D2d MOP 7 – Appendix 2

tishcon corp.
GEL-TEC

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GEL-TEC Plant: 30 New York Ave. P.O. Box 331 Westbury, NY 11590
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Maryland Plant: 2410 North Zion Rd. Salisbury, MD 21801
Phone: (410) 860-0046 Fax: (410) 860-0324

NSF GMP Registered

FINISHED PRODUCT SPECIFICATIONS

Product Name	VITAMIN D3 4000 IU SOFTGELS
Customer Name	VA
Product Code Number	11246-SEG
Date of Manufacture	TBD
Category	Dietary Supplements
Revision #	00

Tests	Specifications	Results
Description	3 minims oval shaped natural clear softgels containing light yellow colored oil.	Conforms
Rupture Test	Not more than 15 minutes	TBD
Fill Weight	Limit: 150 mg/softgel ± 10% (135 mg – 165 mg)	TBD
Weight Variation	Limit: 250 mg/softgel ± 10% (225 mg –275 mg)	TBD

Active Ingredients	Label Claim / Softgel	Test Method	Results	% of label claim
Vitamin D3 (as cholecalciferol in corn oil)	4000 IU	HPLC	NLT 4000.0 IU	20

Other ingredients: Soybean oil, gelatin, glycerin, purified water and corn oil.

HEAVY METALS TEST

Tests	Test Method	Specifications (mcg/ Daily Dose)	Results (mcg/Softgel)
Pb (Lead)	ICP-MS	< 0.5	TBD
Hg (Mercury)	ICP-MS	Not more than 20	TBD
Cd (Cadmium)	ICP-MS	Not more than 4.1	TBD
As (Arsenic)	ICP-MS	Not more than 10	TBD

MICROBIOLOGICAL TEST

Test Performed	Test Method	Specifications	Results
Total Aerobic Microbial Count	Current USP <2021>	Not more than 3,000 cfu /gram	TBD
Total Yeast & Mold Count	Current USP <2021>	Not more than 300 cfu /gram	TBD
Salmonella	Current USP <2022>	Absent/10 gram	TBD
E.coli	Current USP <2022>	Absent/10 gram	TBD
Staphylococcus aureus	Current USP <2022>	Absent/10 gram	TBD
Pseudomonas aeruginosa	Current USP <62>	Absent/10 gram	TBD

N/A=Not Applicable
NLT=Not Less Than
TBD= To Be Determined
<=Less Than
Allergen statement: contains soy
Storage condition: Store at temperature 59° to 86°F (15° to 30°c) and relative humidity below 50%

Prepared By & Date: 04/10/13
Abdul M Siddiqui
(Manager Documentation)

Approved By & Date: 04/10/13
Mythili Nagarajan
(VP of Corporate Quality Control)

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