© August 2014	August 2014 Introduction Type: New Item							x F	inal Version		Date:			
PRODUCT INFORMATION									SPECIAL HA	NDLING AND S	TORAGE REQU	JIREMENTS*		
Company Name: AvKARE, Inc Application: ANDA						4	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device: 87-946								I. Freezer – between -25 and -10 C (-13° – 14° F)						
Rx Product/Proprietary Name: Isosorbide Dinitrate 30mg Tablet 100ct							II. Cold – between 2 and 8 C (36° – 46° F)							
NDC: 42291-0350-01 UPC: MVX Code:							III. Cool – between 8 and 15 C (46° – 59° F)							
CVX Code:								x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
Description: Isosorbide Dinitrate 30mg Tablet 100ct								allows for excursions between 15 and 30 C (59° – 86° F)						
Active inwestigates							V. Avoid Excessive Heat – above 40 C (>104° F)							
Active ingredients:							VI. Other Temperature Range Requirement (write in)							
URL for Additional Product Information:									II. No Requirer	ment			J	
Address: 615 North First Street Address 2:							b. Contact for temperature excursion questions:							
City:	Pulaski					8478		Name:						
Key Contact:	Kim Bracey		Email:	kbracey@avkare.com				Number:						
Phone Number:	931-908-0028	Fax:	931-292-6229)			Is this produ	ct to be shipp	ed to custome	rs on ice?				
FOR GENERIC DRUG PRODUCTS								Is this produ	ıct to be shipp	ed to custome	rs on dry ice?			
I. Orange Book Rating: AB II. Brand Name: Isordii													_	
III. Generic Equivalent for Brand: Isosorbide Din								c. Special reg	ulations for pr	roduct in certa	in states?			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							Special retu	rns requiremen	its for this prod	duct?				
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394							·	·				_		
Is product exempt from DSCSA? No			_				d. Store product (unit of sale) upright?							
If yes, select exemption:							Protect pro	oduct (unit of	sale) from ligh	it?				
Other exemption - Write in:												=		
Is product repackaged? Yes If Yes, was original product purchased direct from mfr? Yes								e. Shelf life:		Months			_	
Is product sold by manufacturer's exclusive distributor? Yes									Initial shelf I	ife at launch (if different):		Months	
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA														
ADDITIONAL PRODUCT INFORMATION									ITEM AND	PACKING INF	ORMATION			
Is the Product	Direct and Drop Ship			ORDER INFOR				Weight Lbs.		ensions (US m		Volume	# Pieces:	
Legend Device?		No No	Unit of Sale		DC selling unit?			TTO I GITT ELLO	Depth	Height	Width:	(Cube)	# T TOOGO.	
State Control? ARCOS reportable?		No	x Bottle Box/Carton	1 Bottle of 10	0 Tablets		Item:	45.5g	3.645"	4.50"	2.25"		1	
Co-Licensed?		No	Ampule	(Write-in e a	. 1 Box of 10 Vials)		Box/							
Controlled Substance?		140	Glass	(**************************************	. I Dox of To Vidio)		Carton:							
Schedule No.?			Tube	Minimum ord	er quantity?	Yes	Case:	7	17.25"	7.75"	8.25"		72	
(incl. N for non-narco			Vial Liquid Sgl				ouse.	,	17.20	7.70	0.20		12	
Controlled Substance Controlle			Vial Liquid Multi Vial Powder Sql	If Yes, how n	nany of which package Each	type?	Pallet:							
Hazardous Material/Cyto	otoxic Agent?		Vial Powder Sqi Vial Power Multi	-	Inner/Carton/Pack			Case:		l	1	1	l .	
Is Item			Other: Write In	1	Case		UPC:	Carton:						
If Unit Dose, is item bar	coded to unit dose for													
hospital scanning?				PHARMACY ORDER / BILL UNIT Other Product Information						COST INFO	ORMATION			
Is it reverse numbered?			Rec. sell unit to custor	ner?	Size/Strength/Form:			Regular Cost Per Unit of		Invoice Cost (WAC) (\$)		Federal Excise Tax Per		
					100ct/30mg/Tablet			Sale (\$)		INVOICE COST (VVAC) (\$)		Unit of Sale		
WHOLESALER USE ONLY:			(Write-in, e.g. 1 Vial)		Product Shape: round									
Vendor #:			Rx billing unit to pharmacy:		Product Color: blue		\$155	5.98	\$12	\$124.79				
Whsl. Code #:			Each		bido									
Fineline Code:				Milliter							7/5/16			
			Milliliter		_					As of date:	773/10	_		
	A	tach copy of SA	AFETY DATA SHEET (SDS)	or non hazard l	etter, PACKAGE INSE	RT, LABEL A	ND PHOTO	OF PRODUCT PA	CKAGING and		113/10			
					etter, PACKAGE INSER		ND PHOTO	OF PRODUCT PA	ACKAGING and		773/10			