

STABILITY OF COMPOUNDED PREPARATIONS (BUDs)

MEDISCA'S HRT CREAM BASE (FOR WOMEN)

FORMULA	PREPARATION NAME		TIME ZERO	30 DAYS AT RT	30 DAYS AT 4°C	60 DAYS AT RT	60 DAYS AT 4°C	90 DAYS AT RT	90 DAYS AT 4°C
F 002 488	Progesterone 10%	API (Mean, % w/w)	9.951	10.149	10.129	10.040	9.813		
		Conserved Potency %	99.51%	101.49%	101.29%	100.04%	98.13%		
F 001 243v2	Estriol, Estradiol, Estrone Estriol 2mg/mL (0.2%)	API (Mean, % w/w)	0.202	0.198	0.194	0.198	0.197	0.188	0.191
		Conserved Potency %	100.99%	99.14%	96.86%	99.24%	98.42%	94.10%	95.56%
F 001 243v2	Estriol, Estradiol, Estrone Estradiol 0.25mg/mL (0.025%)	API (Mean, % w/w)	0.025	0.024	0.025	0.024	0.025	0.023	0.024
		Conserved Potency %	99.36%	95.99%	101.31%	96.32%	99.78%	90.50%	95.76%
F 001 243v2	Estriol, Estradiol, Estrone Estrone 0.25mg/mL (0.025%)	API (Mean, % w/w)	0.025	0.025	0.026	0.025	0.025	0.023	0.024
		Conserved Potency %	101.65%	101.66%	102.57%	98.20%	98.80%	92.90%	94.92%
F 001 539	Testosterone 1%	API (Mean, % w/w)	0.997	1.018	1.019	0.992	0.951	1.026	0.912
		Conserved Potency %	99.68%	101.78%	101.90%	99.19%	95.09%	102.56%	91.20%
F 004 542	DHEA (Prasterone) 2%	API (Mean, % w/w)	1.979	1.916	1.959	1.948	2.017	2.049	2.019
		Conserved Potency %	98.96%	95.81%	97.95%	97.40%	100.83%	102.45%	100.93%

All preparations were compounded in HRT Cream Base (Women) as per standard compounding procedure. Analysis of samples was done following established USP protocols and results were extrapolated from an average of 4 runs. RT indicated room temperature.

DISCLAIMER: This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.

