

CERTIFICATE OF ANALYSIS

Code: 4693A

Product: Ultra Calcium Tablets

Lot No.: 117304

REF: QCTR Revision-03

TEST	METHOD	SPECIFICATION	RESULT
Description (Core)	Visual	Modified oval-shaped tablet	Conforms
Description (FP)	Visual	Film-coated white	Conforms
Weight Variation	USP<2091>	Meets the current USP requirements	Conforms
		Theoretical core wt.: 1.030 grams ±5%	1.031 grams
		Theoretical coated wt.: 1.052 grams ±5%	1.072 grams
Disintegration	USP<2040>	Maximum 30 minutes	Conforms
Calcium (Egg shell)	TM-514	125 mg Limit: 100.0% - 135.0%	121.2%
Magnesium (Oxide)	TM-514	100 mg Limit: 100.0% - 135.0%	123.5%
Vitamin D (as Cholecalciferol)	TM-551	250 IU. Limit: 100.0% - 165.0%	149.4%
Vitamin K	TM-551	20 mcg mcg Limit: 100.0% - 165.0%	108.6%
Dissolution (Calcium)	TM-514	Min.75% after 60 minutes in 900 ml of 0.1N HCl @ 75rpm. App.2 (Pooled)	114%
Water activity*	USP<1112>	Limit: NMT:0.6 _{aw}	0.3 _{aw}
Microbial ¹			
Total Plate Count	USP<2021>	NMT: 3000 cfu/g	Conforms
Yeast & Mold	USP<2021>	NMT: 300 cfu/g	Conforms
Specified Microorganism ¹			
Salmonella	USP<2022>	Absent	Conforms
Escherichia coli	USP<2022>	Absent	Conforms
Staphylococcus	USP<2022>	Absent	Conforms

*For information purposes

The results reported for Vitamins affected by the new CFR update (21 CFR Part 101) may be reported in either Metric Units or International Units (IU), which may not reflect the units on the product label for this lot. The specification in Metric Units has been confirmed to meet the specification in IU.

¹ This product code is excluded from the SOP Q-034 skip lot microbial testing program and must be tested for each release.

Ref. Vol/Page: VMS-WV-0206/90; VMS-WV-0207/20; VMS-FP-0162/1-3; VMS-FP-0158/101; VMS-DT-002/160; VMS-WA-0029/176; Micro-testing#32687; Core-lot#117305		Date: 01/10/2022
Released: <input checked="" type="checkbox"/>	Rejected: <input type="checkbox"/>	By: <i>David Naranjo</i> Date: 01/10/2022
Date Manufacture: 11/05/2021		