batch Production Record, both the Operator and Licensed Nurse acknowledge that hydrometer check was properly performed and documented.
23.	If the hydrometer reading is not within the acceptable range, do not transfer and do not use the solution. Notify the Facility Administrator and Biomed Team. Place a DO NOT USE label on the Dissolution Tank.	23.	If the hydrometer reading for the solution is not within the acceptable range, the mixed solution may not have the correct composition and must not be used.  The Biomed Team will be responsible for verifying appropriate disposal of the large batch non-transferrable solution.
24.	If the hydrometer reading is within the acceptable range, continue following the appropriate transfer process steps below.	24.	
25.	After completing documentation of hydrometer reading, place the solution from the graduated cylinder into the Residual Solution Bucket. Rinse the graduated cylinder and hydrometer with RO water and air dry for future use.	25.	Concentrated solution can only be discarded in the Residual Solution Bucket.



# Granuflo Concentrate Mixer Procedures

<b>D-Solution Transfer to Acid Concentrate Storage Tank</b> <ul style="list-style-type: none"> <li><i>This procedure applies when entire contents of dissolution mixer are transferred to a bulk storage tank. If filling to individual containers, see following procedure.</i></li> <li><i>Do not use this procedure if the hydrometer reading is outside the acceptable range.</i></li> </ul>			
1.	If the result from the hydrometer reading is within the acceptable range, replace the Tank Access Port Lid. Make sure the Transfer Line is disconnected from the top of the Dissolution Tank.	1.	The Transfer Line and Filter Housing are not rinsed during the RINSE CYCLE. This step fills the transfer line and filter housing with prepared solution.
2.	Attach the Concentrate Transfer Hose to the appropriate Acid Concentrate Storage Tank fill port.  Note: Verify the Granuflo acid concentrate formula was just mixed. Be CERTAIN the CORRECT valve is being opened for the formula mixed!  Note: Some facilities have a set up that the acid concentrate tanks are hard plumbed and may have a secondary transfer valve, if this is applicable verify the supplemental secondary acid transfer valve is CLOSED.	2.	Provides connection between Dissolution Tank and Acid Concentrate Storage Tank.
3.	Operator and Licensed Nurse must compare Catalog Number on Batch Record and Mixer Label to Catalog Number on Acid Concentrate Storage tank to be filled; this will verify they are the same and then document on the Granuflo® Batch Production Record.	3.	Verifies and documents that the Acid Concentrate Storage is filled with the correct formulation of Acid Concentrate Solution.



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4.	Rotate ball valve on top of filter housing clockwise and press the "START" or HOLD button to start acid solution transfer into storage tank.	4.	Allows for the Acid Concentrate to be transferred into the appropriate Acid Concentrate Storage Tank.
5.	When transfer is complete, the mixer will be in idle mode or press the STOP button. Close ball valve.	5.	
6.	Disconnect the transfer line from storage tank fill port and reconnect to top of dissolution tank.	6.	
7.	Remove label from dissolution tank and file Granuflo® Batch Production Record in designated location.	7.	Removing the label from the Dissolution Tank helps avoid potential mix-ups during subsequent procedures.  Granuflo® Batch Production Records will be retained for future reference.
<b>E-Solution Transfer to Individual Concentrate Containers</b> <ul style="list-style-type: none"> <li><i>This procedure applies when the dissolution mixer is to be used as a distribution storage tank for filling individual containers. If filling bulk storage tank, see previous procedure.</i></li> <li><i>Do not use this procedure if the hydrometer reading is outside the acceptable range.</i></li> <li><i>Do not store product in mixer beyond 14 days.</i></li> </ul>			
1.	If the result from the hydrometer reading is within the acceptable range, replace the Tank Access Port Lid.	1.	<b>Note:</b> Some models will not have an idle mode therefore the CONTINUE/STEP button may need to be pressed.
2.	Disconnect the Transfer Line from the top of the Dissolution Tank and attach the Transfer Line to the Transfer Nozzle.	2.	Attaching the Transfer Nozzle will allow filling individual concentrate containers.
3.	Place the Transfer Nozzle into the opening of an individual container.	3.	Provides connection between Dissolution Tank and individual concentrate container to be filled.
4.	Turn the Ball Valve on the Transfer Nozzle clockwise ¼ turn. Press the START button, if applicable.	4.	Initiates flow from the Dissolution Tank to the individual concentrate container.





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5.	Once the manual transfer has been completed and the individual containers are filled, close Transfer Nozzle Ball Valve, then press the PAUSE or STOP button.	5.	
6.	Properly dispose of all empty Granuflo® packets.	6.	Verifies that information from the packets used for the current batch is not inadvertently transferred to the Granuflo® Batch Production Record during the next Mixing Procedure.
7.	When Dissolution Tank is empty, remove label from tank and file Granuflo® Batch Production Record in designated location.	7.	Removing the label from the Dissolution Tank helps avoid potential mix-ups during subsequent procedures.  Granuflo® Batch Production Records will be retained for future reference.

# Questions

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