

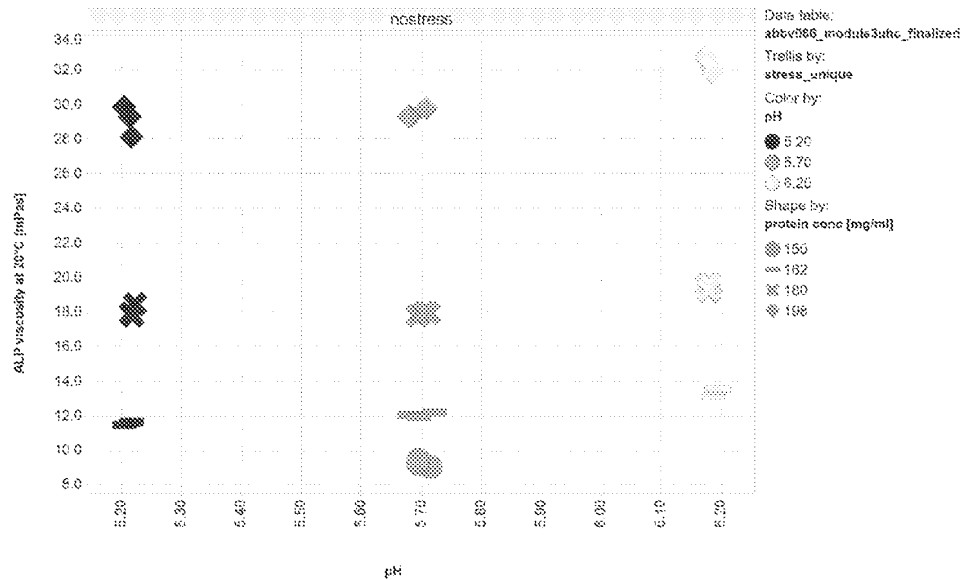


FIG. 1A

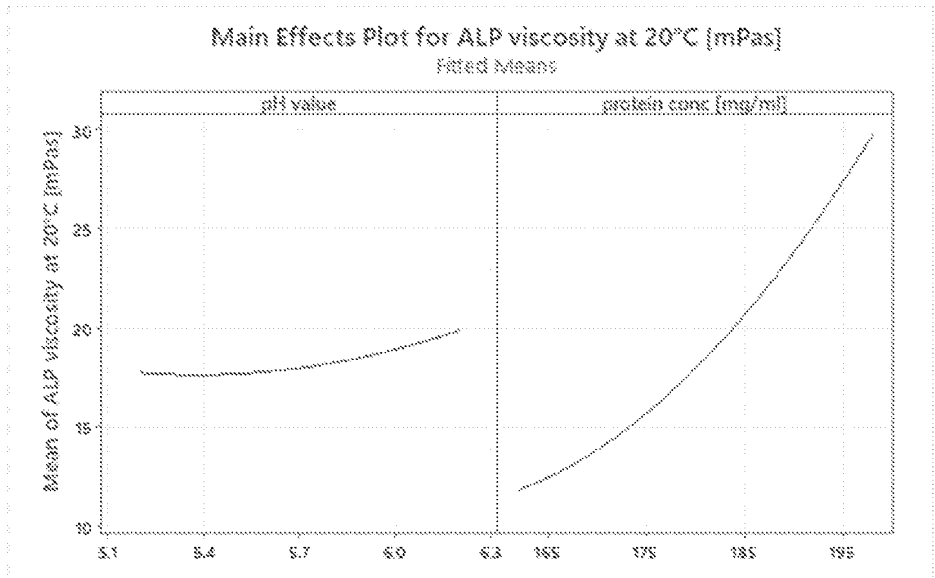


FIG. 1B

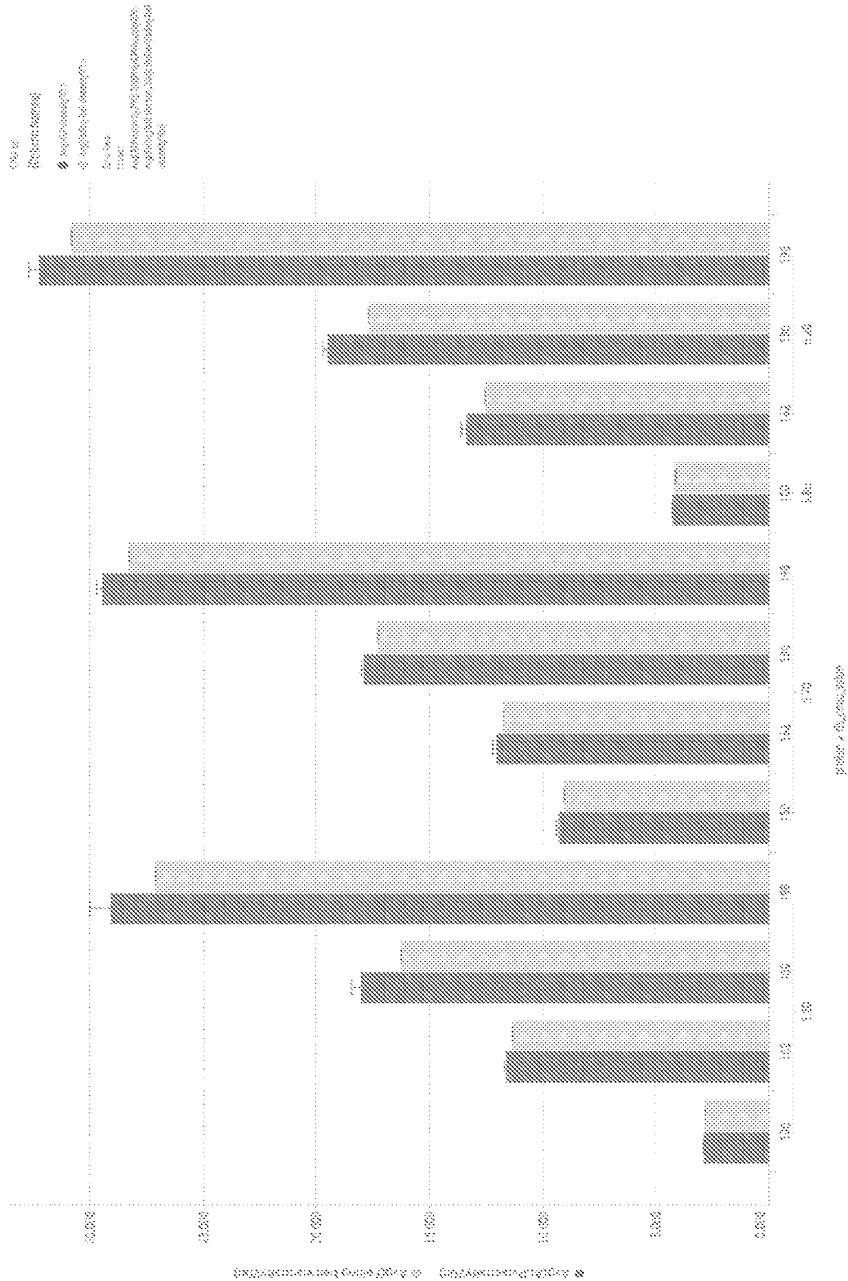


FIG. 2

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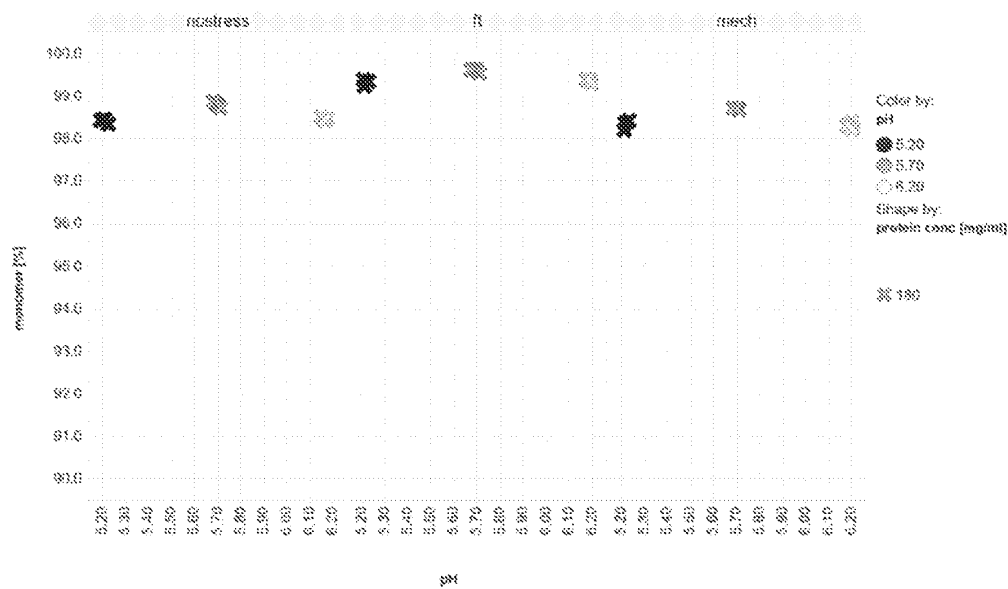


FIG. 3A

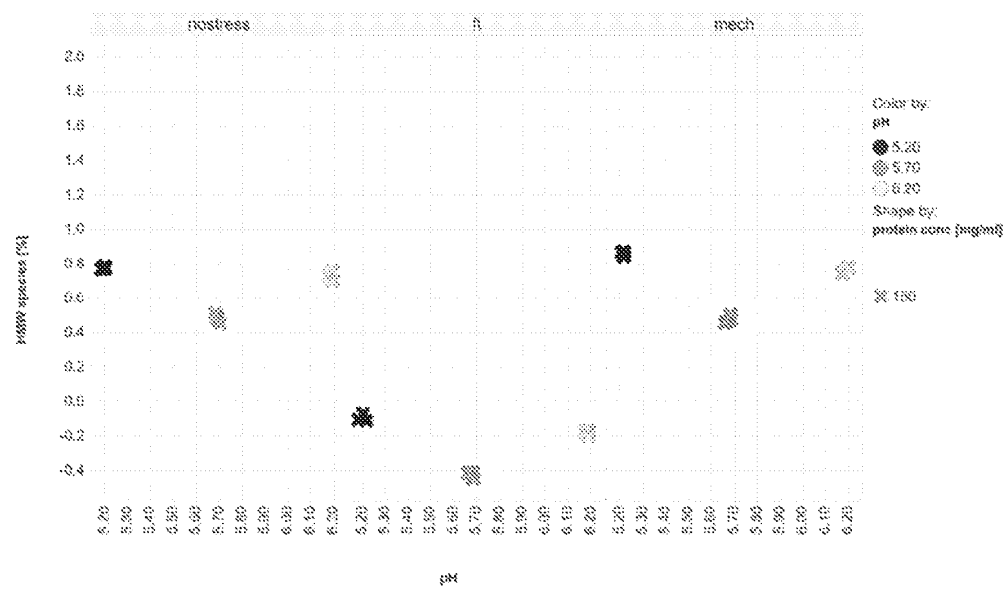


FIG. 3B

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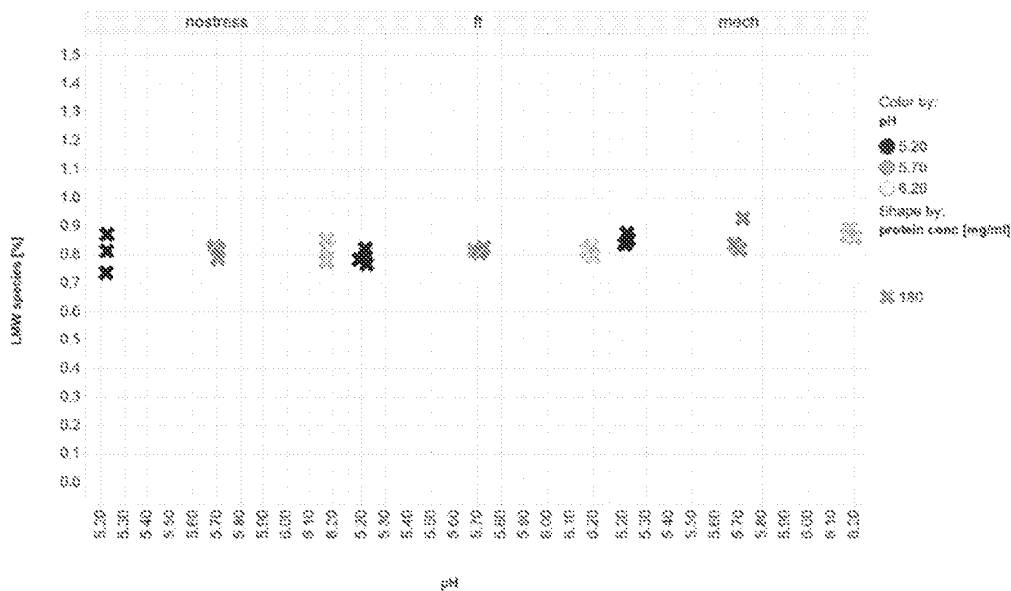


