

# Fitalite™ Cream Base



## Stability Study

Fitalite™ Cream Base is a natural, light, hydrophilic gel cream base with a unique formulation. This vehicle contains vitamin E and oil bodies from plant sources known as phytosomes, which give Fitalite™ Cream Base its unique antioxidant and skin-moisturizing properties. Fitalite™ Cream Base is an elegant, non-greasy topical vehicle, compatible with a broad range of active pharmaceutical ingredients (APIs).

### Stability Study – Fitalite™ Cream Base

The formulation samples were assayed by HPLC using validated, forced-degradation indicative methods at pre-determined time points to verify the stability of the APIs in the tested vehicle. Sampling times were: initial (T = 0), 30 days (T = 30), 60 days (T = 60), 90 days (T = 90), 120 days (T = 120), 150 days (T = 150), and 180 days (T = 180). Formulations were immediately assayed six times (6 aliquots) at each time. The evaluation parameter is the percent recovery with respect to T = 0, using the HPLC method. Results are given as percentage ± standard deviation (SD).

### Formulation Tested

Estriol 2% / Estradiol 1% / Estrone 1% / Progesterone 20% / Testosterone 5% with Ethoxy Diglycol 10% and Fitalite™ Cream Base 61% (all w/w %)

### Assay Results at Time Points as % of Indicated Formulation Amount

Chemical	°C	T=0	T=30	T=60	T=90	T=120	T=150	T=180
Estriol (20 mg/g)	2-8	100	95.49	94.49	94.58	93.61	91.27	93.00
	15-25	100	90.05	90.66	92.07	94.74	94.69	91.99
Estradiol (10 mg/g)	2-8	100	96.54	96.85	94.68	91.54	91.14	92.95
	15-25	100	94.25	94.72	93.69	92.08	94.75	93.91
Estrone (10 mg/g)	2-8	100	96.77	94.02	97.01	92.28	91.14	92.92
	15-25	100	92.24	90.83	92.97	95.25	95.73	92.82
Progesterone (200 mg/g)	2-8	100	103.41	94.40	97.81	97.85	94.81	99.35
	15-25	100	99.94	94.84	96.11	97.23	96.85	96.65
Testosterone (50 mg/g)	2-8	100	101.69	98.65	99.83	101.36	99.04	98.74
	15-25	100	96.74	95.94	101.09	102.10	101.89	101.29

The results presented suggest that the APIs studied are stable alone or in combination in Fitalite™ Cream Base for the time period indicated..

### Disclaimer

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