Fig. 1A

	Weeks						
	Temp (°C)	0	1	1.571429	2.142857	3.428571	6.571429
T1	25	0.08			0.88		2.81
T2	40	0.08		3.47		4.48	

Fig. 1B

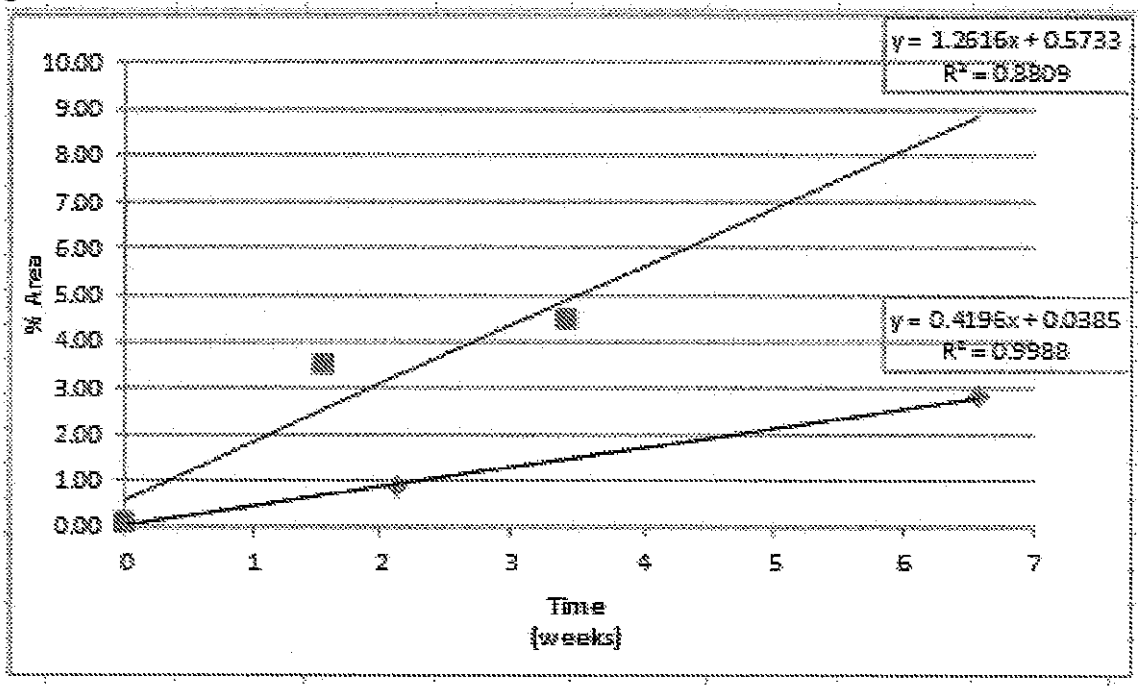


Fig. 1C

Formulation:		Average of Analysis		
Stability Prediction:		RRT 0.87		
	spec limit:	0.50	% (not more than)	
			shelf life	
			weeks	months
rate	1.24844	at 40C	0.4	0.1
rate	0.60617	at 30C	0.8	0.2
rate	0.41477	at 25C	1.2	0.3
rate	0.07932	at 2-8C	6.3	1.6
rate	0.00694	at -20C	N/A	N/A

Fig. 2A

	Weeks					
	Temp (°C)	0	1	2.142857	4	6.571429
T1	25	0.08		0.9		2.8
T2	60	0.08	10.5		11.3	

