

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014			intr	oduction Type:				x F	inal Version		Date:			
		Р	RODUCT INFORMATIO	N					SPECIAL HAN	NDLING AND S	TORAGE REQU	IREMENTS*		
Company Name: Citron Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device:			ANDA079170					I. Freezer – between -25 and -10 C (-13° – 14° F)						
Rx Product/Proprietary Name: Rosuvastatin C			Calcium Tabs 40 mg 30											
NDC: 57237-171-30			UPC: 357237171301					II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code:								x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
CVX Code: MVX Code:  Description: Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or "statins." Rosuvastatin reduces levels of "bad"						allows for excursions between 15 and 30 C (59° – 86° F)								
cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of "good" cholesterol (high-							V. Avoid Excessive Heat – above 40 C (>104° F)							
Active ingredients: Rosuvastatin Calcium Tabs									rature Range Re	` '				
· ·									(write in)	Ü	•			
URL for Additional Produ	ct Information:							v	/II. No Requirem	nent			_'	
Address:	2 Tower Center Boule	vard Suite 1101		Address 2:				b. Contact for	temperature e	xcursion quest	ions:			
City:	East Brunswick		State: NJ		<b>Zip:</b> 08816		Name: Vikram Ganesh							
Key Contact:	Kaitlin Alexander		Email: kalexander@citronpharma.com					Number: 732-917-6062						
Phone Number:	,			Fax: 732-227-1513				Is this product to be shipped to customers on ice?						
FOR GENERIC DRUG PRODUCTS							Is this product to be shipped to customers on dry ice?							
I. Orange Book Rating:	AB		II. Brand Name:	Crestor								•	•	
III. Generic Equivalent for		Rosuvastatin	2	0.00.0.				c. Special req	ulations for pro	oduct in certair	states?	No		
			ANN SECUDITY ACT (DSCSA) INFORMATION					-	-	s for this produc		No	•	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								Special retu	iris requirement	s for this produc	t:	INU	•	
Does supplier meet DSC			Yes	DUNS:	078731527									
Is product exempt from DSCSA?		No	No					d. Store prod	luct (unit of sal	e) upright?		No		
If yes, select exemptio	n:							Protect pro	oduct (unit of s	ale) from light?	•	No	_	
Other exemption - Writ	te in:													
Is product repackaged?		No	If Yes, was origin	nal product purc	hased direct from mfr	?		e. Shelf life:	24	Months				
Is product sold by manufacturer's exclusive distributor?			No						Initial abolf li	fe at launch (if	different).		Months	
				_					mittai Sneii ii	ie at iaulicii (ii	umerem).		WOITINS	
Are any waivers granted	for product ID/barcod		No	If yes, attach	documentation from I	FDA			initiai sneii ii	ie at iauncii (ii	unierentj.		Wonths	
Are any waivers granted	for product ID/barcod	e?		- •	documentation from I	FDA				PACKING INF	•		Months	
Are any waivers granted  Is the Product	for product ID/barcod	e?	No	- •		FDA		Weight I ho	ITEM AND		ORMATION	Volume		
		e?	No	ORDER INFOR		FDA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION	Volume (Cube)	# Pieces:	
Is the Product Legend Device? State Control?		e? ADDITIONAL F  No No	No PRODUCT INFORMATIO Unit of Sale  X Bottle	ORDER INFOR	RMATION NDC selling unit?	FDA	Item:	1	ITEM AND	PACKING INFO	ORMATION smts.) Width:	(Cube)	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable?		ADDITIONAL F  No No No	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton	ORDER INFORMATION What is the Market 1 Bottle of 30	RMATION NDC selling unit?	FDA	Item:	Weight Lbs.	ITEM AND Dim Depth	PACKING INFo	ORMATION smts.)			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?		NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule	ORDER INFORMATION What is the Market 1 Bottle of 30	RMATION NDC selling unit?	FDA	Box/	1	ITEM AND Dim Depth	PACKING INFO	ORMATION smts.) Width:	(Cube)	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?		ADDITIONAL F  No No No	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit?  1 Box of 10 Vials)			0.075	Dim Depth  1 10.16	PACKING INFo tensions (US m Height 3.526 3.53	ORMATION smts.) Width:  1.562 6.89	(Cube) 5.507612 247.108472	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	NO NO NO	No  Unit of Sale  x Bottle Box/Carton Ampule Glass Tube	ORDER INFORMATION What is the Market 1 Bottle of 30	RMATION NDC selling unit?  1 Box of 10 Vials)	FDA Yes	Box/	0.075	Dim Depth	PACKING INFo ensions (US m Height 3.526	ormation smts.) Width:	(Cube) 5.507612	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	Direct Ship Item	NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass	ORDER INFORM What is the M 1 Bottle of 30  (Write-in, e.g.	RMATION NDC selling unit?  1 Box of 10 Vials)	Yes	Box/ Carton: Case:	0.075 1.904 4.39	Dim Depth 1 10.16 11.22	DPACKING INFO Densions (US m Height 3.526 3.53 8.46	ORMATION smts.) Width: 1.562 6.89 7.68	(Cube) 5.507612 247.108472 728.994816	# Pieces: 1 24 48	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti	Direct Ship Item	NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl	ORDER INFORM What is the M 1 Bottle of 30  (Write-in, e.g.	RMATION NDC selling unit?  I 1 Box of 10 Vials) der quantity?	Yes	Box/ Carton:	0.075	Dim Depth  1 10.16	PACKING INFo tensions (US m Height 3.526 3.53	ORMATION smts.) Width:  1.562 6.89	(Cube) 5.507612 247.108472	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Co	Direct Ship Item  ic) ide: toxic Agent?	No No No No No No No	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Multi	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	0.075 1.904 4.39 472.25 Case:	Dim Depth 1 10.16 11.22	PACKING INF Densions (US m Height 3.526 3.53 8.46 47.56	ORMATION smts.) Width: 1.562 6.89 7.68	(Cube) 5.507612 247.108472 728.994816	# Pieces: 1 24 48	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic	Direct Ship Item	No No No No No No No	Unit of Sale  X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Powder Sql	ORDER INFORM What is the M 1 Bottle of 30  (Write-in, e.g.	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?	Yes	Box/ Carton: Case:	0.075 1.904 4.39 472.25	1 10.16 11.22 48	PACKING INF Densions (US m Height 3.526 3.53 8.46 47.56	ORMATION smts.) Width: 1.562 6.89 7.68	(Cube) 5.507612 247.108472 728.994816	# Pieces: 1 24 48	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	Direct Ship Item  ic) ide: toxic Agent?  Unit of Use	No No No No No No No	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	0.075 1.904 4.39 472.25 Case:	1 10.16 11.22 48	PACKING INF Densions (US m Height 3.526 3.53 8.46 47.56	ORMATION smts.) Width: 1.562 6.89 7.68	(Cube) 5.507612 247.108472 728.994816	# Pieces: 1 24 48	
