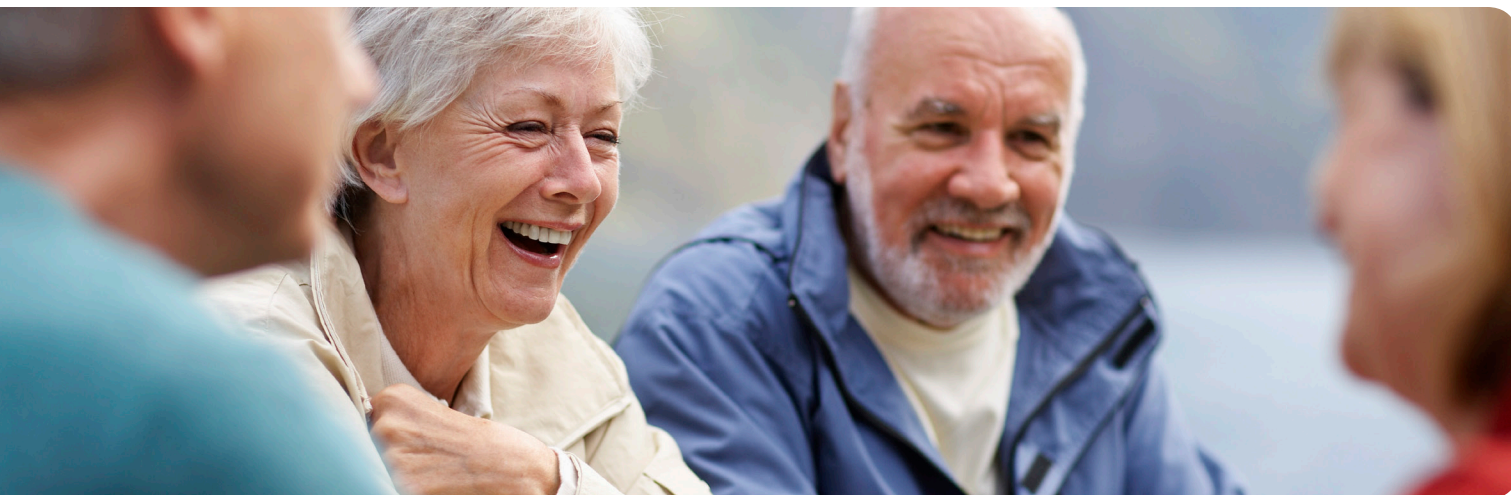


Lipopen Ultra Cream Base



Stability Study

Fagron's Lipopen Ultra Cream Base is a highly elegant transdermal vehicle specially formulated to maintain stability in the presence of high API percentages, solvents, salts and across a wide pH range. Lipopen Ultra Cream Base has a smooth, luxurious feel and quickly absorbs leaving the skin smooth and non-greasy.

Stability Study – Lipopen Ultra 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). 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 \pm standard deviation (SD).

Formulation Tested

Ketoprofen 10% / Baclofen 2% / Cyclobenzaprine Hydrochloride 2% / Lidocaine 2% with Ethoxy Diglycol and Lipopen Ultra Cream Base (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
Ketoprofen (100 mg/g)	2-8	104.89	105.97	105.78	106.25	106.70	100.32
	15-25	104.89	104.97	101.19	103.56	103.37	104.47
Baclofen (20 mg/g)	2-8	98.41	95.87	99.03	100.77	100.26	101.35
	15-25	98.41	95.76	95.57	96.37	97.78	95.12
Cyclobenzaprine Hydrochloride (20 mg/g)	2-8	100.88	98.86	99.44	99.05	98.54	102.73
	15-25	100.88	99.93	99.80	99.73	98.70	98.00
Lidocaine (20 mg/g)	2-8	102.63	96.39	98.56	98.78	99.83	100.00
	15-25	102.63	96.65	96.70	98.68	99.39	99.14

The results presented suggest that the APIs studied are stable alone or in combination in Lipopen Ultra 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.