Fig. 2B

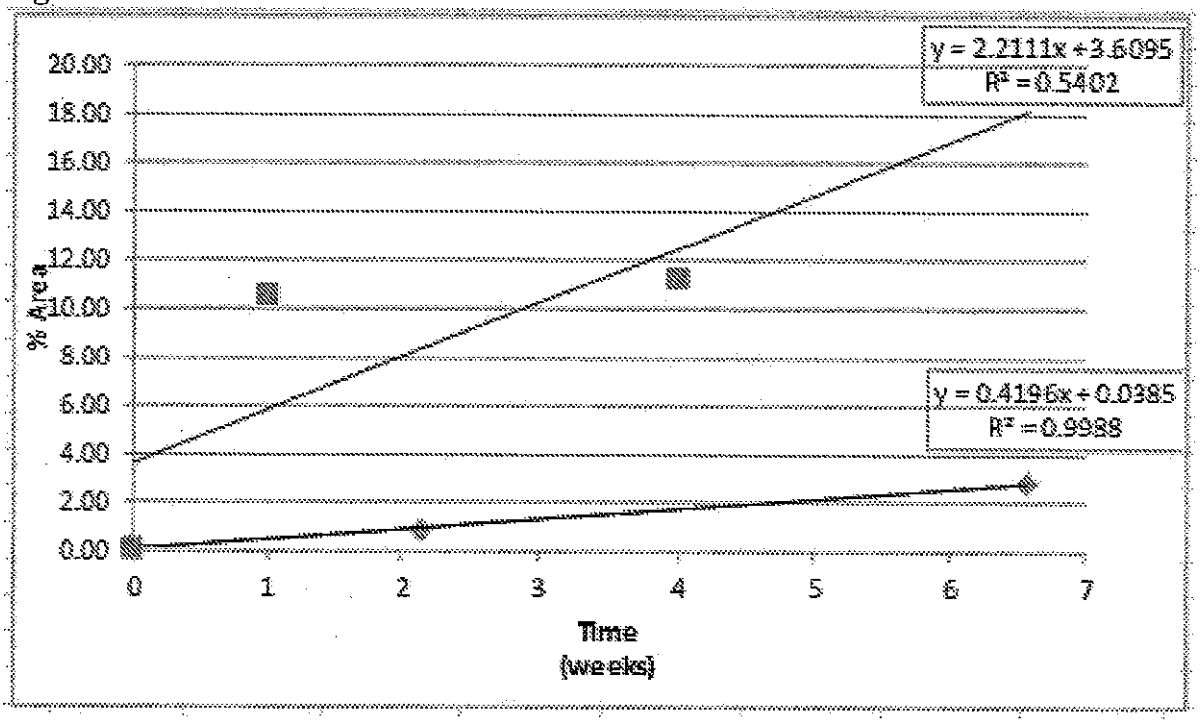


Fig. 2C

Formulation:		Average of Analysis		
Stability Prediction:		RRT 0.87		
	spec limit:	0.50	% (not more than)	
			shelf life	
			weeks	months
rate	0.88876	at 40C	0.6	0.1
rate	0.54051	at 30C	0.9	0.2
rate	0.41627	at 25C	1.2	0.3
rate	0.13331	at 2-8C	3.8	0.9
rate	0.02493	at -20C	N/A	N/A

Fig. 3

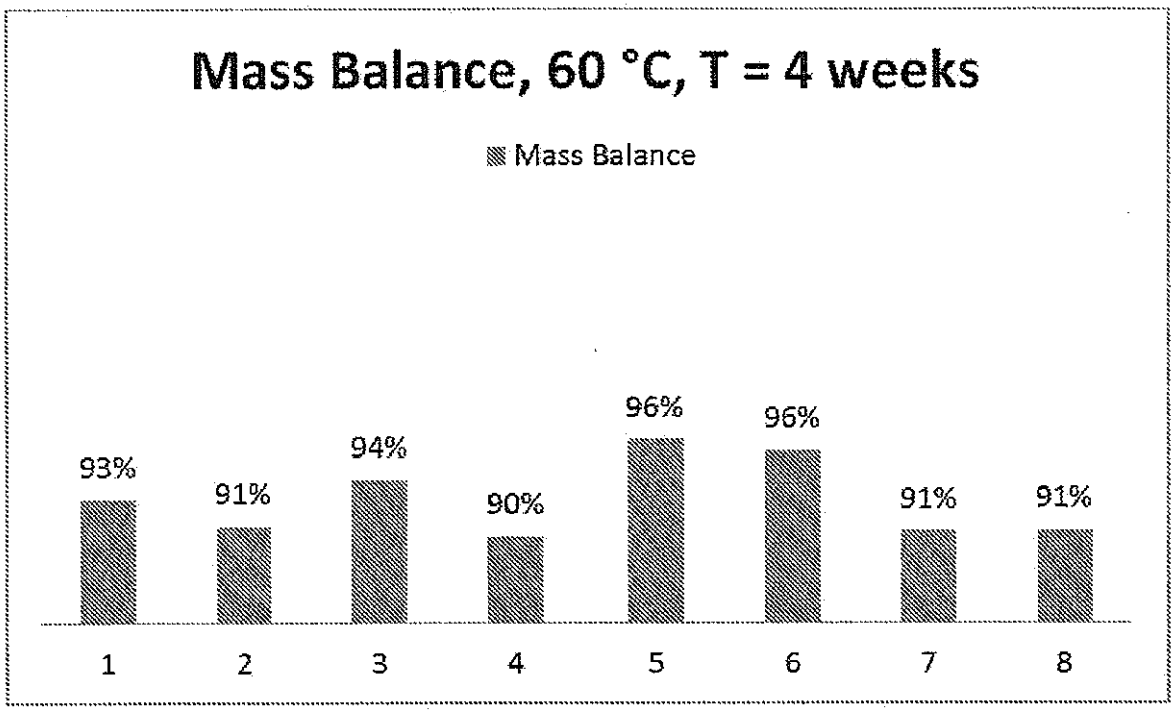

Mass Balance, 60 °C, T = 4 weeks
Mass Balance
93%
91%
94%
90%
96%
96%
91%
91%
1
2
3
4
5
6
7
8

Fig. 4

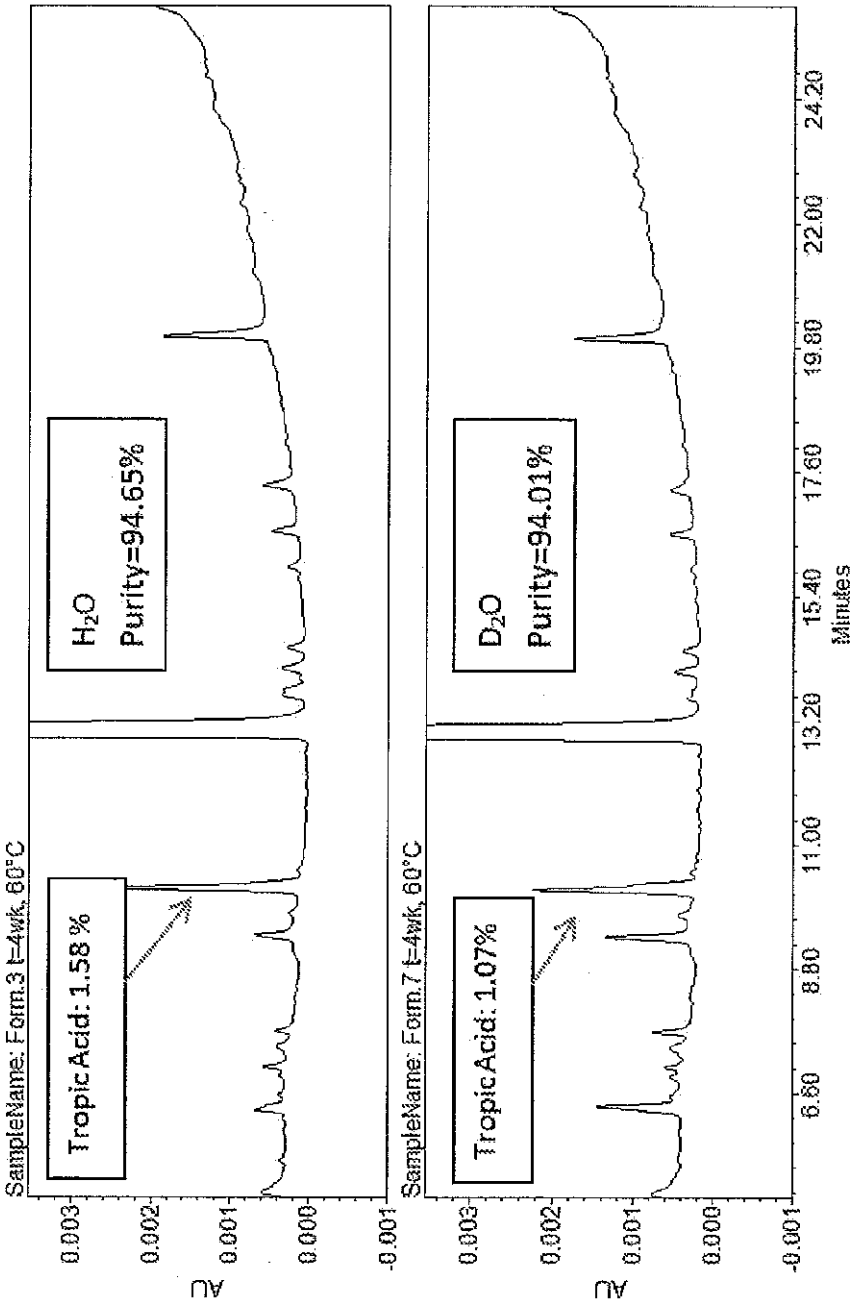

SampleName: Form.3 t=4wk, 60°C
Tropic Acid: 1.58 %
H2O
Purity=94.65%
SampleName: Form.7 t=4wk, 60°C
Tropic Acid: 1.07%
D2O
Purity=94.01%
AU
0.003
0.002
0.001
0.000
-0.001
6.80
8.80
11.00
13.20
15.40
17.60
19.80
22.00
24.20
Minutes

