



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type: New Item Final VersionDate: 8/15/23

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																		
Company Name: Monaghan Medical Corporation Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): K181649 Medical Device Class, if applicable: Class II without exemptions DUNS: 056332380 Proprietary Name (If Applicable) and Established Name: AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber - Medium Mask Selling Unit NDC: UDI Description: AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber with Medium, Yellow Mask for use with either Metered Dose Inhalers or Soft Mist Inhalers Active Ingredient(s): URL for Additional Product Information: https://www.monaghanmed.com/product/aerochamber-plus-flow-vu-avhc/ Address: 153 Industrial Boulevard City: Plattsburgh Key Contact: Lisa Badura Phone Number: (262) 433-8319 Product Therapeutic Classification: NVP Application: Med Device Unit of Use NDC: CVX Code: UPC: 604351502123 MVX Code: State: NY Zip: 12901 Email: lisa.badura@monaghanmed.com Fax: (518) 561-5660				a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text"/> Avoid Excessive Heat – above 40° C (>104° F) Other Temperature Range Requirement <input type="text"/> Storage and operating range 41° F–104° F (5° C–40° C) at 15 to 95% relative humidity Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text"/> No Is this product to be shipped to customers on dry ice? <input type="text"/> No b. Contact for temperature excursion questions: Name: <input type="text"/> Number: <input type="text"/> Group E-mail: <input type="text"/> c. Special regulations for product in any states? <input type="text"/> No Special returns requirements for this product? <input type="text"/> No d. Store product (unit of sale) upright? <input type="text"/> No Protect product (unit of sale) from light? <input type="text"/> No e. Shelf life: <input type="text"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																		
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																		
The product is? a legend device? <input type="text"/> Yes if yes, enter class # <input type="text"/> Class II a product kit? <input type="text"/> No if yes, list NDCs of component parts <input type="text"/> reverse numbered? <input type="text"/> No co-licensed? <input type="text"/> No latex-free? <input type="text"/> Yes preservative-free? <input type="text"/> Yes correctional institution block? <input type="text"/> No opioid? <input type="text"/> No Cannabinoid? <input type="text"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> If Unit Dose, indicate NDC here: <input type="text"/> Is the Product... <input type="text"/> Direct And Drop-Ship Is the Product... <input type="text"/> Neither Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> None Country of Origin <input type="text"/> USA Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> Yes Size: <input type="text"/> 1 Strength: <input type="text"/> Dosage Form: <input type="text"/> Product Shape: <input type="text"/> Cylinder Product Color: <input type="text"/> Orange Product Imprint: <input type="text"/>																																						
FOR GENERIC DRUG PRODUCTS																																						
I. Orange Book Rating: <input type="text"/> II. Generic Equivalent to What Brand?: <input type="text"/> <input type="text"/> Authorized Generic *If Authorized Generic, other section fields are not applicable																																						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																						
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Is product exempt from DSCSA? <input type="text"/> If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text"/> Is product sold by manufacturer's exclusive distributor? <input type="text"/> Has FDA granted waiver/exception/exemption for product? <input type="text"/> If yes, attach documentation from FDA. <input type="text"/> GLN: <input type="text"/> GCP: <input type="text"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/>																																						
GTIN AND HIBCC PRODUCT INFORMATION																																						
<table border="1"><thead><tr><th>Saleable Unit of Measure</th><th>Saleable Quantity</th><th>HIBCC</th><th>GTIN-14</th><th>Unit of Use GTIN-14</th></tr></thead><tbody><tr><td><input checked="" type="checkbox"/> Item/Each</td><td>1</td><td></td><td>00604351501126</td><td></td></tr><tr><td><input type="checkbox"/> Box/Carton/Bundle/Inner Pack</td><td></td><td></td><td></td><td></td></tr><tr><td><input type="checkbox"/> Case</td><td></td><td></td><td></td><td></td></tr><tr><td><input type="checkbox"/> Pallet</td><td></td><td></td><td></td><td></td></tr></tbody></table>								Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	<input checked="" type="checkbox"/> Item/Each	1		00604351501126		<input type="checkbox"/> Box/Carton/Bundle/Inner Pack					<input type="checkbox"/> Case					<input type="checkbox"/> Pallet										
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14																																		
<input checked="" type="checkbox"/> Item/Each	1		00604351501126																																			
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack																																						
<input type="checkbox"/> Case																																						
<input type="checkbox"/> Pallet																																						
ORDER INFORMATION																																						
Unit of Sale <input checked="" type="checkbox"/> Bottle <input checked="" type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In <input type="text"/> What is the NDC selling unit? <input type="text"/> 1 Box of 1 Valved Holding Chamber (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text"/> Yes If Yes, how many of which package type? <table border="1"><thead><tr><th></th><th>1</th><th>Each</th></tr></thead><tbody><tr><td></td><td></td><td>Inner/Carton/Pack</td></tr><tr><td></td><td>12</td><td>Case</td></tr></tbody></table>									1	Each			Inner/Carton/Pack		12	Case																						
	1	Each																																				
		Inner/Carton/Pack																																				
	12	Case																																				
PHARMACY ORDER / BILL UNIT																																						
Rec. sell unit to customer? <input type="text"/> 1 Each Rx billing unit to pharmacy: <input type="text"/> 1 Each (Write-in, e.g. 1 Vial) <input type="text"/> Gram <input type="text"/> Milliliter																																						
ITEM AND PACKING INFORMATION																																						
<table border="1"><thead><tr><th rowspan="2">Item/Each:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cube)</th><th rowspan="2">Saleable # Pieces</th></tr><tr><th>Depth</th><th>Width</th><th>Height</th></tr></thead><tbody><tr><td>Box/Carton/Bundle/Inner Pack:</td><td>0.067</td><td>7.375</td><td>3.375</td><td>3.625</td><td>90.228516</td><td>1</td></tr><tr><td>Case:</td><td>3.381</td><td>15</td><td>11.125</td><td>7</td><td>1168.125</td><td>12</td></tr><tr><td>Pallet:</td><td>237.36</td><td>48</td><td>40</td><td>47</td><td>90240</td><td>720</td></tr></tbody></table>								Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/Carton/Bundle/Inner Pack:	0.067	7.375	3.375	3.625	90.228516	1	Case:	3.381	15	11.125	7	1168.125	12	Pallet:	237.36	48	40	47	90240	720
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces																																
		Depth	Width	Height																																		
Box/Carton/Bundle/Inner Pack:	0.067	7.375	3.375	3.625	90.228516	1																																
Case:	3.381	15	11.125	7	1168.125	12																																
Pallet:	237.36	48	40	47	90240	720																																
COST INFORMATION																																						
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text"/> \$49.04 As of date: <input type="text"/> Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>																																						
WHOLESALE USE ONLY:																																						
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. *Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: <input type="text"/> Lisa Badura																																						



