

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

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

						Introduction Type	: New Item	[	Final Version			Date:	6/14/2	2024
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAND	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Novadoz Pharmad	ceuticals LLC				Application	: ANDA	a Temperatur	e - Indicate the USP temper	rature range for the	nis product			
Application Number for NDA/ANI			:e)·	21	3879	7.ppouo				Controlled Room -		nd 25 C (68	, – 77° F)	
Medical Device Class, if applical								1		-		(		
DUNS:	081109687				1				Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Dabiga	atran Etexilate Capsules 150	mg 60's					(write in)					
	72205-204-60		Unit of Use NDC:	_ <b>J</b>		UPC: 37	2205204607	1	Notes					
UDI			CVX Code:			MVX Code:		†						
Description: White to light yellow colored blend compressing granular powder, pellets in size '0' Capsule having White Opaque cap imprinted 'MD' and White Opaque Is this product to be shipped to customers on ice? No														
Description.	body imprinted '15		pressing grandial powder, pr	311013 111 3120 0	Capsule naving	g vville Opaque cap iiii	orinted IVID and Write Opaque		Is this product to be shipped				No	
Active Ingredient(s):	,							·	io uno product to be empres	to odotomoro on o	y 100 .			
b. Contact for temperature excursion q								temperature excursion que	stions:					
URL for Additional Product Inform	nation:								Name:					
Address:	20 Duke Road					Address 2: St	ite A		Number:					
City:	Piscataway				State:	NJ Z	ip: 08854		Group E-mail:					
Key Contact:					Email:	sales@novadozph	narma.com							
Phone Number:	908-360-1500				Fax:	732-902-2113		c. Special regu	ulations for product in any s	states?				
Product Therapeutic Classification	n:								Special returns requirements	for this product?				
					_			.						
	ADDITIO	ONAL PRODUCT INF	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?					
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sal	e) from light?				
a legend device?		No	Is the Product	Neither	-	Size:	60's	e. Shelf life:	• •	,			36	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (if	different):			36	Months
a product kit?		No				Strength:	150 mg							
if yes, list NDCs of			FDA Approval Status			Su eligui.				ORDER INFORM	IATION			
component parts						Dosage Form:	Capsules							
reverse numbered?						2 coago i oiiiii			Unit of Sale		What is the I		unit?	
co-licensed?			Allergens Present				-		Bottle		72205-204-60			
latex-free?		Yes				Product Shape:	Capsule shaped		x Box/Carton		(Write-in, e.c	. 1 Box of 10	Vials)	
preservative-free?		Yes				•	Mile to Political Notice		Ampule					
correctional institution block? opioid?						Product Color:	White to light Yellow		Glass Tube		Minimum or	er quantity	r [	Yes
Cannabinoid?			Country of Origin				White Opaque Cap	-	Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for		Country of Origin			Product Imprint	Imprinted 'MD' and White		Vial Liquid Sgi		If Yes, how r	nany of whi	ch nackado t	wno2
hospital scanning?	Till dose for		Is this product covered u	inder the			Opaque body imprinted		Vial Equid Multi Vial Powder Sql			Each	in package i	yper
If Unit Dose, indicate NDC here:		72205-204-60	Trade Agreements Act (T		No		'150' with black ink		Vial Power Multi			nner/Carton	/Pack	
ii oriii booo, irialoato 1150 iloro.		72200 20 1 00			110				Other: Write In			Case	. don	
			FOR GENERIC DRUG PRO	ODUCTS										
			TOR GENERIO BROOT R	550010							1			
	Authorized Generic *If Authorized Generic; other PHARMACY ORDER / BILL UNIT													
					Au	thorized Generic *If	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I Orango Book Batings	ΛR			=	Au		Authorized Generic, other ction fields are not applicable	Pac sall unit t		ARMACY ORDER		it to phorms	011	
	AB	Pradava			Au			Rec. sell unit t	to customer?	ARMACY ORDER	Rx billing un		су:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Pradaxa			Au			1	to customer? I bottle of 60ct	ARMACY ORDER		Each	ıcy:	
			.Y CHAIN SECURITY ACT (	DSCSA) INFOR					to customer? I bottle of 60ct	ARMACY ORDER	Rx billing un	Each Gram	ісу:	
			Y CHAIN SECURITY ACT (	DSCSA) INFOR				1	to customer? I bottle of 60ct	ARMACY ORDER	Rx billing un	Each	icy:	
	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR				1	to customer? I bottle of 60ct 1 Vial)	ARMACY ORDER	Rx billing un	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPLY	•	DSCSA) INFOR	RMATION	se		1	to customer? I bottle of 60ct 1 Vial)		Rx billing un	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Branch Does supplier meet DSCSA definit Is product exempt from DSCSA?	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION	8904159670843		1	to customer? I bottle of 60ct 1 Vial)	AND PACKING IN	Rx billing un	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Brai	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:	se		1	to customer? I bottle of 60ct 1 Vial)	AND PACKING IN	Rx billing un x	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA?  If yes, select exemption:	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	GLN:	8904159670843	ction fields are not applicable	1	to customer?   bottle of 60ct 1 Vial)   ITEM   Weight Lbs.	AND PACKING II Dimensi Depth	Rx billing un x  NFORMATION ons (US msm Width	Each Gram Milliliter	Volume (Cube)	Pieces
II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: tion of manufactur	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN:	8904159670843 89041596 iginal product purcha	ction fields are not applicable	(Write-in, e.g.	to customer? I bottle of 60ct 1 Vial)	AND PACKING IN	Rx billing un x NFORMATION ons (US msm	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Brain Does supplier meet DSCSA definit is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: is product repackaged?	nd?: tion of manufactur	DRUG SUPPL'	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	8904159670843 89041596 iginal product purcha	ction fields are not applicable	(Write-in, e.g.	to customer? I bottle of 60ct 1 Vial)  ITEM  Weight Lbs.	AND PACKING IN  Dimensi Depth  2.28	Rx billing un x  NFORMATION Ons (US msm Width 2.28	Each Gram Milliliter es.) Height	Volume (Cube) 24.54	Pieces 1