Fig. 5

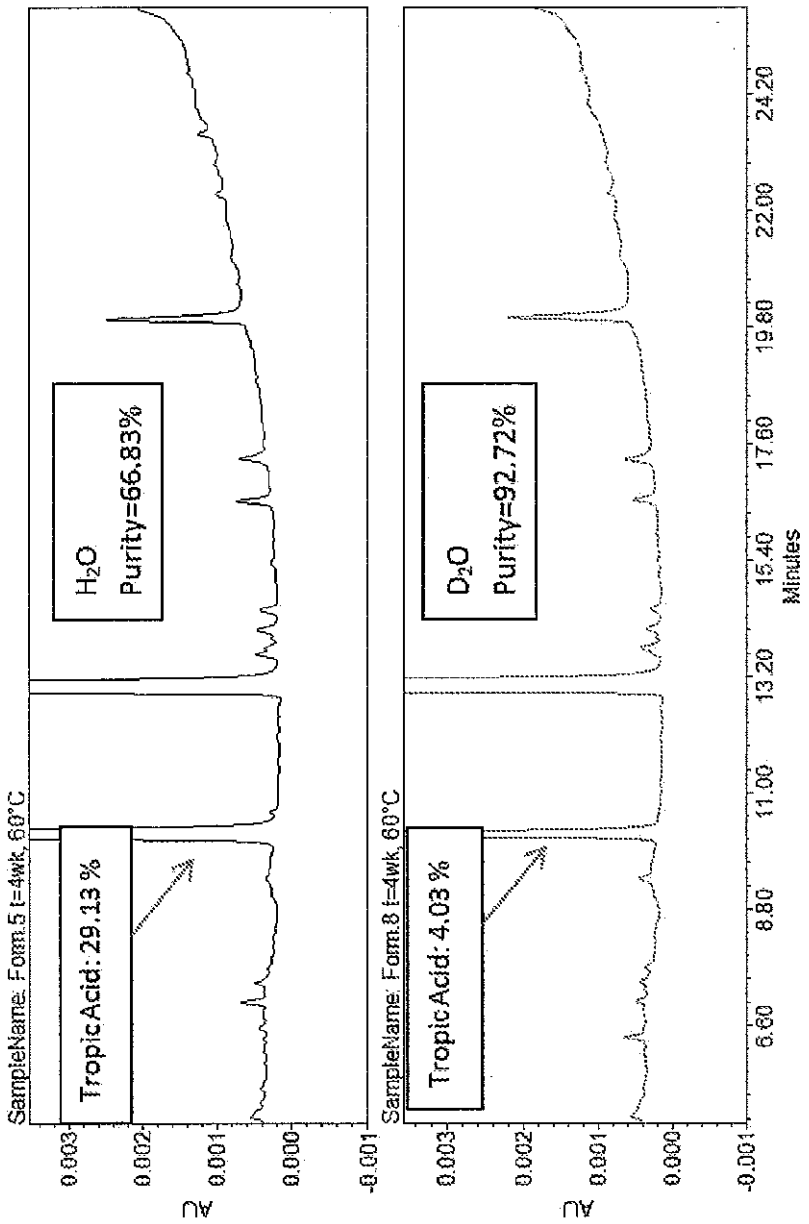

SampleName: Form.5 t=4wk, 60°C
Tropic Acid: 29.13 %
H2O
Purity=66.83%
SampleName: Form.8 t=4wk, 60°C
Tropic Acid: 4.03 %
D2O
Purity=92.72%
AU
0.003
0.002
0.001
0.000
-0.001
6.60
8.80
11.00
13.20
15.40
17.60
19.80
22.00
24.20
Minutes