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Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	Direct Ship Item  ic) ide: toxic Agent?  Unit of Use	No No No No No No No	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Produ	Yes e type?	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFormation (US mensions (US mension	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) bde: toxic Agent?  Unit of Use ded to unit dose for	NO NO NO NO NO NO NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Powder Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custo	ORDER INFOR What is the N 1 Bottle of 30 (Write-in, e.g Minimum ord If Yes, how n 1  R / BILL UNIT	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  ther quantity?  nany of which package Each Inner/Carton/Pack Case  Other Produ	Yes e type?	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFormation (US mensions (US mension	ORMATION smts.) Width: 1.562 6.89 7.68 40	(Cube) 5.507612 247.108472 728.994816 91315.2	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  ic) ide: toxic Agent?  Unit of Use	NO NO NO NO NO NO NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In  PHARMACY ORDER Rec. sell unit to custo  (Write-in, e.g.	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  ther quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets	Yes e type?	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFormation (US mensions (US mension	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) bde: toxic Agent?  Unit of Use ded to unit dose for	NO NO NO NO NO NO NO NO NO	No  PRODUCT INFORMATIO  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Powder Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custo	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets Product Shape:	Yes e type? uct Information:	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFormation (US mensions (US mension	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
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Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) bde: toxic Agent?  Unit of Use ded to unit dose for	NO NO NO NO NO NO NO NO NO	No  PRODUCT INFORMATION  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Power Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custo  (Write-in, e.g.  Rx billing unit to phar  Each  Gram	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets  Product Shape: Product Color:	Yes e type?  uct Information:	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFO	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) bde: toxic Agent?  Unit of Use ded to unit dose for	NO NO NO NO NO NO NO NO NO	No  PRODUCT INFORMATION  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Power Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custo  (Write-in, e.g.  Rx billing unit to phar  Each	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets  Product Shape: Product Color:	Yes e type?  uct Informatio: : OVAL (Biconver)	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:	1 10.16 11.22 48 50357237171	PACKING INFormation (US mensions (US mension	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) Ide: Itoxic Agent? Unit of Use Ided to unit dose for  SALER USE ONLY:	No N	No  PRODUCT INFORMATION  Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Power Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custo  (Write-in, e.g.  Rx billing unit to phar  Each  Gram	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets Product Shape: Product Color:  Product Imprint:	Yes e type?  uct Information:  OVAL (Biconver) PINK	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:  Regular Cos Sal	1 10.16 11.22 48 50357237171 st Per Unit of e (\$)	PACKING INFO Pensions (US m Height 3.526 3.53 8.46 47.56 306  COST INFO Invoice Co	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controlled Subs	Direct Ship Item  Lic) Ide: Ide: Ide: Loxic Agent?  Unit of Use Ided to unit dose for  SALER USE ONLY:	No N	No  PRODUCT INFORMATIO  Unit of Sale  x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In  PHARMACY ORDER  Rec. sell unit to custo  (Write-in, e.g.  Rx billing unit to phar  Each Gram Milliliter	ORDER INFORMATION OF THE PROPERTY OF THE PROPE	RMATION NDC selling unit?  1. 1 Box of 10 Vials)  der quantity?  nany of which package Each Inner/Carton/Pack Case  Other Prode Size/Strength/Form: 30/40mg/Tablets Product Shape: Product Color:  Product Imprint:	Yes e type?  Uct Informatic: :  OVAL (Biconve) PINK  I;32	Box/ Carton: Case: Pallet: UPC:	0.075 1.904 4.39 472.25 Case: Carton:  Regular Cos Sal	1 10.16 11.22 48 50357237171 st Per Unit of e (\$)	PACKING INFO Pensions (US m Height 3.526 3.53 8.46 47.56 306  COST INFO Invoice Co	ORMATION  smts.)  Width:  1.562  6.89  7.68  40	(Cube) 5.507612 247.108472 728.994816 91315.2  Federal Exc	# Pieces:  1 24 48 4800	



## **Standard Pharmaceutical Product Information (Rx Product Only)**

Others Hame							
Application Number for NDA/ANDA/BLA, Med Device: ANDA079170 I. Freezer – between -25 and -10 C (-13° – 14° F)	REMENIS*						
Application Number for NDA/ANDA/BLA, Med Device: ANDA079170 I. Freezer – between -25 and -10 C (-13° – 14° F)	a. Temperature – Indicate the USP temperature range for this product.						
