



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

Version 2024 Introduction Type:   Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> <input type="text" value="Novadoz Pharmaceuticals, LLC"/>		<b>Application:</b> <input type="text" value="ANDA"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b> Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>		Other Temperature Range Requirement (write in) <input type="text" value="NA"/>	
<b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> <input type="text"/>		<b>NDA 505(b) Type:</b> <input type="text"/>		Notes <input type="text"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>	
<b>Medical Device Class, if applicable:</b> <input type="text"/>		<b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Tofacitinib Tablets 5 mg_60's"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>		<b>b. Contact for temperature excursion questions:</b> <b>Name:</b> <input type="text" value="P. Krishna Reddy"/>	
<b>DUNS:</b> <input type="text" value="08-110-9687"/>		<b>Selling Unit NDC:</b> <input type="text" value="72205-139-60"/>		<b>Unit of Use NDC:</b> <input type="text"/>		<b>Number:</b> <input type="text" value="040-30449311"/>	
<b>UDI</b> <input type="text"/>		<b>CVX Code:</b> <input type="text"/>		<b>UPC:</b> <input type="text" value="372205139602"/>		<b>Group E-mail:</b> <input type="text" value="krishna_p@msnlabs.com"/>	
<b>Active Ingredient(s):</b> <input type="text" value="Tofacitinib Citrate"/>		<b>Product Therapeutic Classification:</b> <input type="text"/>		<b>Special regulations for product in any states?</b> Special returns requirements for this product? <input type="text" value="No"/>		<b>c. Special regulations for product in any states?</b> Special returns requirements for this product? <input type="text" value="No"/>	
<b>Description:</b> <input "m"="" and="" defects"="" free="" from="" of="" on="" one="" other="" physical="" side="" side,="" t2"="" type="text" value="Blue colored, round shaped, biconvex, film coated tablets debossed with "/>		<b>URL for Additional Product Information:</b> <input type="text"/>		<b>d. Store product (unit of sale) upright?</b> Protect product (unit of sale) from light? <input type="text" value="No"/>		<b>e. Shelf life:</b> Initial shelf life at launch (if different): <input type="text" value="48"/> Months	
<b>Address:</b> <input type="text" value="20 Duke Road"/>		<b>City:</b> <input type="text" value="Piscataway"/>		<b>State:</b> <input type="text" value="NJ"/>		<b>Address 2:</b> <input type="text" value="Suite A"/>	
<b>Key Contact:</b> <input type="text"/>		<b>Phone Number:</b> <input type="text" value="908-360-1500"/>		<b>Email:</b> <input type="text" value="Sales@novadozpharma.com"/>		<b>Zip:</b> <input type="text" value="08854"/>	
<b>Product Therapeutic Classification:</b> <input type="text"/>		<b>Address 2:</b> <input type="text"/>		<b>Fax:</b> <input type="text" value="678-608-3778"/>		<b>Product Description Information</b>	
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
<b>The product is?</b> a legend device? <input type="text" value="No"/>		<b>Is the Product... Direct-Ship Only</b> <input type="text"/>		<b>Size:</b> <input type="text" value="60's"/>		<b>Strength:</b> <input type="text" value="5 mg"/>	
if yes, enter class # <input type="text"/>		<b>Is the Product... Neither</b> <input type="text"/>		<b>Dosage Form:</b> <input type="text" value="Tablets"/>		<b>Product Shape:</b> <input type="text" value="round"/>	
a product kit? <input type="text" value="No"/>		<b>Orphan Drug Status</b> <input type="text"/>		<b>Product Color:</b> <input type="text" value="Blue"/>		<b>Product Imprint:</b> <input "m"="" and="" on="" one="" other="" side="" side"="" t2"="" type="text" value="debossed with "/>	
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		<b>FDA Approval Status</b> <input type="text"/>					
co-licensed? <input type="text" value="No"/>		<b>Allergens Present</b> <input type="text"/>					
latex-free? <input type="text" value="Yes"/>		<b>Country of Origin</b> <input type="text" value="India"/>					
preservative-free? <input type="text" value="Yes"/>		<b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="text" value="No"/>					
correctional institution block? <input type="text" value="No"/>							
opioid? <input type="text" value="No"/>							
Cannabinoid? <input type="text" value="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" value="72205-139-60"/>							
FOR GENERIC DRUG PRODUCTS							
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/>		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
<b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="XELJANZ"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/>		<b>GLN:</b> <input type="text" value="8904159670843"/>					
<b>Is product exempt from DSCSA?</b> <input type="text" value="No"/>		<b>GCP:</b> <input type="text" value="89041596"/>					
<b>If yes, select exemption:</b> <input type="text"/>		<b>If yes, was original product purchased direct from mfr?</b> <input type="text"/>					
<b>Other exemption - Write in:</b> <input type="text"/>		<b>Provide source manufacturer for repackaged product</b> <input type="text"/>					
<b>Is product repackaged?</b> <input type="text" value="No"/>							
<b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="No"/>							
<b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/>							
<b>If yes, attach documentation from FDA.</b> <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
<b>Saleable Unit of Measure</b>		<b>RFID tag(Y/N)</b>		<b>Saleable Quantity</b>		<b>HIBCC</b>	
<input type="text" value="Yes"/> Item/Each		<input type="text" value="Bottle of 60 tablets"/>		<input type="text" value="00372205139602"/>		<input type="text" value="00372205139602"/>	
<input type="text" value="NA"/> Box/Carton/Bundle/Inner Pack		<input type="text" value="NA"/>		<input type="text" value="NA"/>		<input type="text" value="NA"/>	
<input type="text" value="Yes"/> Case		<input type="text" value="48 Bottles in Case"/>		<input type="text" value="30372205139603"/>		<input type="text" value="30372205139603"/>	
<input type="text" value="Yes"/> Pallet		<input type="text" value="4416 Bottles in Pallet"/>		<input type="text" value="50372205139607"/>		<input type="text" value="50372205139607"/>	
ITEM AND PACKING INFORMATION							
		<b>Weight Lbs.</b>		<b>Dimensions (US msmts.)</b>		<b>Volume</b>	
		<b>Depth</b>		<b>Width</b>		<b>(Cube)</b>	
		<b>Height</b>		<b>Saleable #</b>		<b>Pieces</b>	
<b>Item/Each:</b>		<input type="text" value="0.104"/>		<input type="text" value="NA"/>		<input type="text" value="54"/>	
<b>Box/Carton/Bundle/Inner Pack:</b>		<input type="text" value="NA"/>		<input type="text" value="NA"/>		<input type="text" value="NA"/>	
<b>Case:</b>		<input type="text" value="6.57"/>		<input type="text" value="10.43"/>		<input type="text" value="7.28"/>	
<b>Pallet:</b>		<input type="text" value="644.41"/>		<input type="text" value="47.24"/>		<input type="text" value="36.61"/>	
		<input type="text" value="39.37"/>		<input type="text" value="36.61"/>		<input type="text" value="68088.698"/>	
		<input type="text" value="4.416"/>					
COST INFORMATION							
<b>Regular Cost</b>		<input type="text"/>		<b>WHOLESALE USE ONLY:</b>		<input type="text"/>	
<b>Invoice Cost (WAC) (\$)</b>		<input type="text" value="\$50.00"/>		<b>Vendor #:</b>		<input type="text"/>	
<b>As of date:</b>		<input type="text"/>		<b>Whsl. Code #:</b>		<input type="text"/>	
				<b>Fineline Code:</b>		<input type="text"/>	