Fig. 6

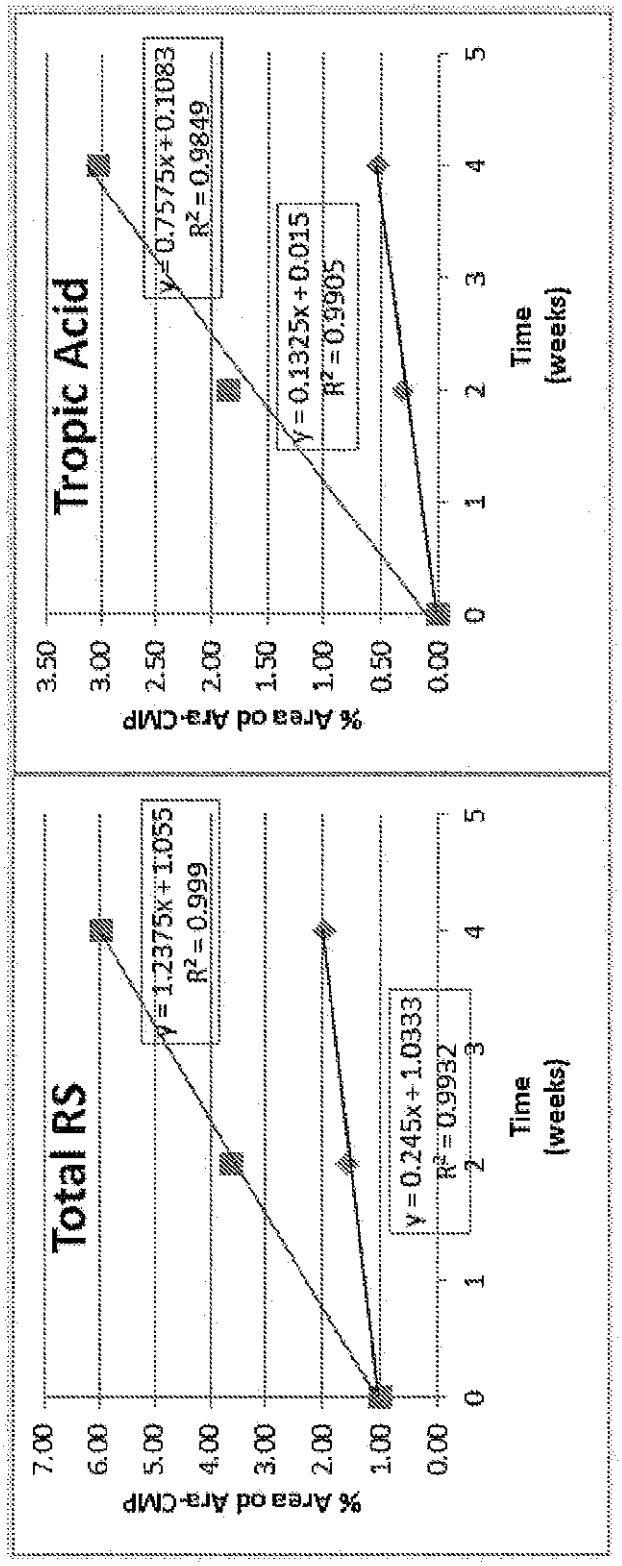

Tropic Acid
% Area od Ara-CMP
Time (weeks)
y = 0.7575x + 0.1083
R² = 0.9849
y = 0.1325x + 0.015
R² = 0.9905
Total RS
% Area od Ara-CMP
Time (weeks)
y = 1.2375x + 1.055
R² = 0.999
y = 0.245x + 1.0333
R² = 0.9932