Rx Product/Proprietary Name: Rosuvastatin Calcium Tabs 40 mg 90 II. Cold – between 2 and 8 C (36° – 46° F)	I. Freezer – between -25 and -10 C (-13° – 14° F)						
NDC: 57237-171-90 UPC: 357237171905 III. Cool – between 8 and 15 C (46° – 59° F)	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: Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or "statins." Rosuvastatin reduces levels of "bad" allows for excursions between 15 and 30 C (59)	allows for excursions between 15 and 30 C (59° – 86° F)						
cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of "good" cholesterol (high-	V. Avoid Excessive Heat – above 40 C (>104° F)						
Active ingredients: Rosuvastatin Calcium Tabs VI. Other Temperature Range Requirement	VI. Other Temperature Range Requirement						
(write in)							
	VII. No Requirement						
Address: 2 Tower Center Boulevard Suite 1101 Address 2: b. Contact for temperature excursion questions:							
City: East Brunswick State: NJ Zip: 08816 Name: Vikram Ganesh							
Key Contact: Kaitlin Alexander Email: kalexander@citronpharma.com Number: 732-917-6062							
Phone Number: 732-227-1515 Fax: 732-227-1513 Is this product to be shipped to customers on ice?	No						
FOR GENERIC DRUG PRODUCTS  Is this product to be shipped to customers on dry ice?	No						
I. Orange Book Rating: AB II. Brand Name: Crestor							
III. Generic Equivalent for Brand: Rosuvastatin c. Special regulations for product in certain states?	No						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Special returns requirements for this product?	No						
Does supplier meet DSCSA definition of manufacturer?  Yes  DUNS: 078731527							
Is product exempt from DSCSA?  d. Store product (unit of sale) upright?	No						
If yes, select exemption:  Protect product (unit of sale) from light?	No						
Other exemption - Write in:							
Is product repackaged?  No If Yes, was original product purchased direct from mfr?  e. Shelf life: 24 Months							
Is product sold by manufacturer's exclusive distributor?  No  Initial shelf life at launch (if different):	Months						
is product sold by individual section we distributor?							
Are any waivers granted for product ID/barcode?  No If yes, attach documentation from FDA	Months						
	Months						
Are any waivers granted for product ID/barcode?  No If yes, attach documentation from FDA  ADDITIONAL PRODUCT INFORMATION  ITEM AND PACKING INFORMATION  Direct Ship Item  ORDER INFORMATION  Dimensions (ILS marms.)	Volume						
Are any waivers granted for product ID/barcode?  No If yes, attach documentation from FDA  ADDITIONAL PRODUCT INFORMATION  ITEM AND PACKING INFORMATION	Volume (Cube) # Pieces:						
Are any waivers granted for product ID/barcode?    No	Volume (Cube) # Pieces:						
Are any waivers granted for product ID/barcode?  No If yes, attach documentation from FDA  ADDITIONAL PRODUCT INFORMATION  Is the Product Direct Ship Item Legend Device?  No Unit of Sale What is the NDC selling unit?  If yes, attach documentation from FDA  ITEM AND PACKING INFORMATION  Weight Lbs. Dimensions (US msmts.)  Depth Height Width:	Volume # Biococc						
Are any waivers granted for product ID/barcode?    No	Volume (Cube) # Pieces:						
Are any waivers granted for product ID/barcode?    No	Volume (Cube) # Pieces: 6.088875 1						
Are any waivers granted for product ID/barcode?    No	Volume (Cube) # Pieces: 6.088875 1						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
Are any waivers granted for product ID/barcode?    Application   Applica	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
Are any waivers granted for product ID/barcode?    No	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
Are any waivers granted for product ID/barcode?   No   If yes, attach documentation from FDA	Volume (Cube)         # Pieces:           6.088875         1           296.1855         24           830.117322         48           78086.4         4800						
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