FIG. 3C

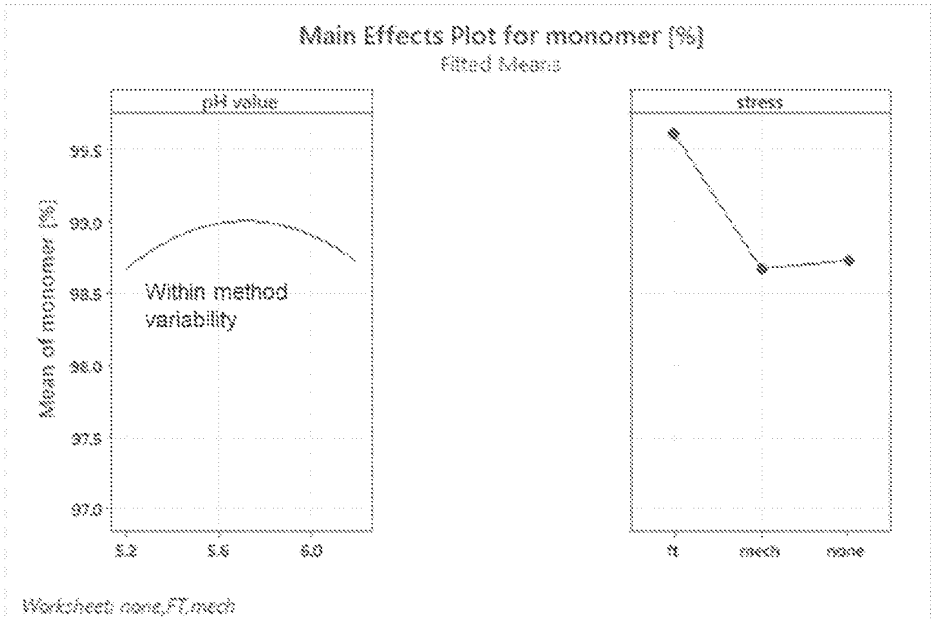


FIG. 3D

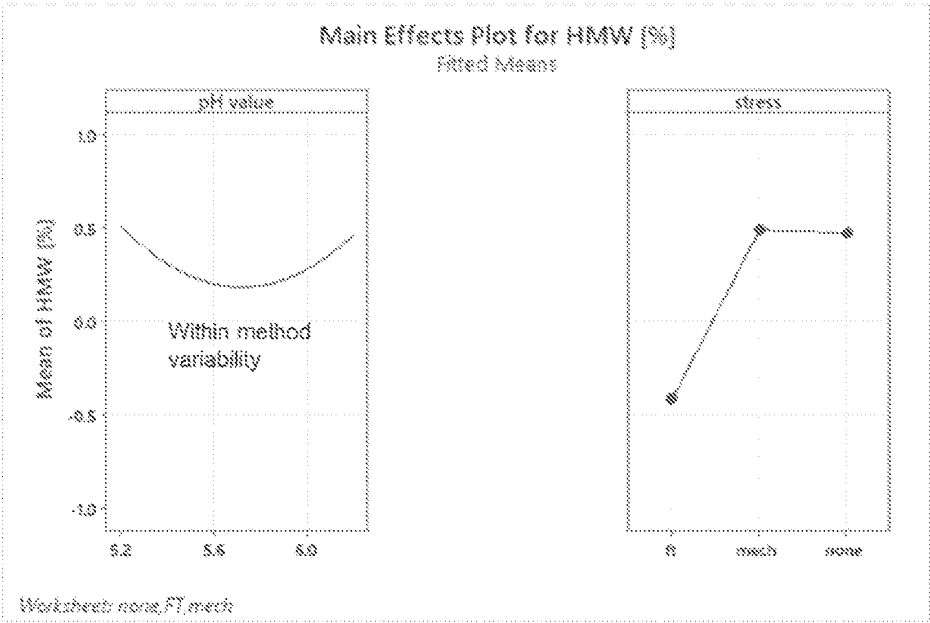


FIG. 3E

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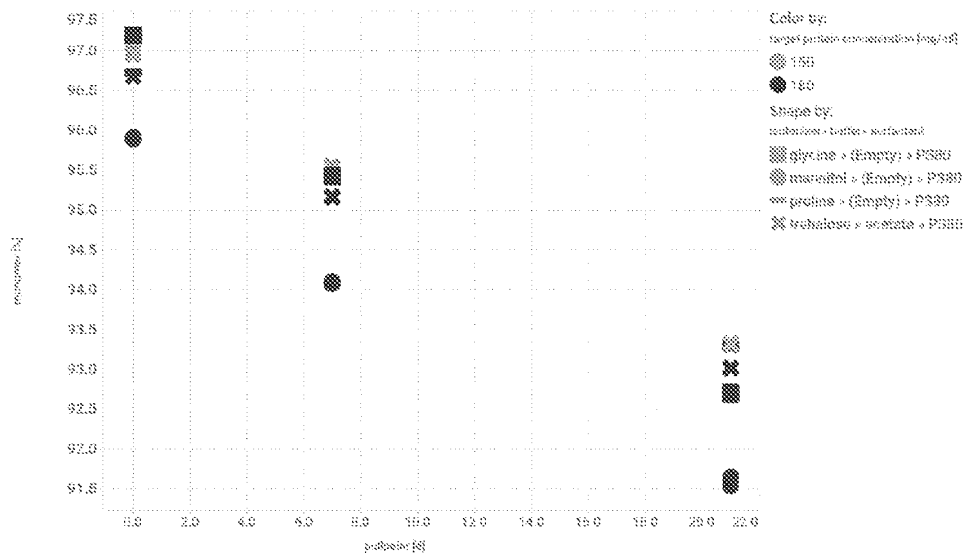


FIG. 4A

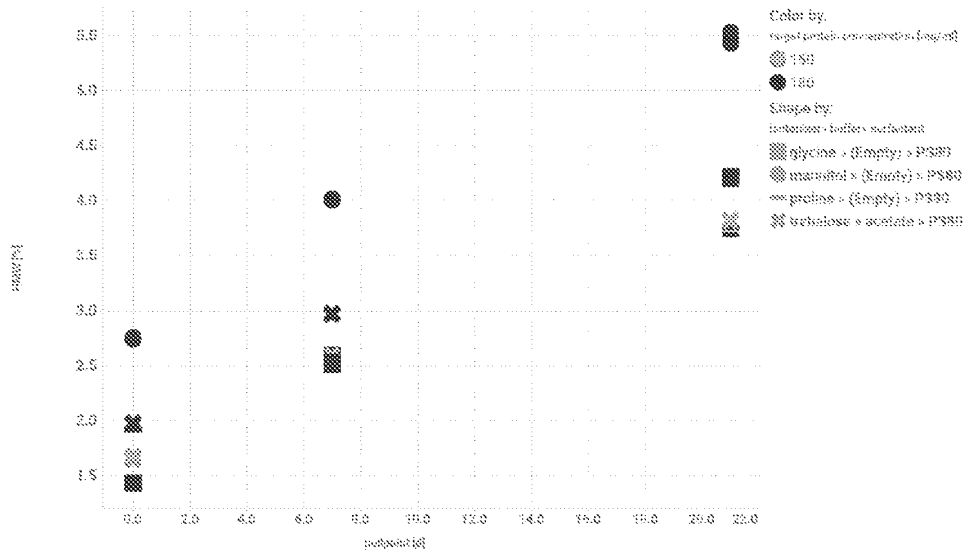


FIG. 4B

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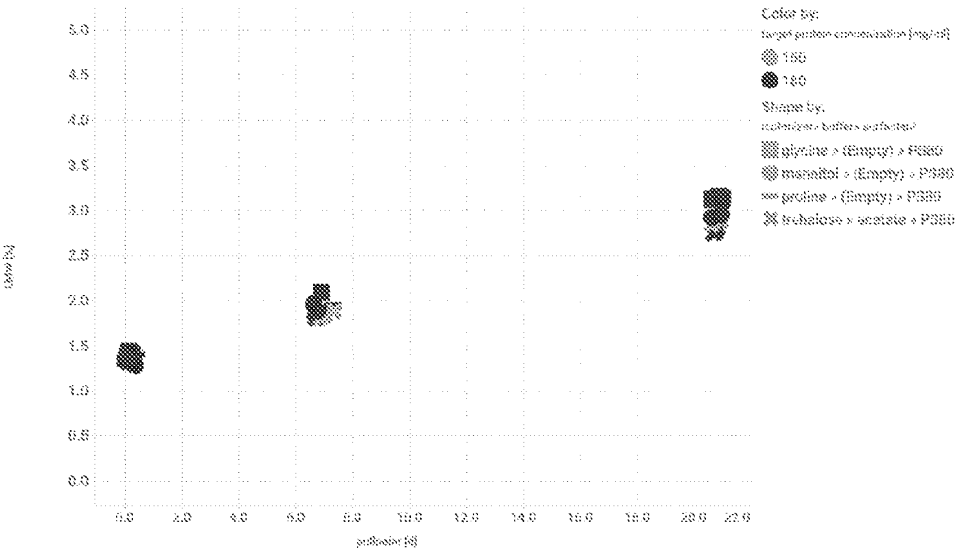


