

Supporting information

Application of Accelerated Predictive Stability Studies (APS) in extemporaneous compounding formulations of chlorhexidine to assess the shelf-life

Table S1: Long-term assays of DCHX content (%).

Temperature (° C)	Time (days)	Predicted content (%)	Experimental content(%) in clear glass	Experimental content (%) in clear plastic	Experimental content (%) in amber glass	Experimental content (%) in amber plastic
5	30	99.74	99.79	99.72	99.74	99.66
	60	99.48	99.38	99.19	99.3	99.19
	180	98.45	98.47	98.32	98.4	98.38
	360	96.9	96.78	96.5	96.8	97.2
25	30	98.55	99.67	99.59	99.52	99.48
	60	97.1	99.09	99.07	98.91	99.01
	180	91.29	95.46	93	93.91	92.4
	360	82.58	90.5	84.2	91.4	83.12
30	30	97.84	99.26	98.67	98.79	98.77
	60	95.69	99.08	98.76	98.96	98.55
	180	87.06	91.01	83.55	90.04	84.62
	360	74.12	80.6	71.6	78.7	79.21

Validation of chromatographic method

Different columns were analyzed to determine which one was the most suitable according to the number of plates and peak resolution (Table S2) at 8.77 min and 4.97 of retention time DCHX and PCA respectively. The BDS Hypersil C18-RP column (250 x 4.6 mm, 5 μ m) showed the least interferences at 25° C with PCA degradants and exhibited an overall better resolution for both active ingredients 87.96 (DCHX) and 104.69 (PCA).

Table S2: RP-C18 column dimensions and calculated parameters.

Type of Column	Column dimensions			Column parameters			
	Length (mm)	Internal diameter (mm)	Particle size (μ m)	API	Resolution	Number of plates (plates)	Pressure (MPa)
Acclaim 300 C18 (Dionex-Thermo Fisher Scientific, California, EEUU)	150	4.6	3	DCHX	57.56	359,553.211	24
				PCA	31.11	302,789.68	
Nova-pak C18 (Waters Corporation, Massachusetts, EEUU)	300	3.9	4	DCHX	38.98	177,903.10	28.1
				PCA	60.1	543,103.78	
BDS Hypersil C18 (Hypersil-Keystone, Nueva Orleans, EEUU)	200	4.6	5	DCHX	93.06	408,315.93	12
				PCA	64.46	663,214.63	
BDS Hypersil C18 (Hypersil-Keystone, Nueva Orleans, EEUU)	250	4.6	5	DCHX	87.96	646,521.15	12.7
				PCA	104.69	1,201,957.67	

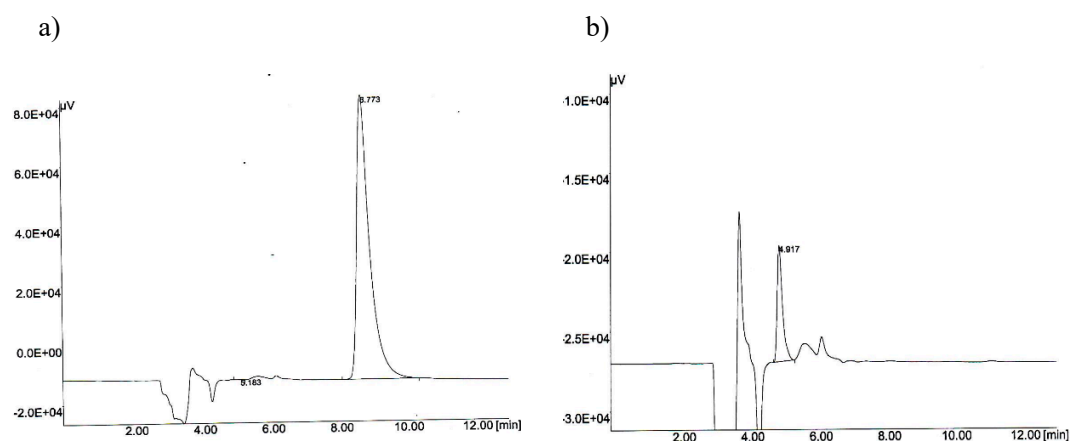


Figure S1: Chromatogram of DCHX pattern (a) and PCA pattern (b) with BDS Hypersil C18 250 mm column.