II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	nd?: tion of manufactur exclusive distribu	DRUG SUPPL'	Yes No No	DSCSA) INFOF	GLN: GCP: If yes, was or direct from m	8904159670843 89041596 iginal product purcha	ction fields are not applicable	(Write-in, e.g. 1	to customer?   bottle of 60ct 1 Vial)  ITEM  Weight Lbs.  0.249	AND PACKING II Dimensi Depth	Rx billing un x  NFORMATION ons (US msm Width	Each Gram Milliliter	Volume (Cube)	Pieces
II. Generic Equivalent to What Brain Does supplier meet DSCSA definition is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?: tion of manufactur exclusive distribu	DRUG SUPPL' rer?  utor? roduct?	Yes No No No No		GLN: GCP: If yes, was or direct from m	8904159670843 89041596 iginal product purcha	ction fields are not applicable	(Write-in, e.g. :	to customer?   bottle of 60ct 1 Vial)  ITEM  Weight Lbs.  0.249  undle/ NA	AND PACKING IN  Dimensi Depth  2.28  NA	Rx billing un x  NFORMATION ons (US msm Width 2.28  NA	Each Gram Milliliter  ss.) Height 4.72 NA	Volume (Cube) 24.54 NA	1 NA
II. Generic Equivalent to What Brain Does supplier meet DSCSA definition is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?: tion of manufactur exclusive distribu	DRUG SUPPL' rer?  utor? roduct?	Yes No No		GLN: GCP: If yes, was or direct from m	8904159670843 89041596 iginal product purcha	ction fields are not applicable	Item/Each: Box/Carton/Bu Inner Pack: Case:	to customer? I bottle of 60ct 1 Vial)  ITEM  Weight Lbs.	AND PACKING IN  Dimensi Depth  2.28	Rx billing un x  NFORMATION Ons (US msm Width 2.28	Each Gram Milliliter es.) Height	Volume (Cube) 24.54	Pieces 1
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II. Generic Equivalent to What Brai	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re	ction fields are not applicable	Item/Each: Box/Carton/Bu Inner Pack: Case:	bottle of 60ct     bottle of 60ct     Vial)	AND PACKING IN  Dimensi Depth  2.28  NA  14.96	Rx billing un x  NFORMATION Ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter Height 4.72 NA 10.83 38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brai	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source  GTII 003	8904159670843  89041596  iginal product purcha fir? ce manufacturer for re	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bu Inner Pack: Case:	Na	AND PACKING IN  Dimensi Depth  2.28  NA  14.96	Rx billing un x  NFORMATION Ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter Height 4.72 NA 10.83 38.38	Volume (Cube) 24.54 NA 1689.84	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivale	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity  48	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re  N-14 72205204607 72205204608	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bulnner Pack: Case: Pallet:	bottle of 60ct     bottle of 60ct     Vial)	AND PACKING IN  Dimensi Depth  2.28  NA  14.96	Rx billing un x  NFORMATION Ons (US msm Width 2.28 NA 10.43 39.37	Each Gram Milliliter Height 4.72 NA 10.83 38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brai	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha fir? ce manufacturer for re	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet:	Dottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96  47.24	Rx billing un x  IFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  Iss.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivale	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity  48	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re  N-14 72205204607 72205204608	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bulnner Pack: Case: Pallet:	Dottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96	Rx billing un x  NFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  s.s.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivale	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity  48	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re  N-14 72205204607 72205204608	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bulnner Pack: Case: Pallet: Regular Cost (Note: 100 to 10	No customer?     bottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96  47.24	Rx billing un x  IFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  s.s.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivale	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity  48	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re  N-14 72205204607 72205204608	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet:	Dottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96  47.24	Rx billing un x  NFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  s.s.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brai	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  utor? roduct?  GTIN Saleable Quantity  48	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	8904159670843  89041596  iginal product purcha ffr? ce manufacturer for re  N-14 72205204607 72205204608	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bulnner Pack: Case: Pallet: Regular Cost (Note: 100 to 10	No customer?     bottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96  47.24	Rx billing un x  NFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  s.s.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivale	nd?: tion of manufactur exclusive distribu n/exemption for promerous	DRUG SUPPLY rer?  stor? roduct?  GTIN  Saleable Quantity  1  48  1440	No No No No No HIBCC	NFORMATION	GLN: GCP: If yes, was or direct from m Provide source  GTII  003  303  503	8904159670843  89041596  iginal product purcha fir? cc manufacturer for re  N-14 72205204607 72205204608 772205204602	sed Unit of Use GTIN-14	Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet: Regular Cost (National Cost (N	No customer?     bottle of 60ct	AND PACKING IN  Dimensi Depth  2.28  NA  14.96  47.24	Rx billing un x  NFORMATION ons (US msm Width 2.28  NA 10.43 39.37	Each Gram Milliliter  s.s.)  Height  4.72  NA  10.83  38.38	Volume (Cube) 24.54 NA 1689.84 71380.61	Pieces  1  NA  48  1,440



