HDMA Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:	New Item		Final Version		Date:	3/8/16

PRODUCT INFORMATION

Company Name:	AvKARE, INC	Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	202128	
Rx Product/Proprietary Name:	Potassium Chloride ER 10mEq (750mg) Capsule	
NDC:	50268-0671-13	UPC:
CVX Code:		MVX Code:
Description:	Potassium Chloride ER 10mEq (750mg) Capsule	
Active ingredients:		
URL for Additional Product Information:		
Address:	615 North First Street	Address 2:
City:	Pulaski	State: TN Zip: 38478
Key Contact:	Kim Bracey	Email: kbracey@avkare.com
Phone Number:	931-908-0028	Fax: 931-292-6229

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:	AB	II. Brand Name: potassium chloride
III. Generic Equivalent for Brand:	potassium chloride	

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	DUNS: 796560394
Is product exempt from DSCSA?	No	
If yes, select exemption:		
Other exemption - Write in:		
Is product repackaged?	Yes	If Yes, was original product purchased direct from mfr? Yes
Is product sold by manufacturer's exclusive distributor?	Yes	
Are any waivers granted for product ID/barcode?	No	If yes, attach documentation from FDA

ADDITIONAL PRODUCT INFORMATION

Is the Product...	Direct and Drop Ship
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.? (incl. N for non-narcotic)	
Controlled Substance Code:	
Hazardous Material/Cytotoxic Agent?	No
Is Item...	Unit Dose
If Unit Dose, is item bar coded to unit dose for hospital scanning?	Yes
Is it reverse numbered?	No

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
	Bottle	30 pills per box
x	Box/Carton	10 boxes per case
	Ampule	(Write-in, e.g. 1 Box of 10 Vials)
	Glass	
	Tube	Minimum order quantity? Yes
	Vial Liquid Sgl	
	Vial Liquid Multi	If Yes, how many of which package type?
	Vial Powder Sgl	Each
	Vial Power Multi	Inner/Carton/Pack
	Other: Write In 1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	
	(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:	
	Each
	Gram
	Milliliter

Other Product Information

Size/Strength/Form:	30ct/750mg/capsule
Product Shape:	capsule
Product Color:	blue
Product Imprint:	amneal;542

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

	I. Freezer – between -25 and -10 C (-13° – 14° F)
	II. Cold – between 2 and 8 C (36° – 46° F)
	III. Cool – between 8 and 15 C (46° – 59° F)
x	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
	V. Avoid Excessive Heat – above 40 C (>104° F)
	VI. Other Temperature Range Requirement (write in)
	VII. No Requirement

b. Contact for temperature excursion questions:

Name:	
Number:	
Is this product to be shipped to customers on ice?	
Is this product to be shipped to customers on dry ice?	

c. Special regulations for product in certain states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life: ____ Months

Initial shelf life at launch (if different): ____ Months

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	0.3	2.00"	4.25"	3.25"		1
Box/Carton:						
Case:	3	9.50"	4.50"	6.50"		10
Pallet:						
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale
$119.97	$29.21	

As of date: 3/8/16

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

*Please provide any additional information on page 2.   See new p. 3 for Designated Drop Ship Only.   Signature: