

Finished Product Specifications

Product: Vitamin A 100,000 IU Soft Gelatin Capsule – Vitamin Angels

Capsule Size: 11 with snip-top feature

Criteria		Test	Test Method	Limits
Identification		Appearance Size/Shape/Color	Visual	Yellow colored elongated capsule
		Vitamin A	USP<571>	Positive
		Vitamin E	USP<571>	Positive
Performance		Disintegration	USP<2040>	≤ 45minutes
		Weight Variation	USP<2091>	90 – 110%
Purity	Chemical contaminants	Heavy Metals	USP<231>	NMT 10ppm
	Microbial Contaminants	Total viable aerobic count	USP<2021>	1 x 10 ⁵ cfu/g NMT 3000 cfu/g
		Yeast & Mold	USP<2022>	1 x 10 ⁴ cfu/g NMT 300 cfu/g
		E.coli	USP<2022>	Negative
		Salmonelle spp.	USP<2022>	Negative
		Staph. Aureus	USP<2022>	Negative
		Pesudomonas aeruginosa	USP<2022>	Negative
	Pesticides*	Pesticide residues	USFDA Pesticide Analytical Manual 1 (PAM 1)	Negative
Potency / Assay (per capsule)		Vitamin A (as palmitate)	USP<571>	100,000.0 IU (95 to 120% LC)
		Vitamin E (as DL alpha tocopherol)	USP<571>	20.0 IU (95 to 120% LC)

Note: Oil—any oils used in the formulation must at least be food grade oil and meet appropriate suspension parameters.

* only required if vitamin A or vitamin E are NOT synthetic