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

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant?	No No	Organic Inorganic	OS Hazard Classification  Corrosive Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard				
c. Contact Hazard?      d. Does this product require special clean-up instructions?         (If yes, attach SDS with special instructions.)      e. Does the product contain DEHP?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class			Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
		EFA Hazaidous Wasie Code.		Waste Characteristics			
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)	No	REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	No	Website OILE.					
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No				
Passenger		Limited Distribution Requirement	No				
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo		DEMO.	NI-				
Is this a reportable quantity? No RQ Threshold:		REMS Program Manager Name:	No	Phone:			
Is this a marine pollutant?		Supplier Manages REMS registry exclusively:		. Holler			
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:					
No (if yes, identify method below)  Limited Quantity		Provider Name: Site Enrollment Number assigned		DEA #: NCPDP#:			
Consumer Commodity, ORM-D		by Supplier:		NPI #:			
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Pariety:	No				
3F#		Registry:  Registry Program Contact Name:	INO	Phone:			
ADD'L STORAGE INFORMATION		Comments					
Is the Product							
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II)  ARCOS Reportable? No If yes, indicate which:	No	Contact tol. # if and just received demonstrat					
Schedule No. Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged:					
CLASS OF TRADE RESTRICTION:		Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	Cita zinik to rotamo ponoji					
Restricted to retail pharmacy only:	No	Charles and standard and standard and standard from the					
	No	Special regulations or returns requirements for this product in certain states?	No				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?	INU				
Comments:							
	SCELLANEC	DUS NOTES and/or Image of Product Barcode:					
			<u> </u>				



# **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 fo	r Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday
		Priority Overnight receipt available:
Class	of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficunt Comments:	offices only:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged:  Is product returnable for credit:  URL/Link to returns policy:  Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?