

# Versatile™ Cream Base



## Stability Study

Versatile™ Cream Base is a highly elegant vanishing O/W cream base with a unique formulation. This vehicle offers versatility for compounding challenges because it can retain its consistency with a broad range and high concentrations of active pharmaceutical ingredients (APIs).

### Stability Study – Versatile™ 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 Versatile™ 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	100.75	97.60	103.81	102.77	99.82	97.46
	15-25	100	100.09	101.22	98.33	100.82	100.49	99.45
Estradiol (10 mg/g)	2-8	100	99.79	98.54	99.95	96.61	100.43	98.25
	15-25	100	99.17	98.16	98.86	96.12	98.91	98.38
Estrone (10 mg/g)	2-8	100	101.72	97.92	101.69	101.40	101.46	96.98
	15-25	100	100.44	98.98	102.10	102.38	103.85	95.97
Progesterone (200 mg/g)	2-8	100	104.56	97.42	100.19	99.19	100.78	102.36
	15-25	100	102.09	97.46	100.73	100.11	100.72	96.66
Testosterone (50 mg/g)	2-8	100	103.56	100.60	104.33	103.52	103.67	98.74
	15-25	100	103.79	103.18	105.12	105.28	103.62	100.75

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

### Disclaimer

Although a great deal of effort has been spent to ensure the accuracy of the content of these statements, no claims are made as to the use, safety, efficacy or bioavailability of mentioned combinations. The content of these statements cannot be construed as medical advice, recommendation or opinion. Medical professionals, doctors and pharmacists reviewing these statements are advised to do so solely based on their own professional opinion, experience and judgment. Fagron does not accept and cannot be held responsible or liable in any case for the information contained herein.