FIG. 4C

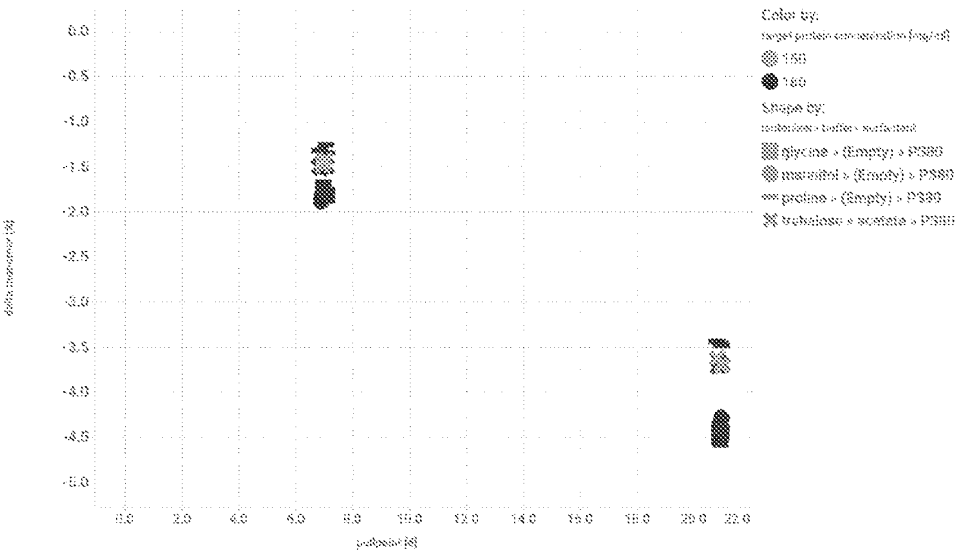


FIG. 4D

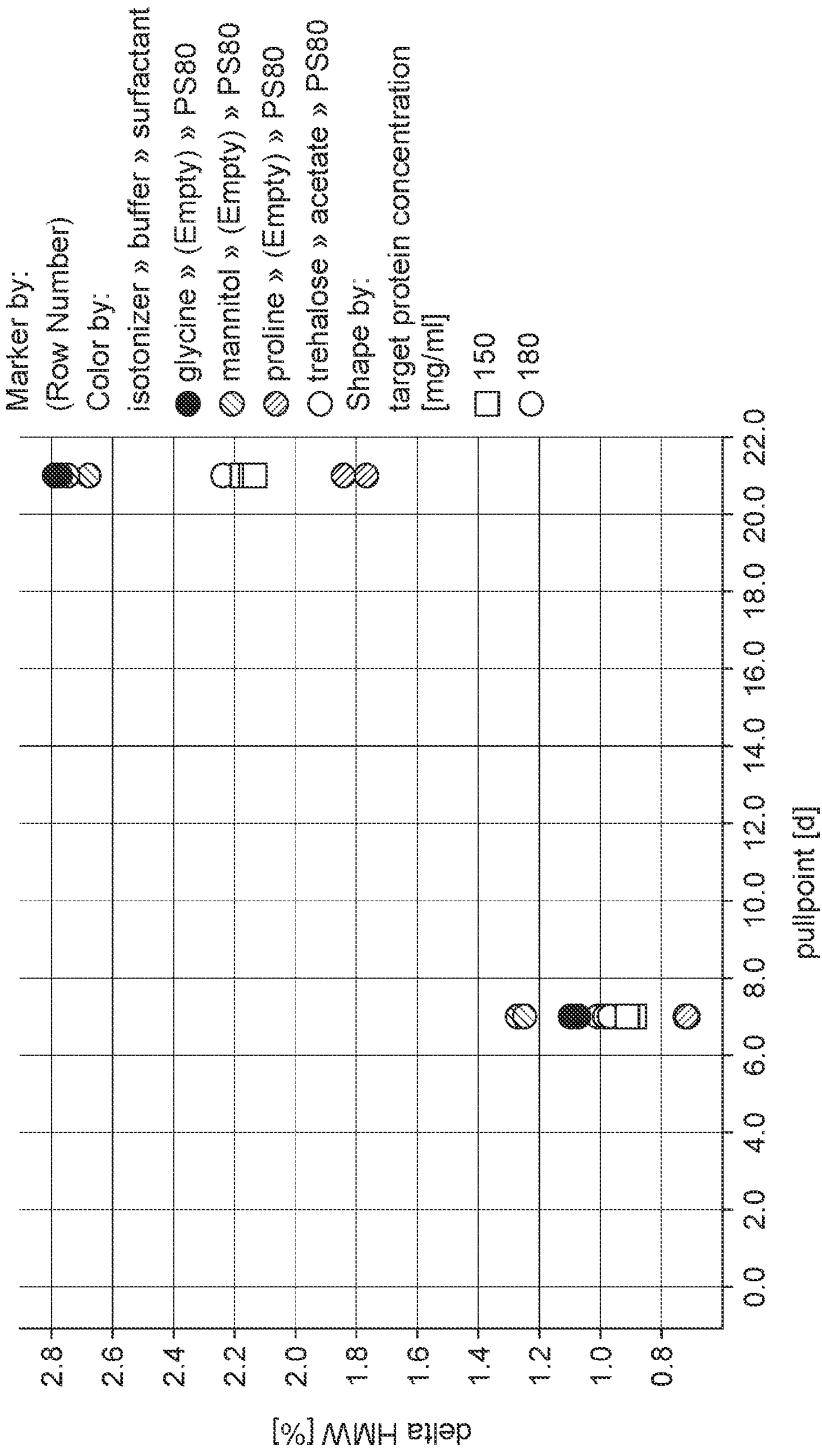


FIG. 4E

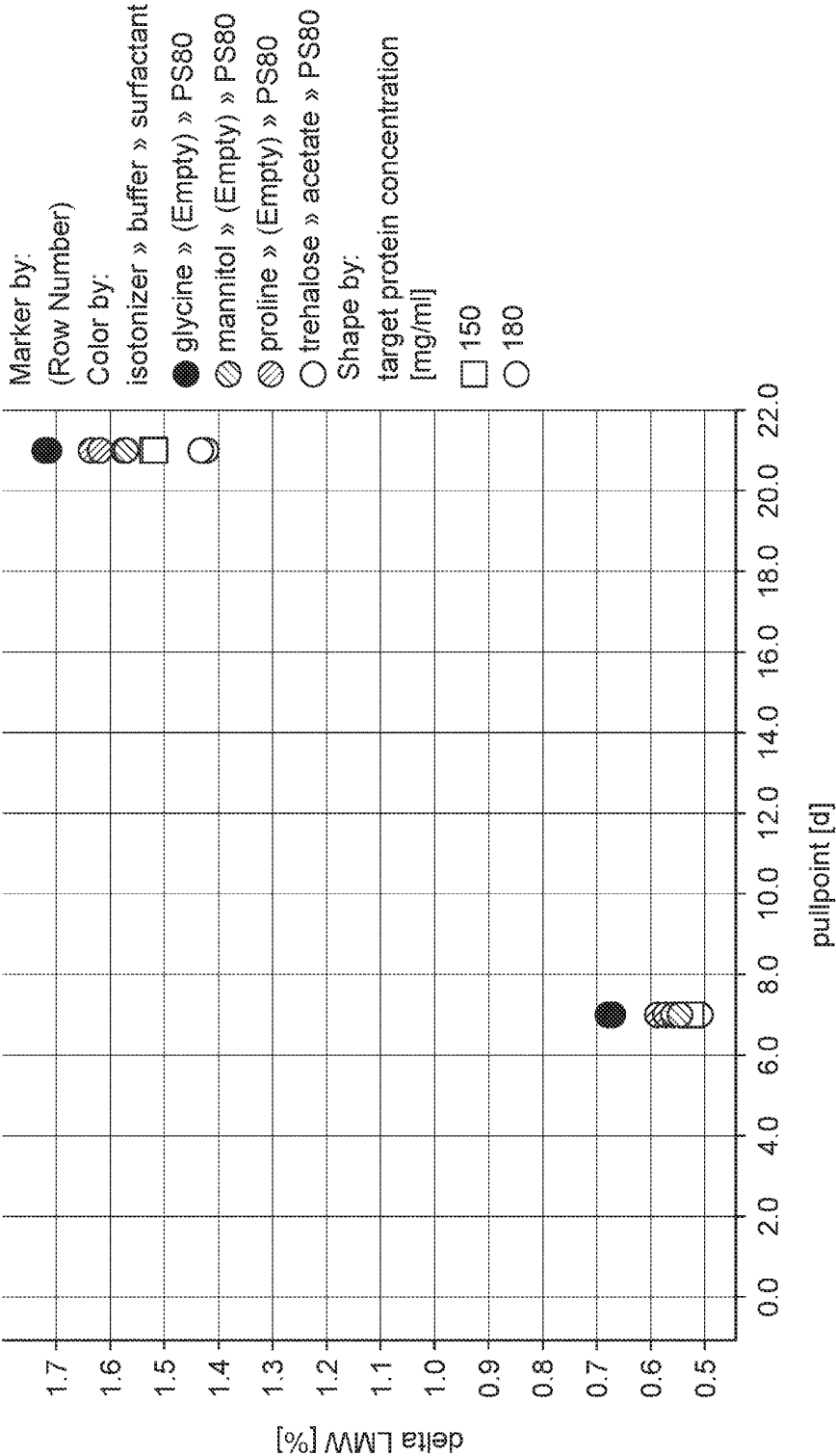


FIG. 4F

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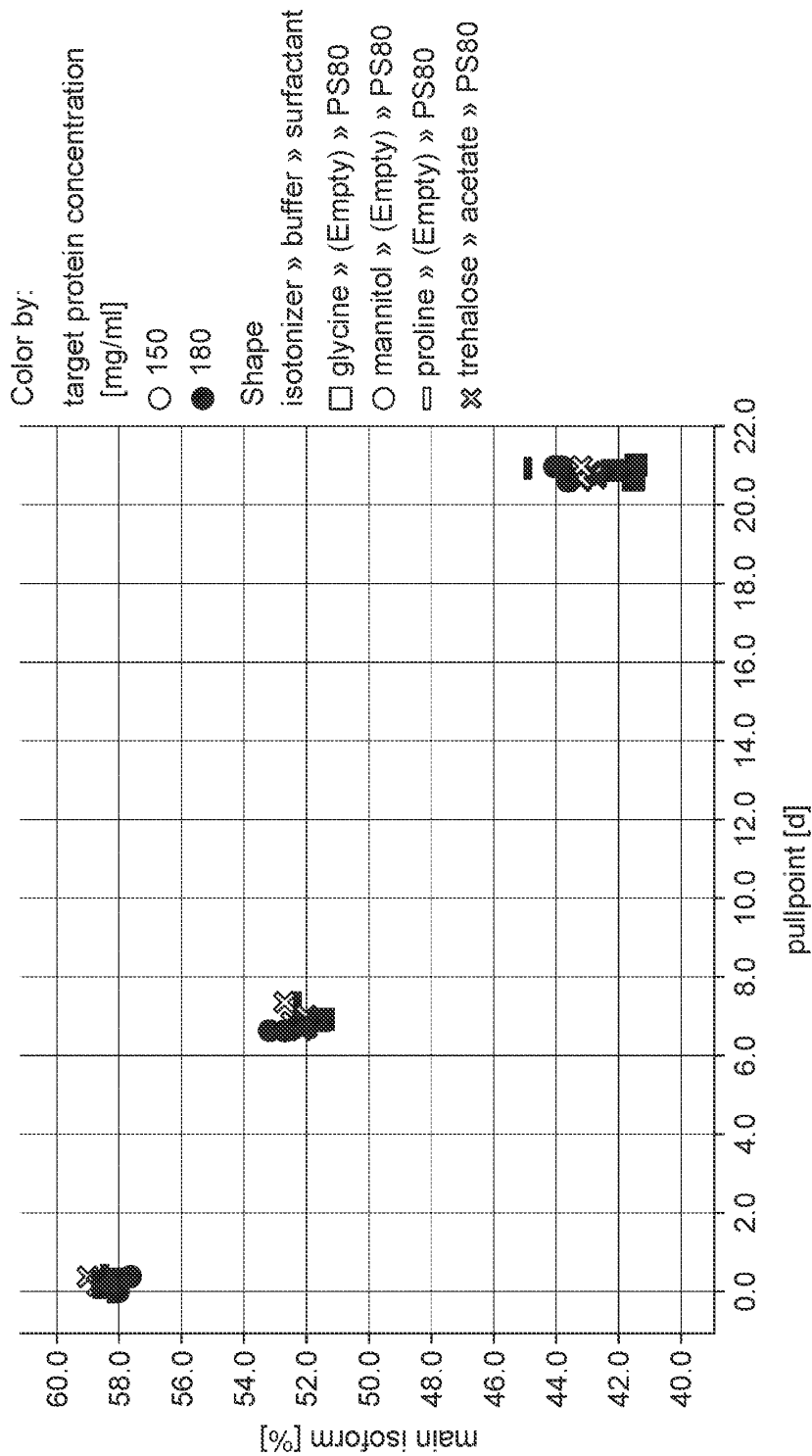


