

## Dry Vitamin E-Acetate 50% DC

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Test parameter	Requirement	Method
<b>Assay</b>		
Vitamin E (HPLC)	Min. 50.0 % Max. 57.5 %	BCPL300C
<b>Characters</b>		
Appearance (Visual)	Free-flowing, almost white, virtually odorless powder consisting of spherical particles, with a uniform particle size	BCPL0052
<b>Tests</b>		
Loss on drying (gravimetric) <sup>1)</sup>	Max. 3 %	BCPL0048
Through mesh 20 USP (sieving)	Min. 100 %	BCPL049A
Through mesh 40 USP (sieving)	Min. 95 %	BCPL049C
Through mesh 80 USP (sieving)	Max. 10 %	BCPL049G
Lead <sup>2)</sup>	Max. 2 mg/kg	BCPS0126
Cadmium <sup>2)</sup>	Max. 1 mg/kg	BCPS0121
Mercury <sup>2)</sup>	Max. 0.1 mg/kg	BCPS0122
Arsenic <sup>2)</sup>	Max. 1 mg/kg	BCPL0017
Heavy metals <sup>2)</sup>	Max. 10 mg/kg	BCPL053C
Total aerobic microbial count (TAMC)	Max. 1000 cfu/g	Ph. Eur./USP
Total combined yeasts/mould count (TYMC) <sup>2)</sup>	Max. 100 cfu/g	Ph. Eur./USP
Salmonella <sup>2)</sup>	Abs. in 25 g	ISO 6579
Staphylococcus aureus <sup>2)</sup>	Abs. in 10 g	Ph. Eur./USP
E. coli <sup>2)</sup>	Abs. in 10 g	Ph. Eur./USP
Ps. Aeruginosa <sup>2)</sup>	Abs. in 10 g	Ph. Eur./USP
Enterobacteria <sup>2)</sup>	Abs. in 1 g	ISO 21528

<sup>1)</sup> Performed at 105 °C

<sup>2)</sup> This test is verified on random samples only

Dry Vitamin E-Acetate 50% DC meets the specification requirements of the current monographs:

“α-tocopherol acetate concentrate (powder form) Ph. Eur.

“Vitamin E preparation” USP

Furthermore, the included active ingredient complies with the specification requirements stipulated in the current monographs:

“all-rac-alpha-tocopheryl acetate” Ph. Eur.

“Vitamin E” USP

“all-rac-alpha-tocopheryl acetate FCC

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The statements under the heading “Characters” are not to be interpreted in a strict sense and are not requirements.