www.tpgs.com

Antares Vitamin E TPGS
cGMP and Food Safety Statement

Products	Antares Vitamin E TPGS Pharmaceutical Grade (NF) Antares Vitamin E TPGS Food Grade (FG) Antares Vitamin E TPGS SF Pharmaceutical Grade (NF) – Sunflower TPGS™ Antares Vitamin E TPGS SF Food Grade (FG) – Sunflower TPGS™
Product Codes	TG0100NF TG0101NF TG0105NF TG0115NF TG0100FG TG0101FG TG0105FG TG0115FG SF0100NF SF0101NF SF0105NF SF0115NF SF0100FG SF0101FG SF0105FG SF0115FG
Chemical Name	d-α-tocopheryl polyethylene glycol 1000 succinate
Empirical Formula	$C_{33}O_5H_{54}(CH_2CH_2O)_n$
Synonyms / Acronyms	Vitamin E TPGS, TPGS, Tocophersolan (International Nomenclature of Cosmetic Ingredients – INCI and United States Adopted Names - USAN)
CAS Number	9002-96-4 (Chemical Abstracts Service registration number)

Antares Vitamin E TPGS (TPGS) meets the Current Good Manufacturing Practice (cGMP) in the manufacturing, processing, packing, or holding of drugs in the FDA Code of Federal Regulations Title 21 Part 210 and the cGMP for finished pharmaceuticals in FDA 21 CFR Part 211. TPGS also meets the International Pharmaceutical Excipients Council (IPEC) and the Pharmaceutical Quality Group (PQG) guidelines for pharmaceutical excipients.

cGMP compliance as practiced by Antares exceed and replace the Hazard Analysis and Critical Control Point (HACCP) concept introduced by the FAO/WHO Codex Alimentarius. These include the design of the product, its traceability, release analysis, and the comprehensive documentation of procedures. The quality system is based on risk management for technical systems, production, control of processes, cleaning procedures, and analytical methods. In addition, microbiological monitoring is done on the water used, the production plant, personnel, and the rooms used in loading out the product.

All steps of the working procedure are individually documented in Standard Operating Procedures (SOP). In Process Controls (IPC) are carried out to monitor and control production steps. The final products are subjected to analysis of predefined specifications before being released. Essential goals of our cGMP system are the exclusion of deviations in production steps, the final product, and avoidance of biological, chemical, and physical contamination.

Heath Miller
Directory of Quality

02/02/2021
Date

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