FIG. 5A

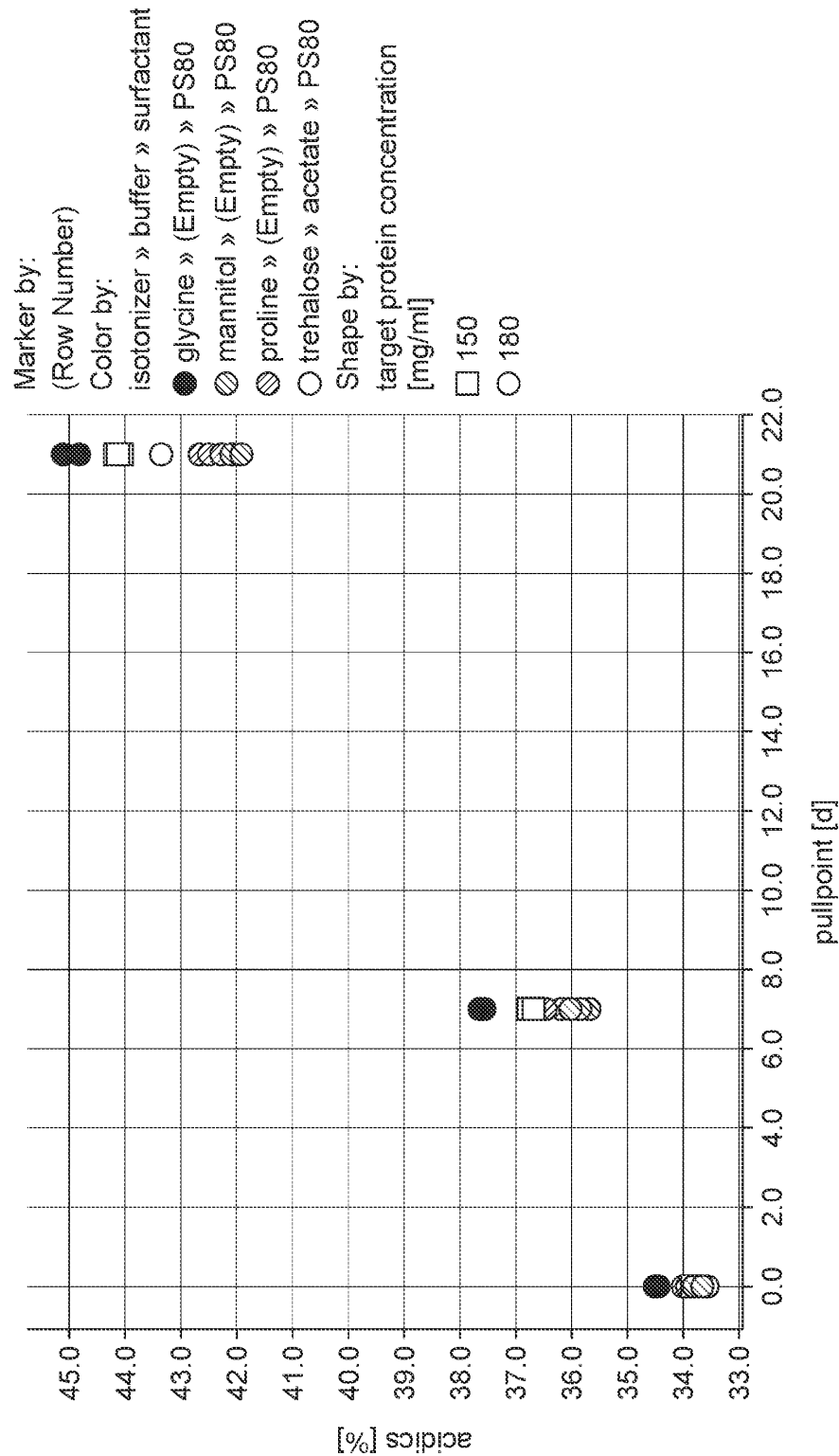


FIG. 5B

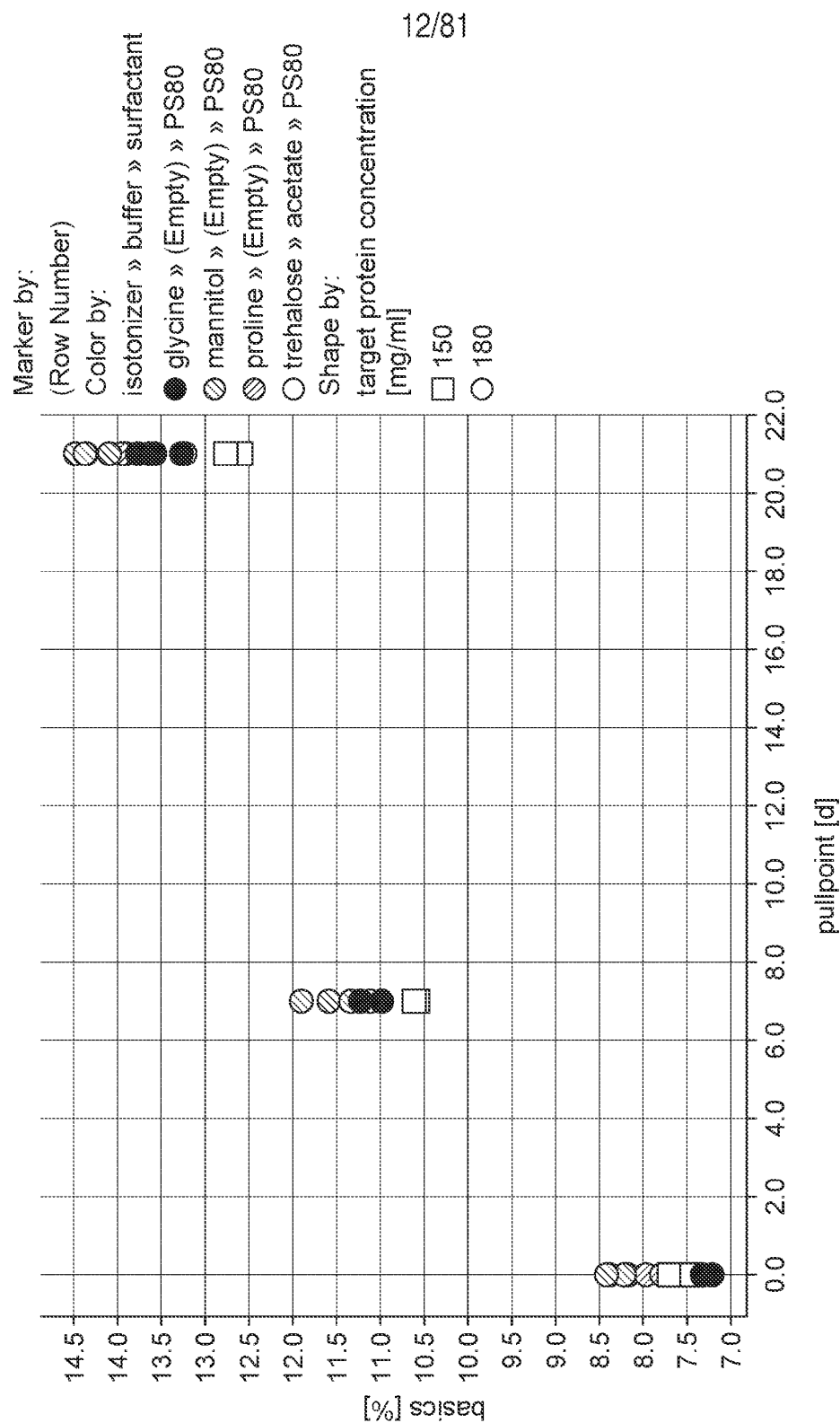


FIG. 5C

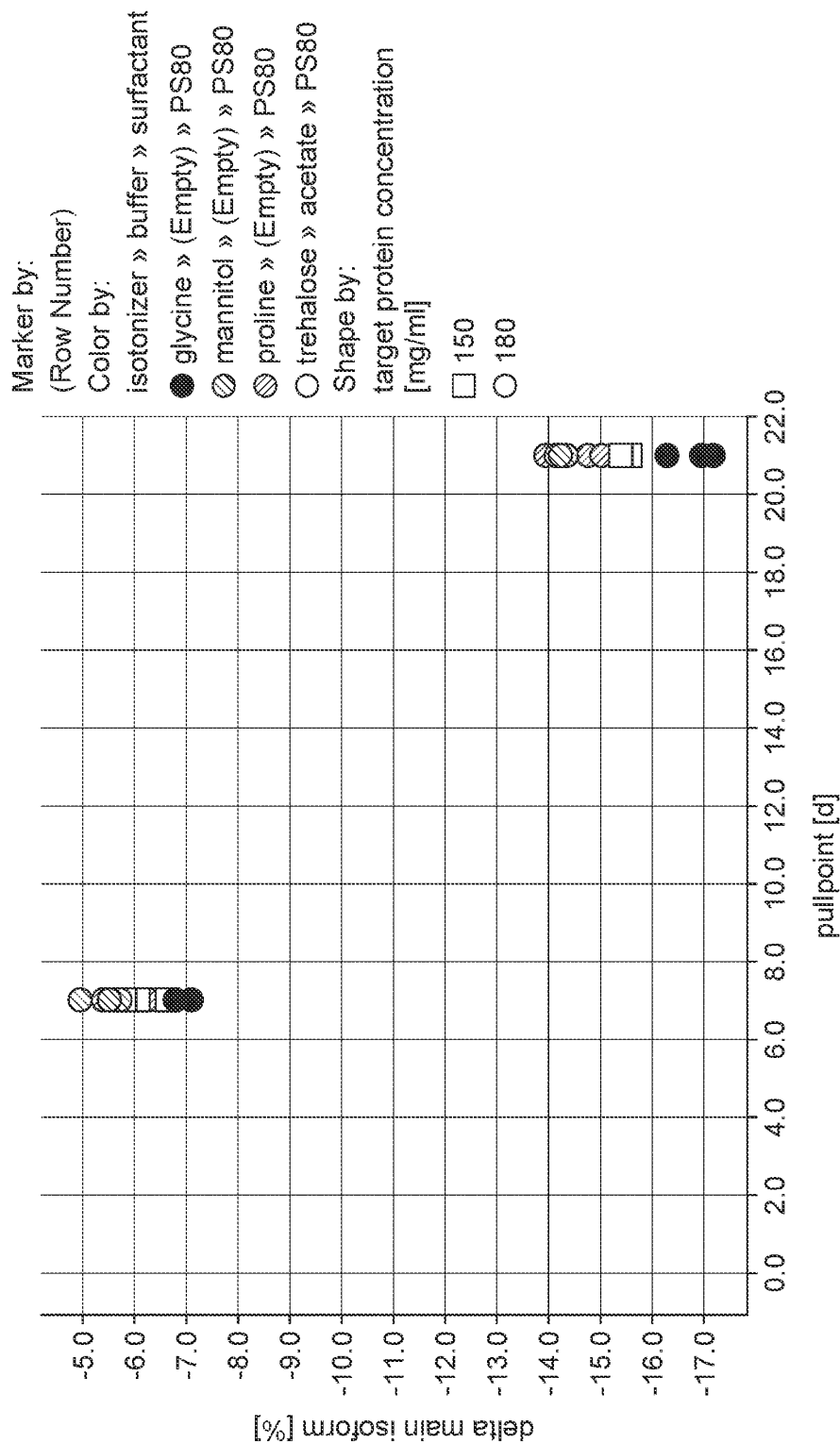


FIG. 5D

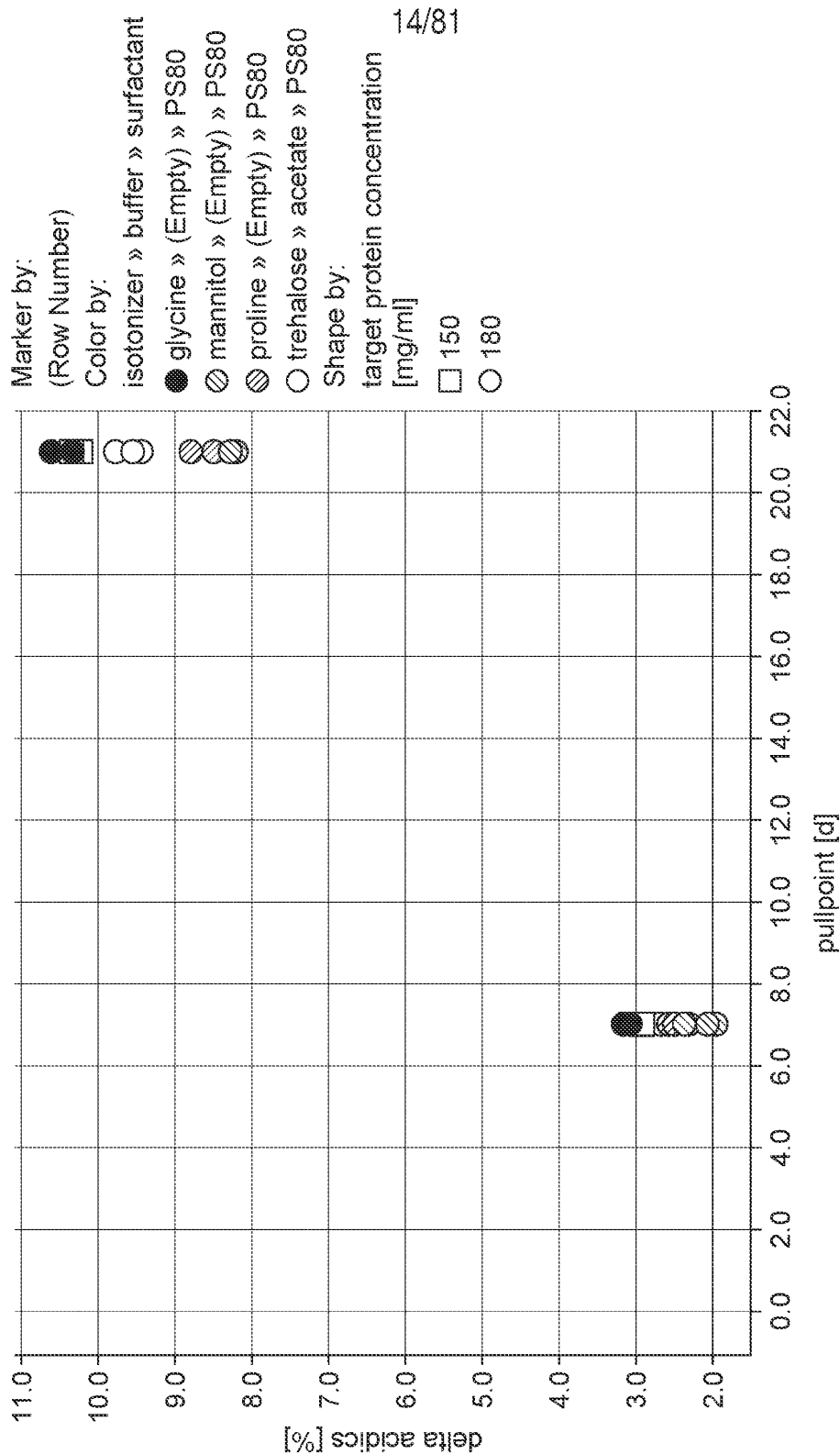


FIG. 5E

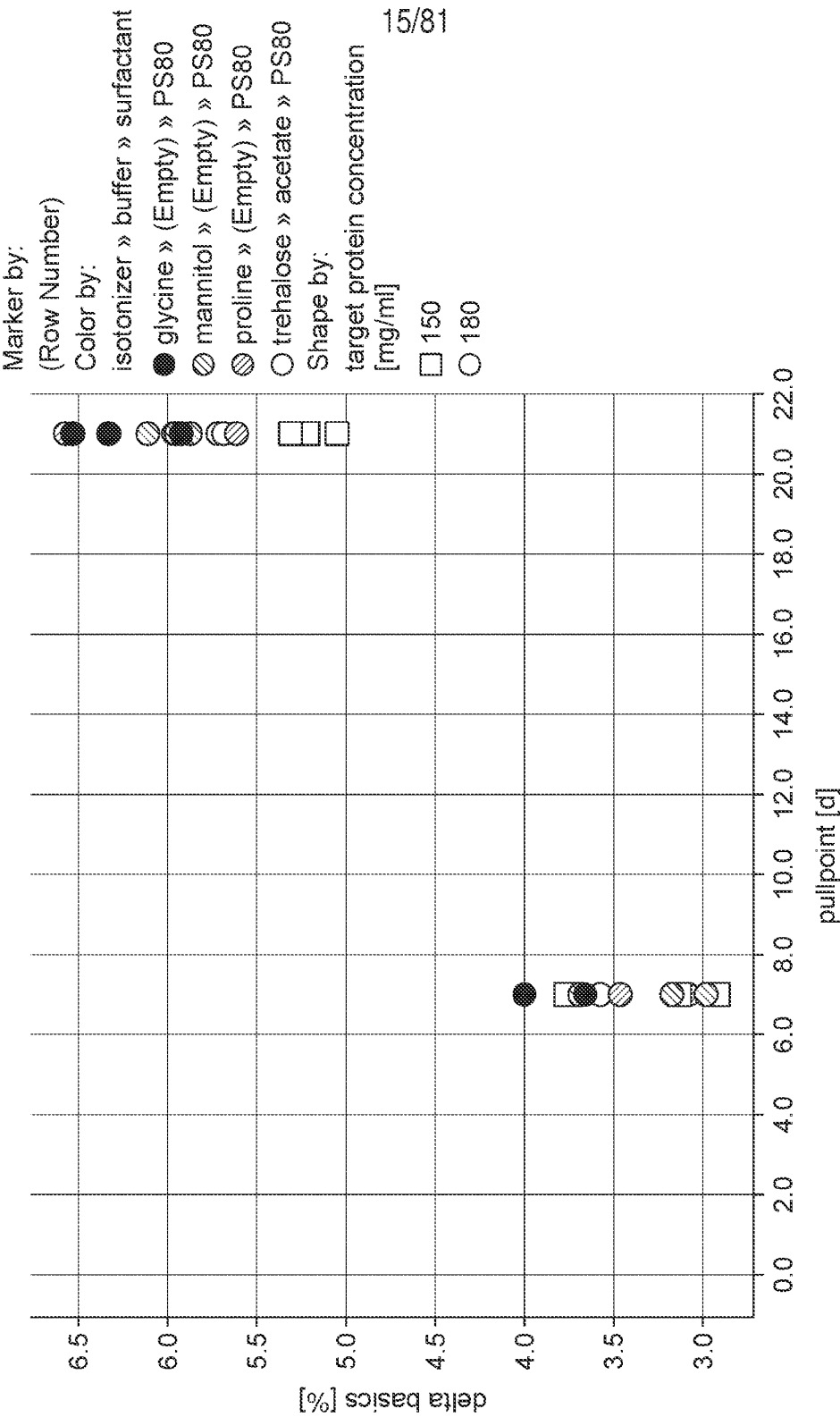


FIG. 5F

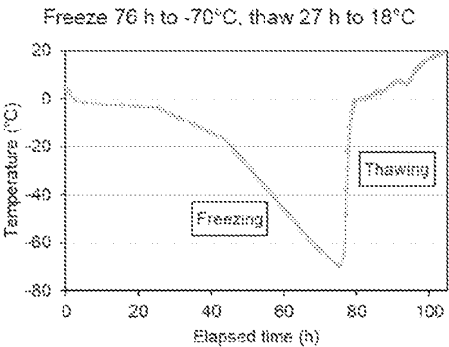


FIG. 6A

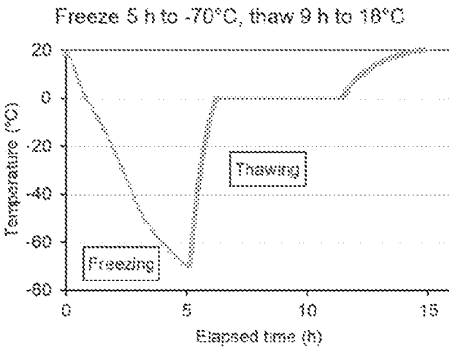


FIG. 6B

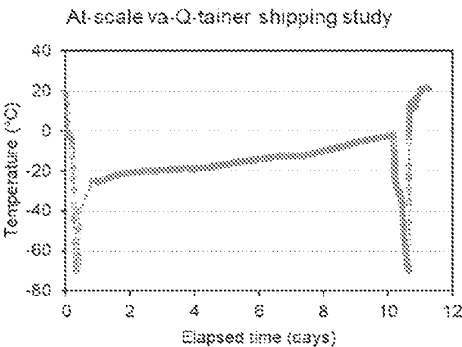


FIG. 6C

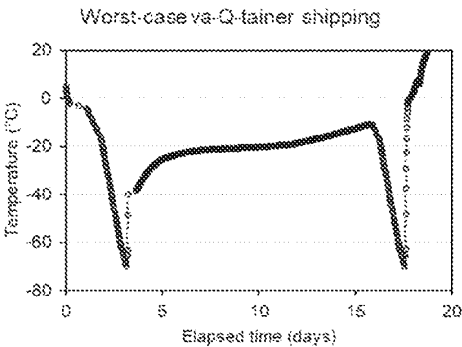


FIG. 6D

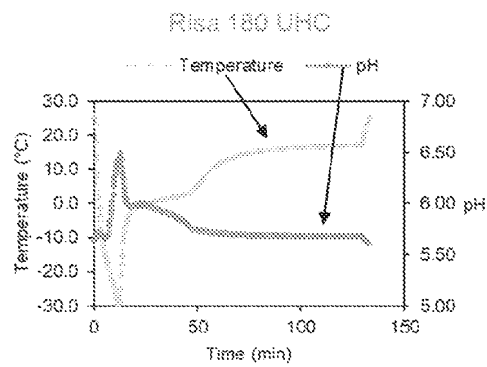


FIG. 7A

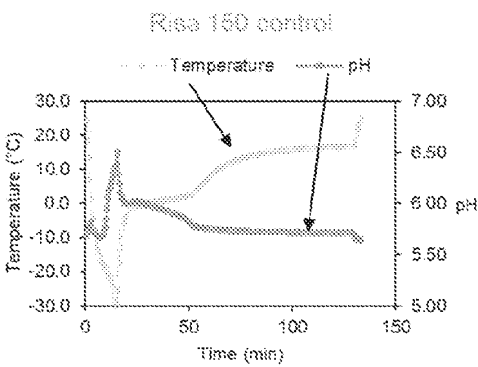