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?

No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Is the product a CA Prop 65 carcinogen?

No

Is the product a CA Prop 65 reproductive toxicant?

No

Does the product label bear a CA Prop 65 warning?

No

c. Contact Hazard?

No

d. Does this product require special clean-up instructions?

No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

No

(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

No

Is this product regulated for shipment by IATA?

No

(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

No

Is the product restricted for air shipment? If so, indicate restriction:

No

☐ Passenger

☐ Cargo

☐ Passenger & Cargo

Is this a reportable quantity?

No

RQ Threshold:

Is this a marine pollutant?

No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ No (if yes, identify method below)

☐ Limited Quantity

☐ Consumer Commodity, ORM-D

☐ Small Quantity (49 CFR 173.4)

☐ Special Permit; DOT-SP

☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?

No

Controlled Substance Code

Controlled by State(s)?

No

Listed Chemical (List I or II)

No

ARCOS Reportable?

No

If yes, indicate which:

Schedule No.

Is it a scheduled listed chemical product?

No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Yes

Restricted to retail pharmacy only:

No

Restricted to hospital, clinics, and physician offices only:

No

Restricted from US territories? (explain in comments)

No

Comments:

SDS Hazard Classification

☐ Organic

☐ Inorganic

☐ Steroid/Androgen

☐ Corrosive

☐ Oxidizer

☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

No

Limited Distribution Requirement

No

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

No

Supplier Manages REMS registry exclusively:

No

Wholesale distributor support:

No

Provider Name:

Phone:

Site Enrollment Number assigned

DEA #:

by Supplier:

NCPDP#:

NPI #:

Comments

Registry:

No

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

(518) 561-7330

Is product returnable for credit:

Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

No

If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing																													
<p>Purchase orders may be accepted by:</p> <table border="0"><tr><td>a. EDI</td><td><input type="checkbox"/></td><td>Yes</td><td>Fax Number:</td><td>(518) 561-5660</td></tr><tr><td>b. Autofax</td><td><input type="checkbox"/></td><td>Yes</td><td>Fax Number:</td><td>(518) 561-5660</td></tr><tr><td>c. Fax</td><td><input type="checkbox"/></td><td>Yes</td><td>Phone No.:</td><td></td></tr><tr><td>d. Phone only</td><td><input type="checkbox"/></td><td>No</td><td>Site Address:</td><td></td></tr><tr><td>e. Supplier Web Site only</td><td><input type="checkbox"/></td><td>No</td><td></td><td></td></tr></table> <p>Minimum Order Quantity: <input type="text" value="12"/> Units</p> <p>Supplier's Customer Service Number: (518) 561-5660</p> <p>Contracted 3PL company / contact #:</p> <table border="0"><tr><td>Name:</td><td><input type="text"/></td></tr><tr><td>Phone:</td><td><input type="text"/></td></tr></table>	a. EDI	<input type="checkbox"/>	Yes	Fax Number:	(518) 561-5660	b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	(518) 561-5660	c. Fax	<input type="checkbox"/>	Yes	Phone No.:		d. Phone only	<input type="checkbox"/>	No	Site Address:		e. Supplier Web Site only	<input type="checkbox"/>	No			Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text" value="12:00 PM (Noon)"/> Eastern</p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text" value="10"/> Days</p> <p>Ships same day for next day receipt: <input type="text" value="No"/></p> <p>Ships for second day receipt: <input type="text" value="No"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text" value="Yes"/></p>
a. EDI	<input type="checkbox"/>	Yes	Fax Number:	(518) 561-5660																										
b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	(518) 561-5660																										
c. Fax	<input type="checkbox"/>	Yes	Phone No.:																											
d. Phone only	<input type="checkbox"/>	No	Site Address:																											
e. Supplier Web Site only	<input type="checkbox"/>	No																												
Name:	<input type="text"/>																													
Phone:	<input type="text"/>																													
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text" value="Yes"/></p> <p>Drop Ship service fee billed with each order: <input type="text" value="Yes"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text" value="Yes"/></p> <p>Comments: Customer to pay for any expedited shipping fees; billed with each order</p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text" value="Yes"/></p> <p>PO Receipt cut off time: <input type="text" value="10:00 AM"/> Eastern</p> <p>Days of week overnight is available:</p> <table border="0"><tr><td><input checked="" type="checkbox"/></td><td>Monday</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Tuesday</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Wednesday</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Thursday</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Friday</td></tr></table> <p>Priority Overnight receipt available: <input type="text" value="Yes"/></p> <p>PO Receipt Cut off time: <input type="text" value="10:00 AM EST"/></p> <p>Saturday Overnight receipt available: <input type="text" value="No"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table border="0"><tr><td>Phone:</td><td><input type="text"/></td><td>Phone #:</td><td><input type="text"/></td></tr><tr><td>Fax:</td><td><input type="text"/></td><td>Fax #:</td><td><input type="text"/></td></tr><tr><td>EDI:</td><td><input type="text"/></td><td></td><td></td></tr></table> <p>Overnight Fees apply: <input type="text" value="Yes"/></p> <p>Other fees apply: <input type="text" value="Yes"/></p>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	Phone:	<input type="text"/>	Phone #:	<input type="text"/>	Fax:	<input type="text"/>	Fax #:	<input type="text"/>	EDI:	<input type="text"/>									
<input checked="" type="checkbox"/>	Monday																													
<input checked="" type="checkbox"/>	Tuesday																													
<input checked="" type="checkbox"/>	Wednesday																													
<input checked="" type="checkbox"/>	Thursday																													
<input checked="" type="checkbox"/>	Friday																													
Phone:	<input type="text"/>	Phone #:	<input type="text"/>																											
Fax:	<input type="text"/>	Fax #:	<input type="text"/>																											
EDI:	<input type="text"/>																													
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text" value="Yes"/></p> <p>Restricted to retail pharmacy only: <input type="text" value="No"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text" value="No"/></p> <p>Restricted from US territories? (explain in comments) <input type="text" value="No"/></p> <p>Comments: <input type="text"/></p>																														
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: (518) 561-7330</p> <p>Is product returnable for credit: <input type="text" value="Yes"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text" value="No"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>																													
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text" value="No"/></p> <p>Is product order for restocking purposes? <input type="text" value="Yes"/></p>																													