Fig. 7

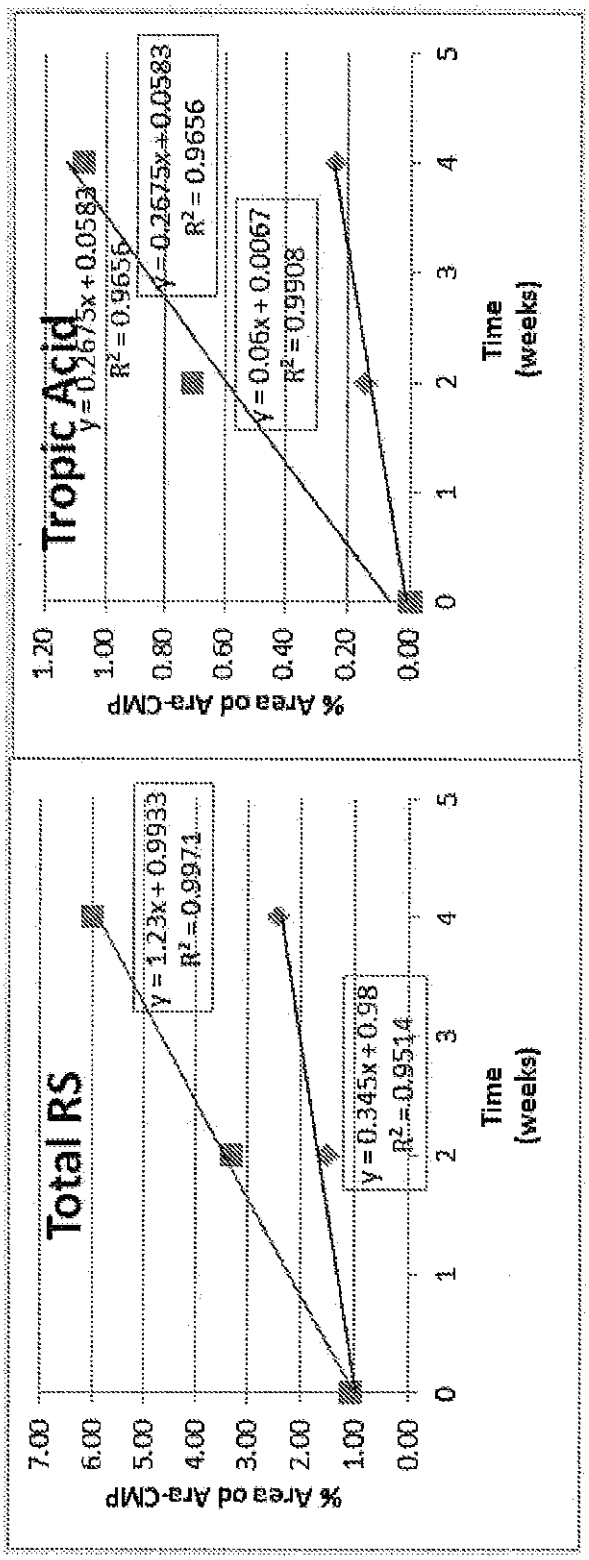
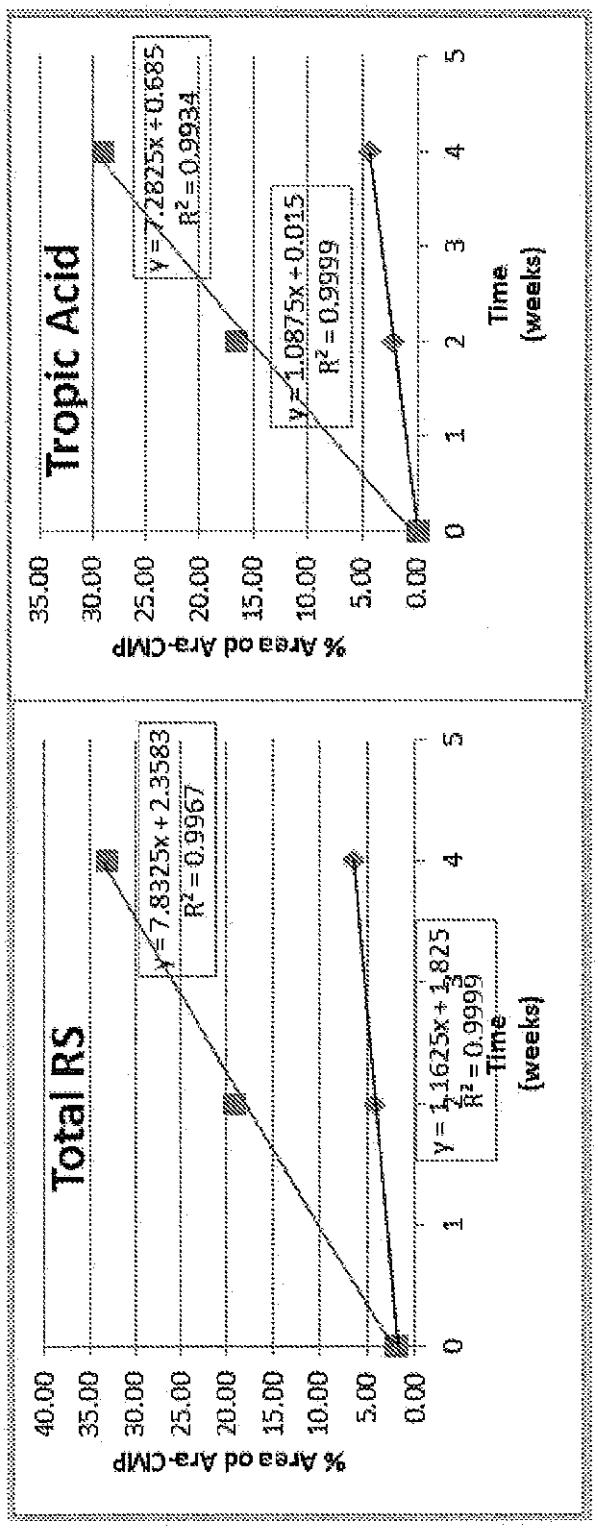