FIG. 7B

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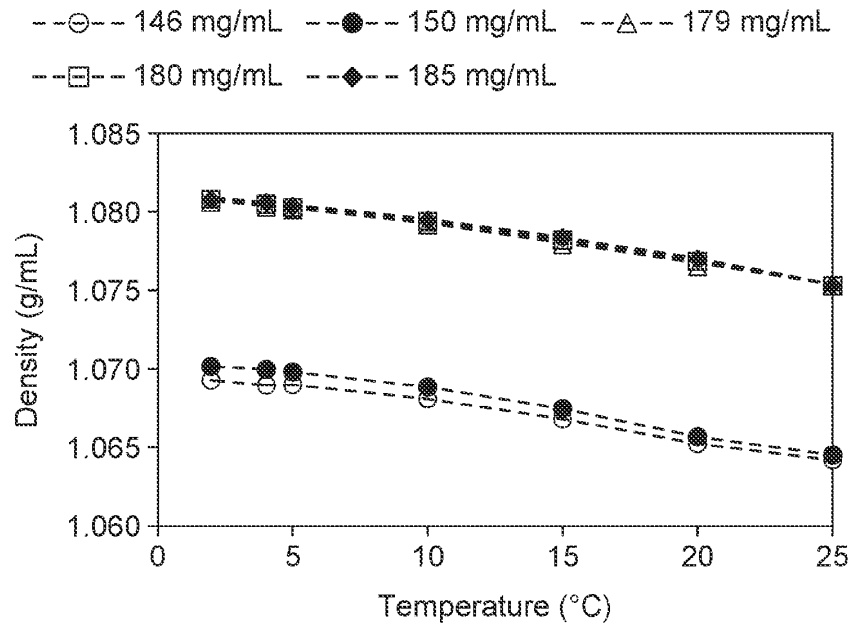


FIG. 8A

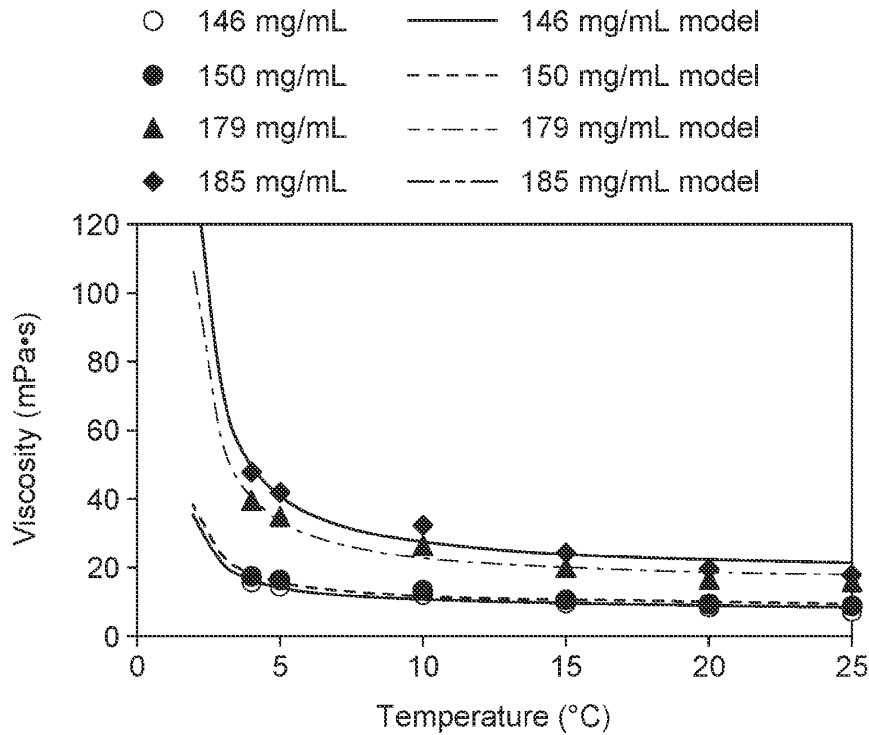


FIG. 8B

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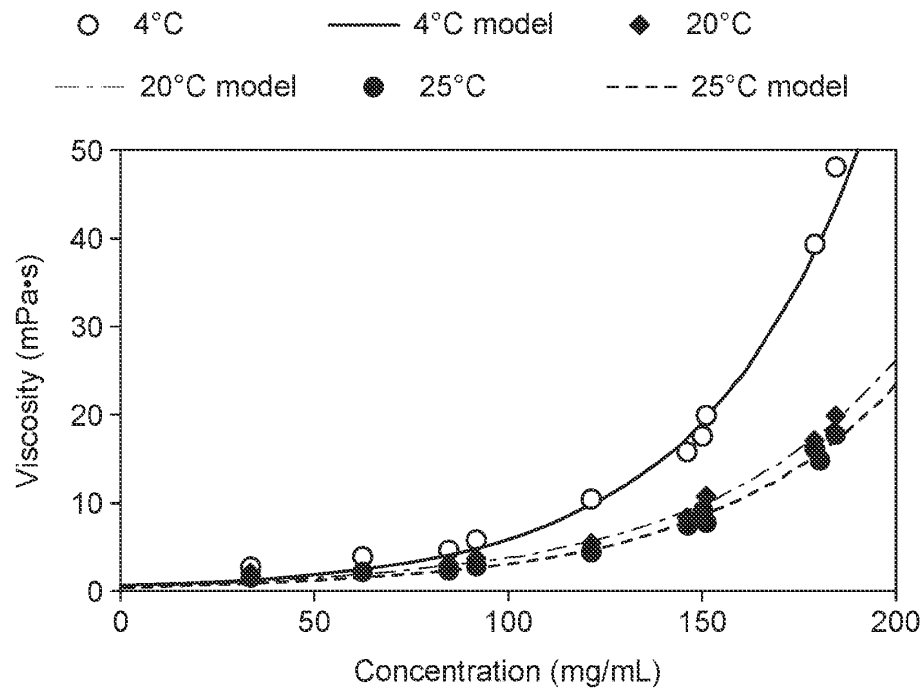


