

Regulatory Labeling Source Document (RLSD) Citracal +D3 Blueberry ECOMM Gummies FP-1000023

RLSD COVER PAGE		
Brand Name	Citracal	
Sub Brand		
Product Name	Citracal +D3 Gummies	
Manufacturing Site	Amapharm	
Synaps UI#	1615516	
Comments	90 Count Blueberry Gummies for Amazon	
	PTP-1000043 (Rev 1 – 05/24/2023) UF-1000043 (Rev 1 – blueberry & raspberry flavors) UF-1000043 (Rev 2 – NCO cancelled by formulator) UF-1000043 (Rev 3 – 06/02/2023)	

06/12/2023 FP-1000023 Citracal +D3 Blueberry ECOMM Gummies

UI 1615516

Page 1 of 3

APPROVED – Refer to Phoenix System for E-sig detail

Change #: NCO-1000914 Change Complete Date: Jun-12-2023



Regulatory Labeling Source Document (RLSD) Citracal +D3 Blueberry ECOMM Gummies FP-1000023

REQUIRED LABELING:

Directions: Adults and children 12 years of age and older: **Fully chew** 1 serving (2 gummies) twice daily with or without food or as recommended by your health professional.

Supplement Facts

Serving Size: 2 Gummies

Servings Per Container: (Net Qty Contents/Serving Size- refer to servings per

container field)

	Amount Per Serving	% Daily Value
Calories	30	
Total Carbohydrate	7 g	3%*
Total Sugars	5 g	**
Includes 5g Added Sugars		10%*
Vitamin D (as cholecalciferol)	25 mcg (1000 IU)	125%
Calcium (as tricalcium phosphate)	500 mg	38%
Phosphorus (from tricalcium phosphate)	225 mg	18%
Sodium	35 mg	2%
*Percent Daily Values are based on a 2 000 calor	rie diet	

^{*}Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: Glucose Syrup, Sucrose, Water; Less than 2% of: Citric Acid, Color (Carrot and Cherry Juice Concentrates), Maltodextrin, Natural Flavor, Pectin.

ANNOTATIONS:

US Pharmacovigilance Approval - 06/09/2023

21 CFR 101.36(e)

21 CFR 101.36(e) 1,2,6,7

21 CFR 101.36(b)(1)(i)

21 CFR 101.36(b)(1)(ii)

21 CFR 101.36(b)(2)(i)(A)

21 CFR 101.36(b)(2)(iii)(A)

21 CFR 101.9(c)(1)

21 CFR 101.9(c)(6)

21 CFR 101.9(c)(6)(ii)

21 CFR 101.9(c)(6)(iii)

21 CFR 101.9(c)(8)(iv)

21 CFR 101.9(c)(4)

UF-1000043 (Rev 3 – 06/02/2023)

Contains: Wheat.

FALCPA (Allergen Act of 2004) Contains Wheat from Glucose Syrup and Blueberry Flavor as per UF-1000043 (Rev 3 – 06/02/2023). FASTER Act of 2021 No Sesame Present as per UF-1000043 (Rev 3 – 06/02/2023).

06/12/2023 FP-1000023 Citracal +D3 Blueberry ECOMM Gummies UI 1615516

Page 2 of 3

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^{**}Daily Value not established.



Regulatory Labeling Source Document (RLSD) Citracal +D3 Blueberry ECOMM Gummies FP-1000023

KEEP OUT OF REACH OF CHILDREN

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If you are pregnant, breastfeeding, taking medication, or have any medical condition, ask a health professional before use.

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Not for children under 12 years of age

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Do not exceed recommended intake

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CHILD RESISTANT CAP

16 CFR 1700.14(a)(13) US Pharmacovigilance Approval -

06/09/2023

Gummy color may change over time. This does not alter the potency or flavor of the product.

Component	Description
NON-CR Statement	Not Applicable
Statement of Identity	CALCIUM SUPPLEMENT
Warnings (non DFL/SF)	Not Applicable
Registration Number	Not Applicable
(NDC/EPA)	
Servings Per Container	45 gummies for 90 count SKU
(non DFL/SF)	
CHPA Icons- denote	Not Applicable
"yes" in adjacent column	
if DXM icon is attached	

06/12/2023 Citracal +D3 Blueberry ECOMM Gummies FP-1000023 UI 1615516

Page 3 of 3

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