Tropic Acid
y = 0.2675x + 0.0583
R² = 0.9656
y = 0.05x + 0.0067
R² = 0.9908
% Area od Ara-CMP
Time (weeks)
Total RS
y = 1.23x + 0.9933
R² = 0.9971
y = 0.345x + 0.98
R² = 0.9514
% Area od Ara-CMP
Time (weeks)

Fig. 8


Tropic Acid
% Area od Ara-CMP
Time (weeks)
y = 7.2825x + 0.685
R² = 0.9934
y = 1.0875x + 0.015
R² = 0.9999
Total RS
% Area od Ara-CMP
Time (weeks)
y = 7.8325x + 2.3583
R² = 0.9967
y = 1.1625x + 1.825
R² = 0.9999

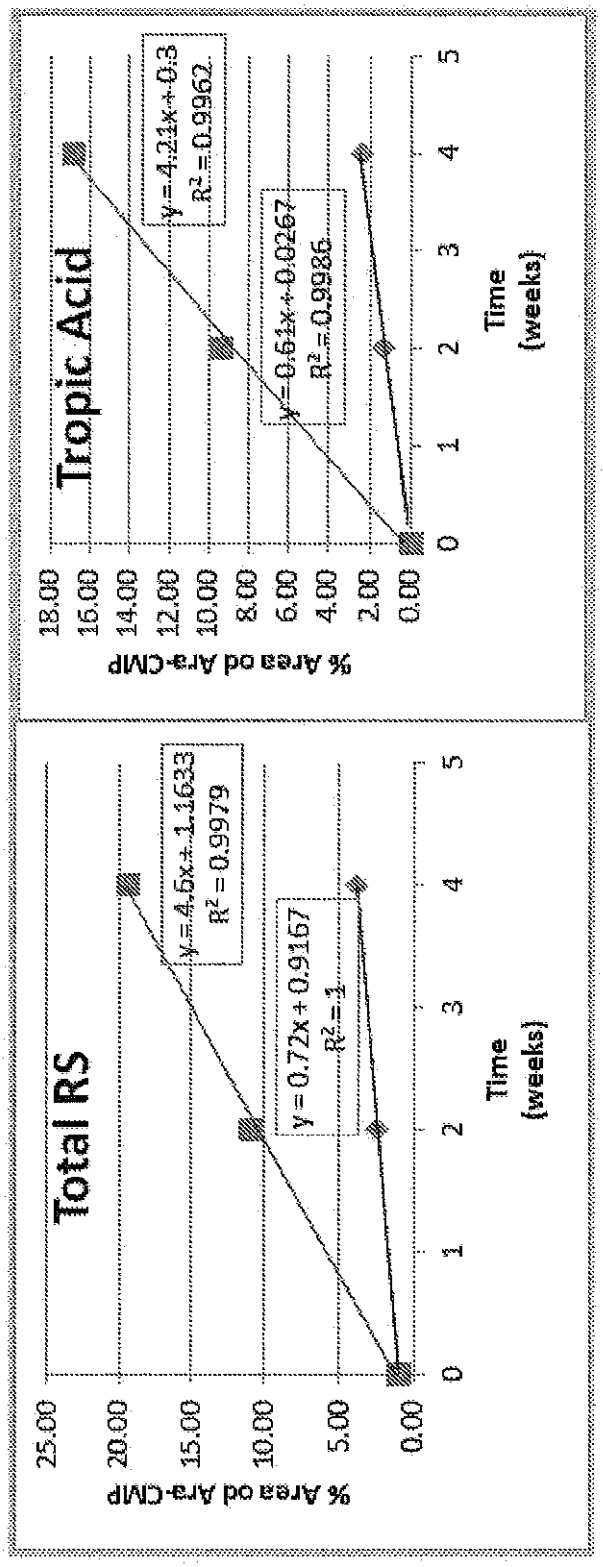
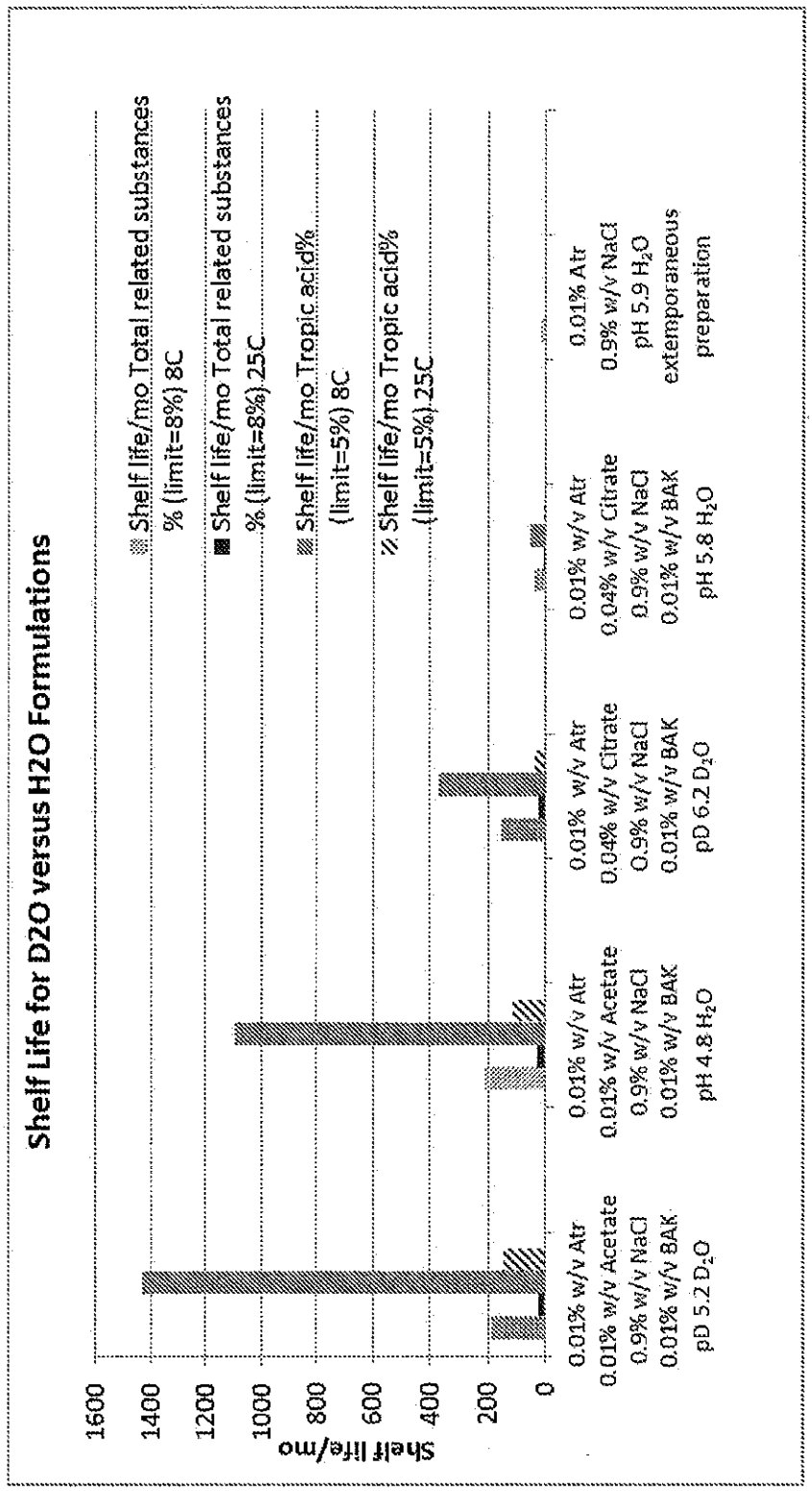