FIG. 8C

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Slow F-T MFI

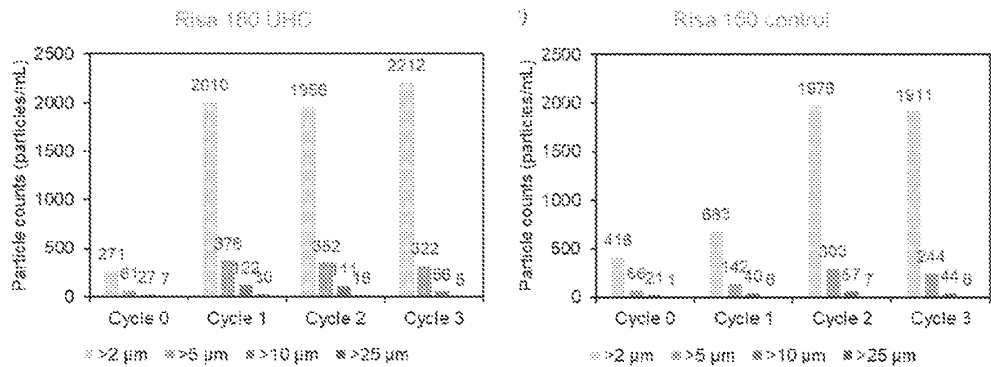


FIG. 9A

FIG. 9B

Fast F-T MFI

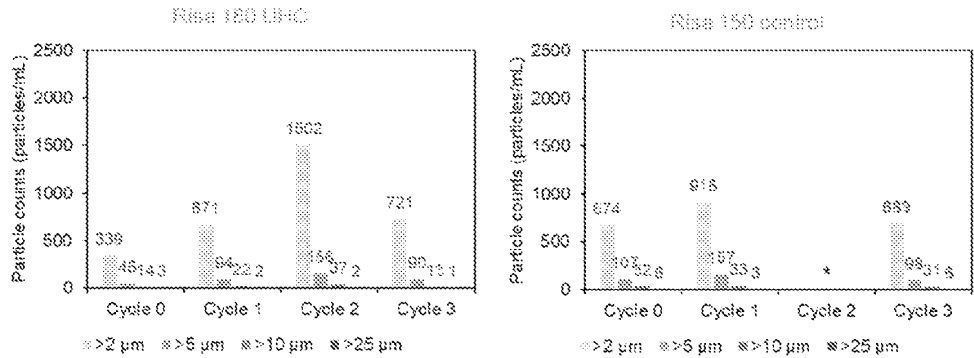


FIG. 9C

FIG. 9D

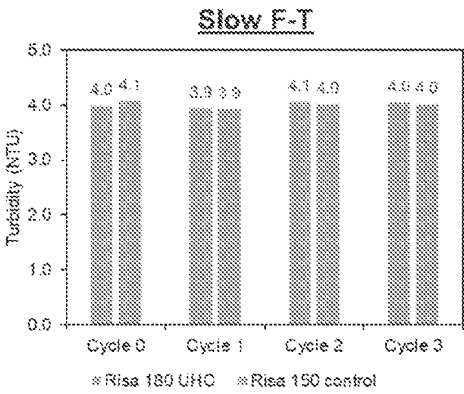


FIG. 10A

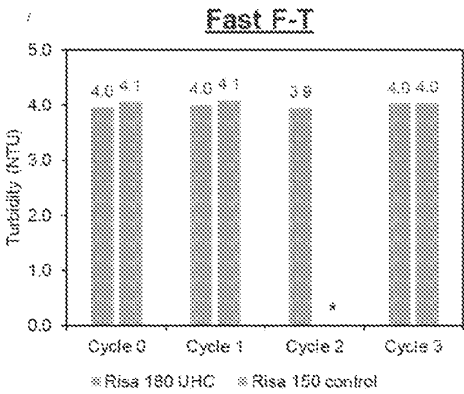


FIG. 10B

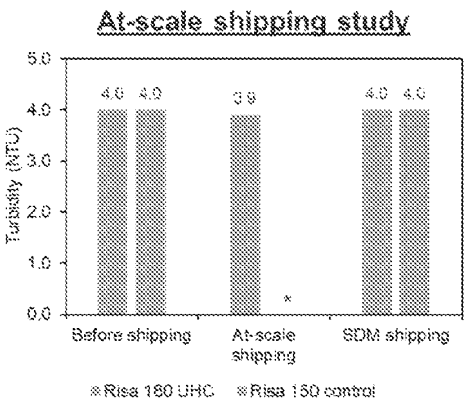


FIG. 10C

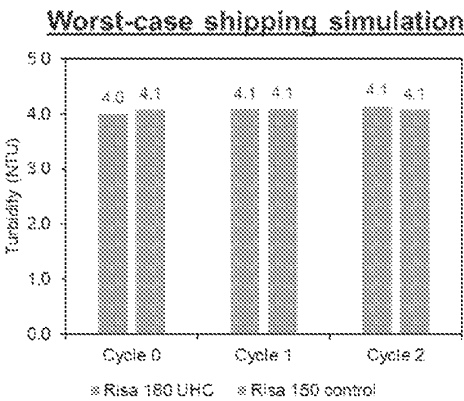


FIG. 10D

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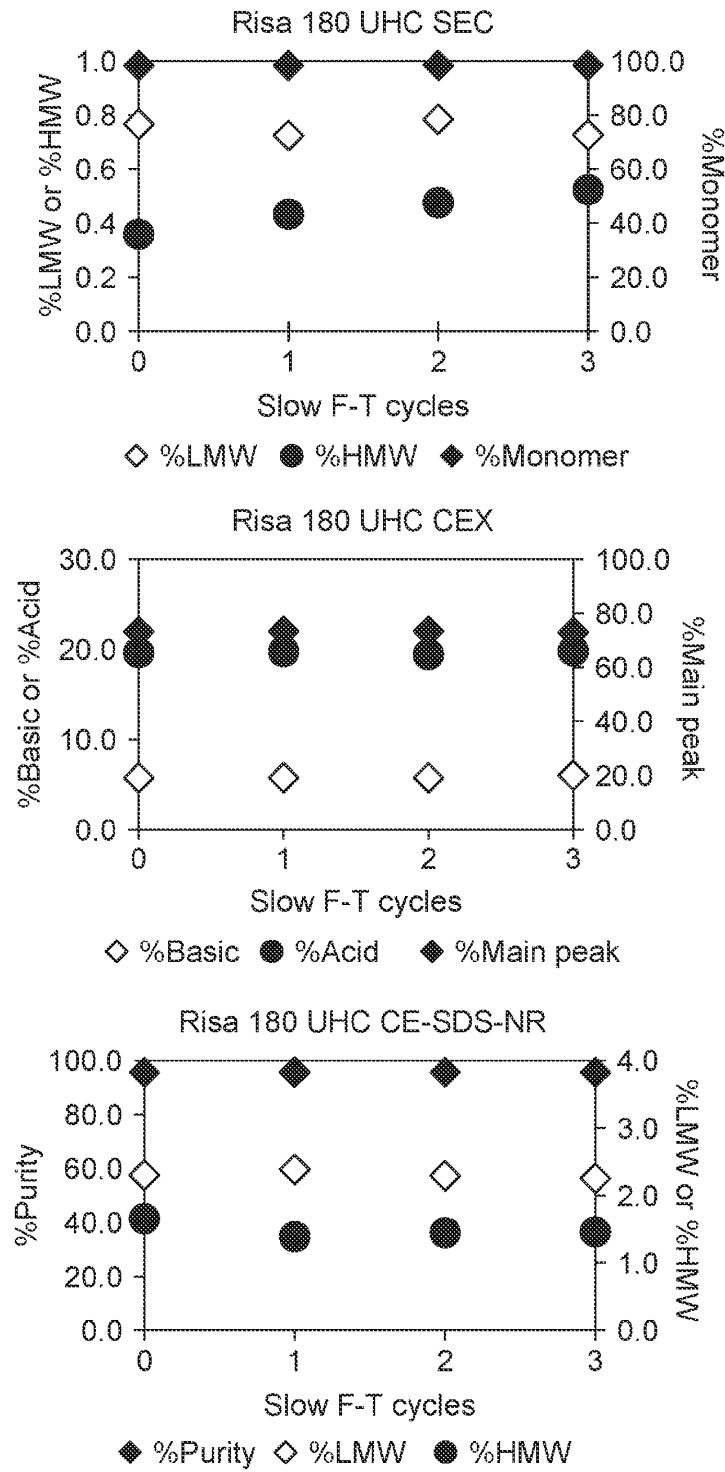


FIG. 11A

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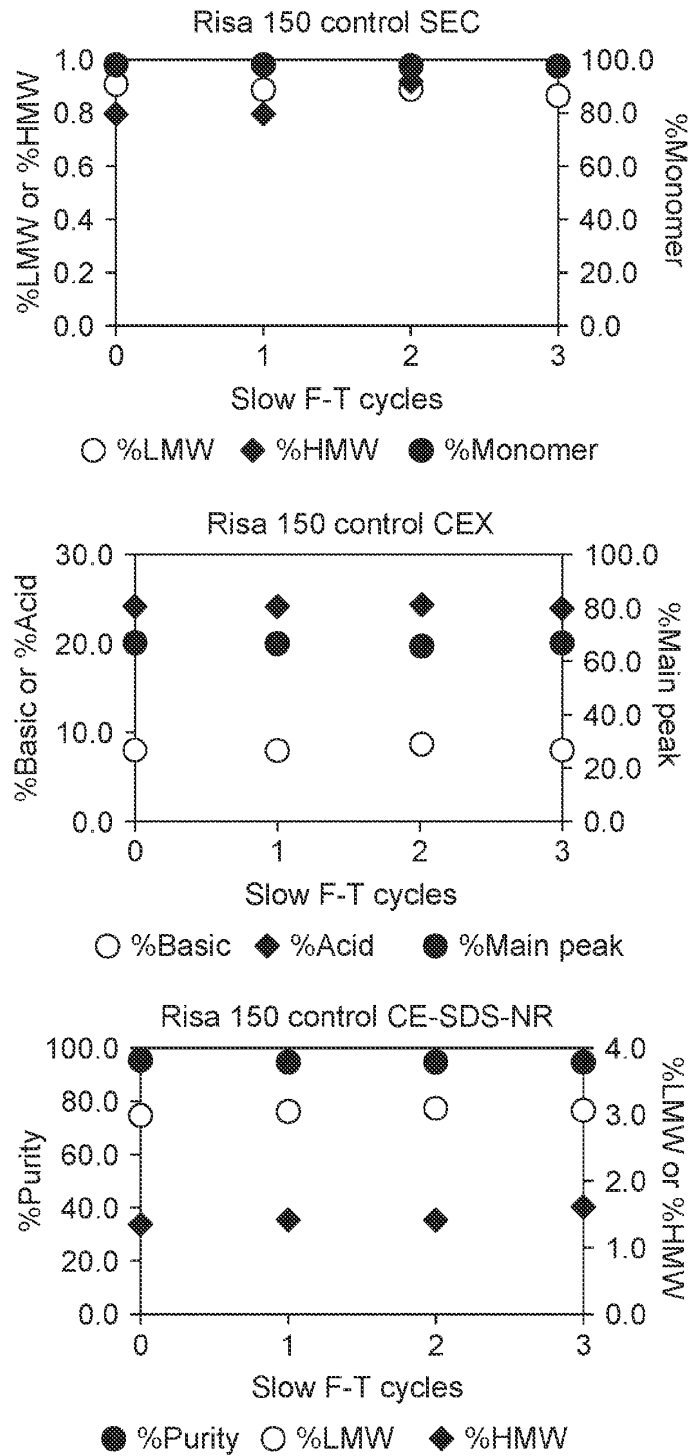


FIG. 11B

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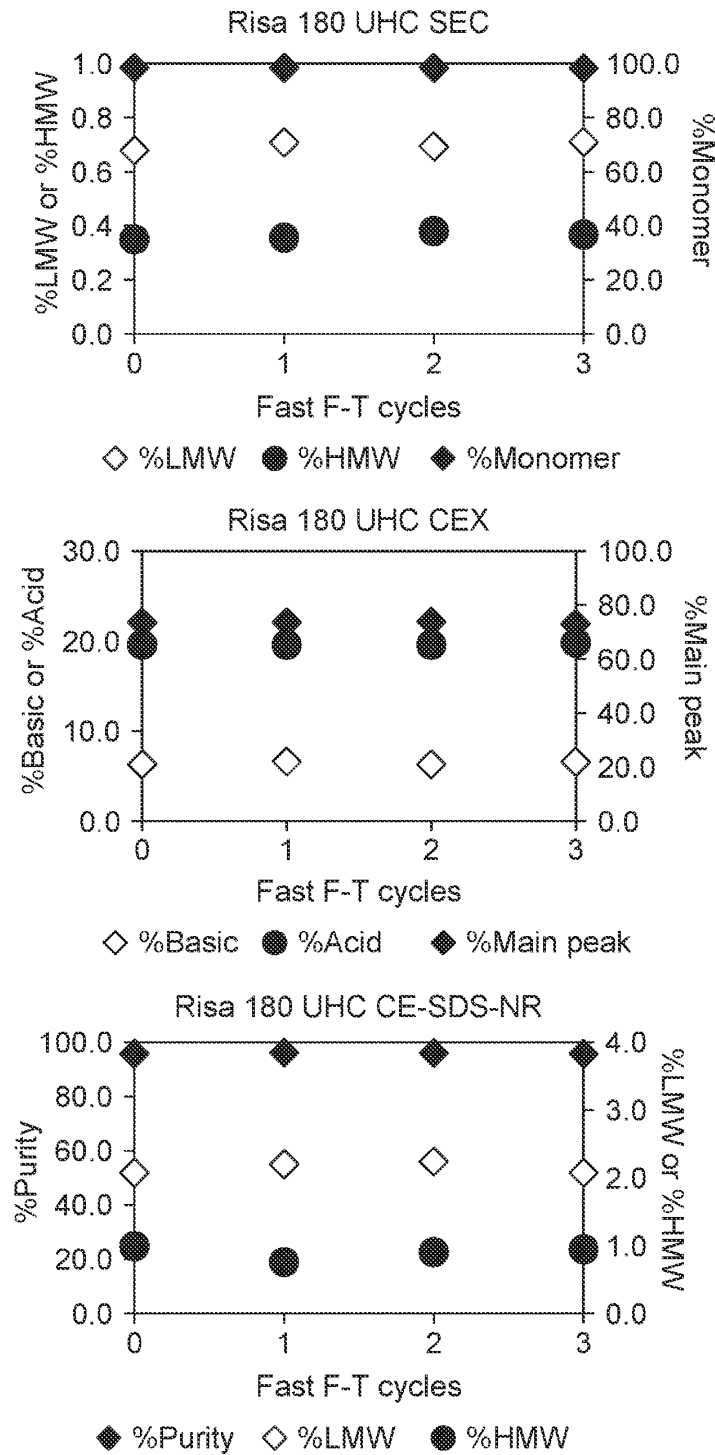


