

Product Data



K₁ 10SD

Product Description-

K₁ 10SD 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 homogenized with non-GMO gum acacia and glucose syrup and then dried to a uniform powder. Tricalcium phosphate is added for flow.

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), mg/g Z Isomer Content, mg/g ¹	J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89	≥ 10 < 2.1
Heavy Metals: Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.0 <0.3 <1.0 <0.1
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. 100 Through Sieve No. 170 Through Sieve No. 325	USP <786>	> 90% >75% < 40%
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 10SD 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 10SD.

Uses-

K₁ 10SD is intended for the fortification of vitamin K₁ in foods and pharmaceutical preparations.

Solubility-

K₁ 10SD 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 10SD decomposes on exposure to light.

Packaging-

PRODUCT CODE PACKAGE /	PACKAGING DETAILS	OPTIMUM ORDER QUANTITIES
PV50600 100gm Sample	Aluminum pouch 100 gram net weight 4" x 6" (10cm x 15cm)	Each / 100gm
PV50653 25kg carton	Fiber carton w/plastic liner 25kg net weight 26kg gross weight 15"x11"x22" (31cm x 31cm x 51cm) 27kg gross weight (over pack) 22"x14"x14" (38cm x 28cm x 56cm) 1 layer of 9 cartons Maximum 3 layers / pallet	25kg Per 40" x 48" pallet: 225kg 675kg