

Product Data



PROVITAS

K₁ 50SD

Product Description-

K₁ 50SD is a uniform water-soluble powder, which is cream to light yellow in color with a bland odor and taste. The active ingredient, phytonadione is dispersed in MCT oil and homogenized with non-GMO modified gum acacia and maltodextrin and then dried to a uniform powder.

TEST	METHOD	SPECIFICATIONS
Description:	Observation	Solid - powder
Color:	Observation	Cream to light yellow
Odor:	Observation	Bland
Moisture:	USP<731>	≤ 5%
Assay: Vitamin K ₁ (phytonadione) Z Isomer Content ¹	J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89	≥ 50 mg/g < 10.5 mg/g
Heavy Metals: Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 <0.3 <1.0 <0.2
Microbial purity: APC, cfu/g Coliforms, cfu/g Yeast & mold, cfu/g E. Coli, cfu/g Staphylococcus aureus, cfu/g Salmonella, cfu/g	USP <2021> USP <2021> USP <2021> USP <2022> USP <2022> USP <2022>	≤1,000 <100 <100 Negative Negative Negative
Particle Size Distribution²: Through Sieve No. 60 Through Sieve No. 230	USP<786>	> 85% < 10%
Residual Solvents (RS)³:	USP <467>	Meets USP Requirements

1. Specification is not part of release testing but is determined by the use of USP grade phytonadione that meets USP specifications.
2. Specification is tested randomly and not reported on Certificate of Analysis.
3. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin K₁ that meets USP (RS) specifications. Water is the only solvent used in the production of K₁ 50SD powder.

Compendia Requirements-

A specific USP or FCC monograph does not exist for vitamin K₁ preparations. USP grade phytonadione and USP/NF and/or FCC grade excipients are used to manufacture K₁ 50SD.

Uses-

K₁ 50SD is intended for the fortification of vitamin K₁ in foods and pharmaceutical preparations.

Solubility-

K₁ 50SD is soluble in cold water

Harmonized Tariff Schedule Code-

2936.2920

Stability-

The shelf life in sealed, original containers under normal storage conditions is 24 months after the date of manufacture.

Storage-

Store in tightly closed containers in cool and dry conditions. Protect from moisture, heat, light and oxygen. K₁ 50SD decomposes on exposure to light.

Packaging-

PRODUCT CODE PACKAGE /	PACKAGING DETAILS	OPTIMUM ORDER QUANTITIES
PV50200 100g Sample	Aluminum pouch 100 gram net weight 4" x 6" (10cm x 15cm)	Each / 100g
PV50253 25kg carton	Fiber carton w/plastic liner 25kg net weight 26kg gross weight 12"x12"x20" (31cm x 31cm x 51cm) 27kg gross weight (over pack) 22"x14"x14" (56cm x 36cm x 36cm) 1 layer of 9 cartons Maximum 3 layers / pallet	25kg Per 40" x 48" pallet: 225kg 675kg