Tropic Acid
% Area od Ara-CMP
Time (weeks)
y = 4.21x + 0.3
R² = 0.9962
y = 0.61x + 0.0267
R² = 0.9936
Total RS
% Area od Ara-CMP
Time (weeks)
y = 4.6x + 1.1633
R² = 0.9979
y = 0.72x + 0.9167
R² = 1

Fig. 9

Fig. 10


Shelf Life for D2O versus H2O Formulations
Shelf life/mo
1600
1400
1200
1000
800
600
400
200
0
Shelf life/mo Total related substances % (limit=8%) 8C
Shelf life/mo Total related substances % (limit=8%) 25C
Shelf life/mo Tropic acid% (limit=5%) 8C
Shelf life/mo Tropic acid% (limit=5%) 25C
0.01% w/v Atr
0.01% w/v Acetate
0.9% w/v NaCl
0.01% w/v BAK
pD 5.2 D2O
0.01% w/v Atr
0.01% w/v Acetate
0.9% w/v NaCl
0.01% w/v BAK
pH 4.8 H2O
0.01% w/v Atr
0.04% w/v Citrate
0.9% w/v NaCl
0.01% w/v BAK
pD 6.2 D2O
0.01% w/v Atr
0.04% w/v Citrate
0.9% w/v NaCl
0.01% w/v BAK
pH 5.8 H2O
0.01% Atr
0.9% w/v NaCl
pH 5.9 H2O
extemporaneous preparation