FIG. 11C

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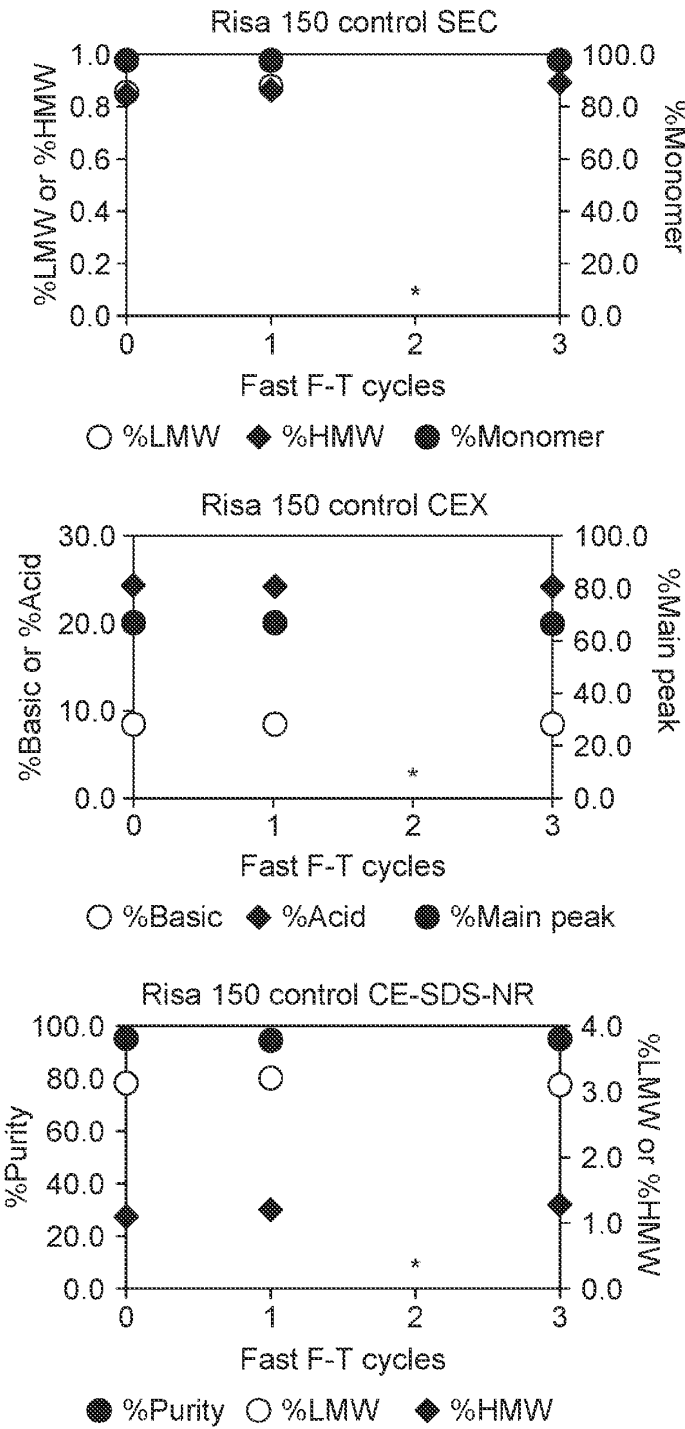


FIG. 11D

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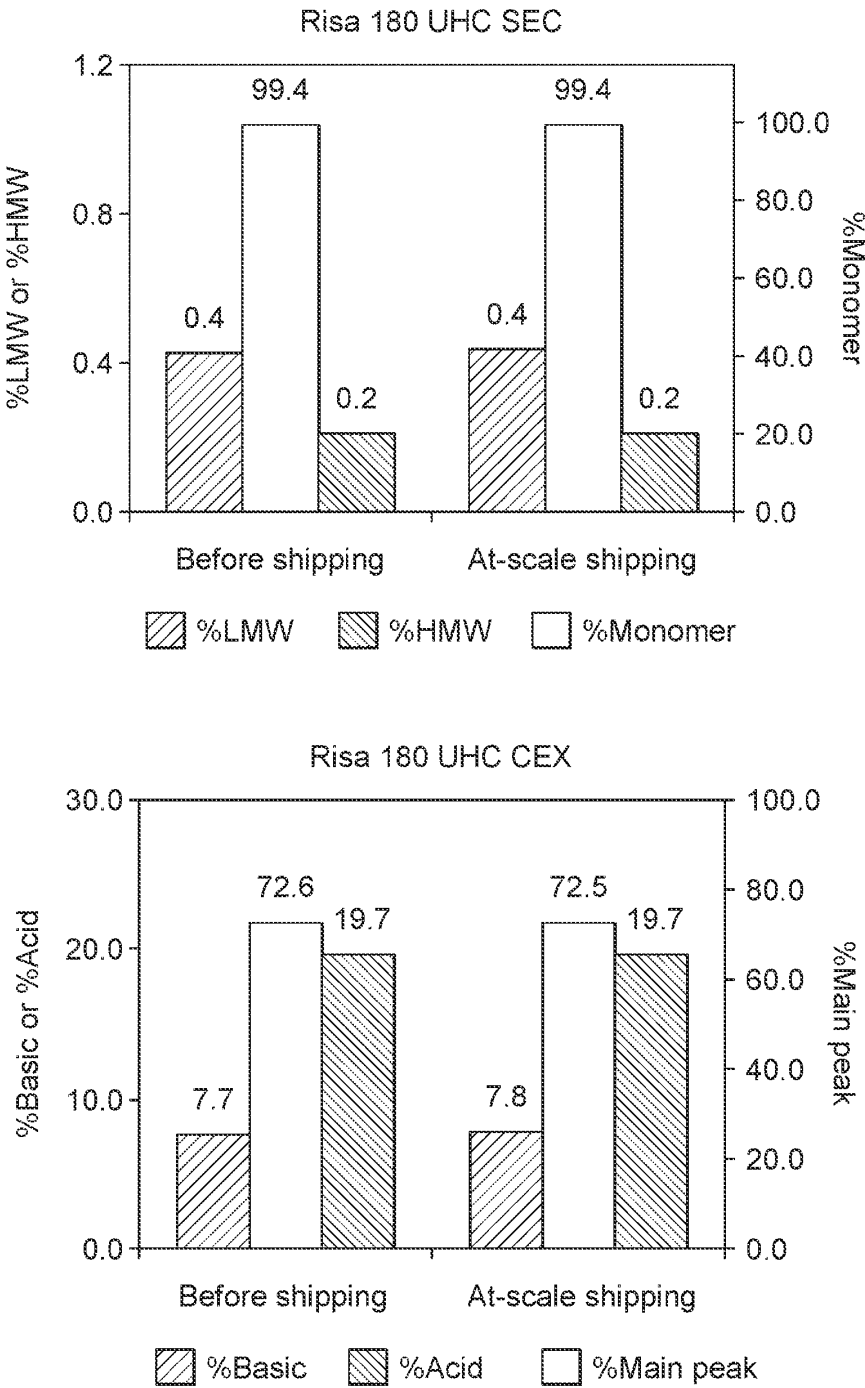


FIG. 12A

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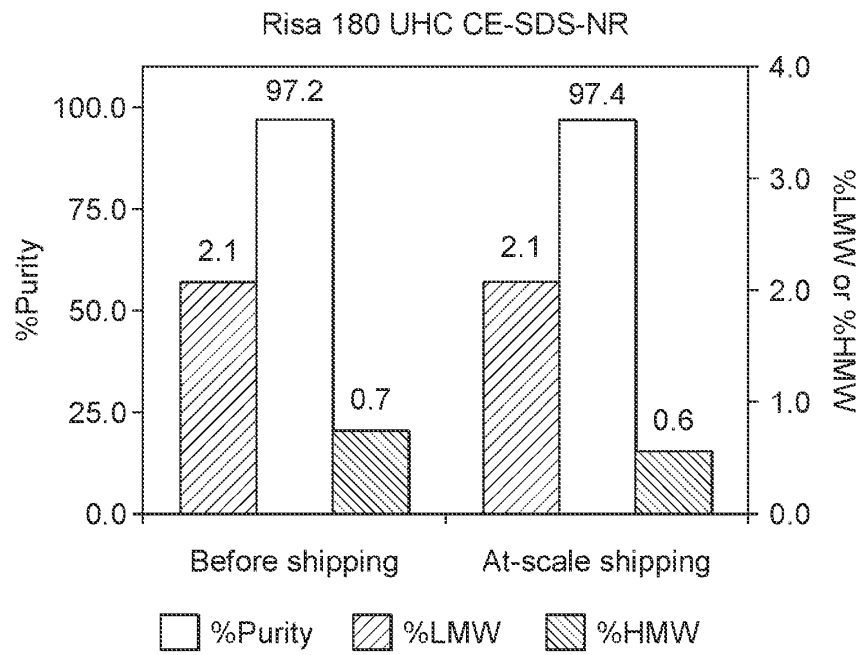


FIG. 12A continued

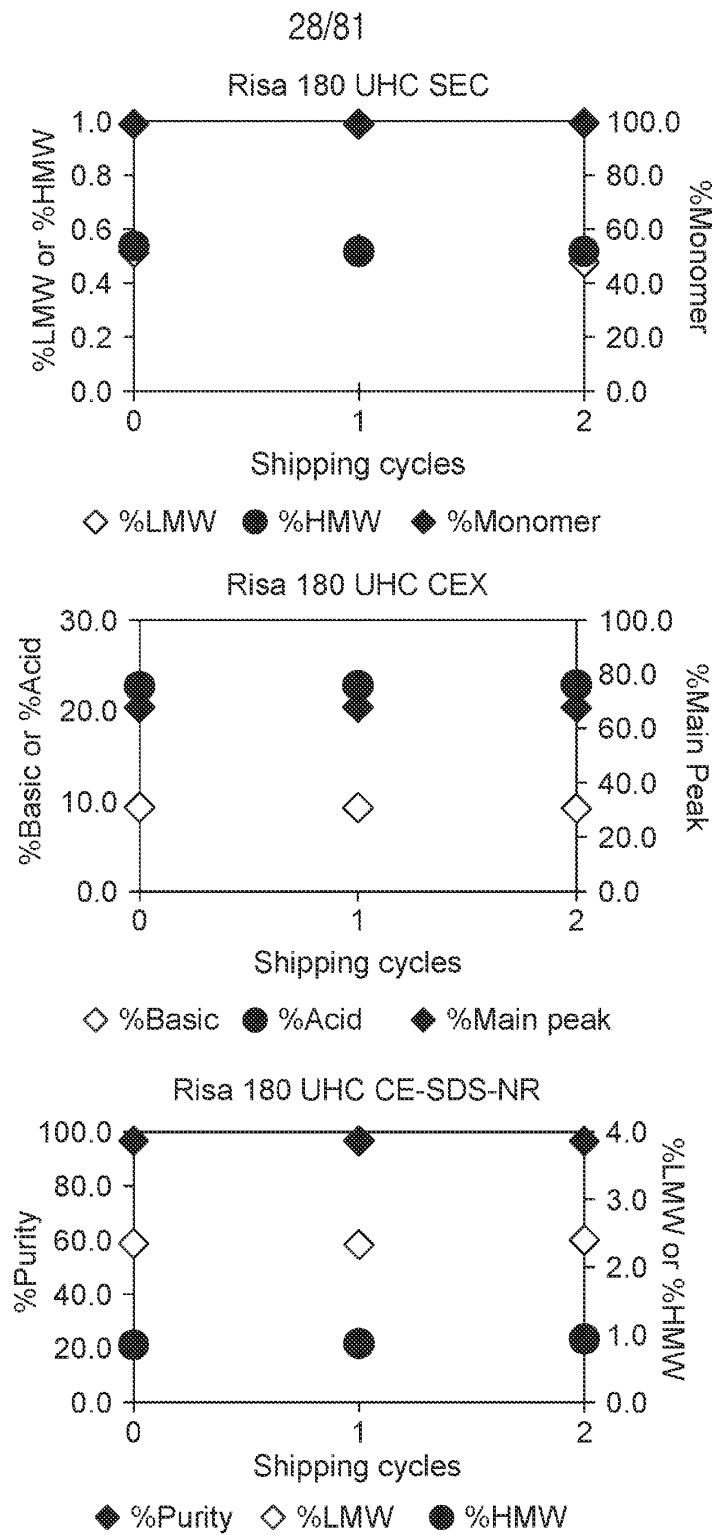


FIG. 12B

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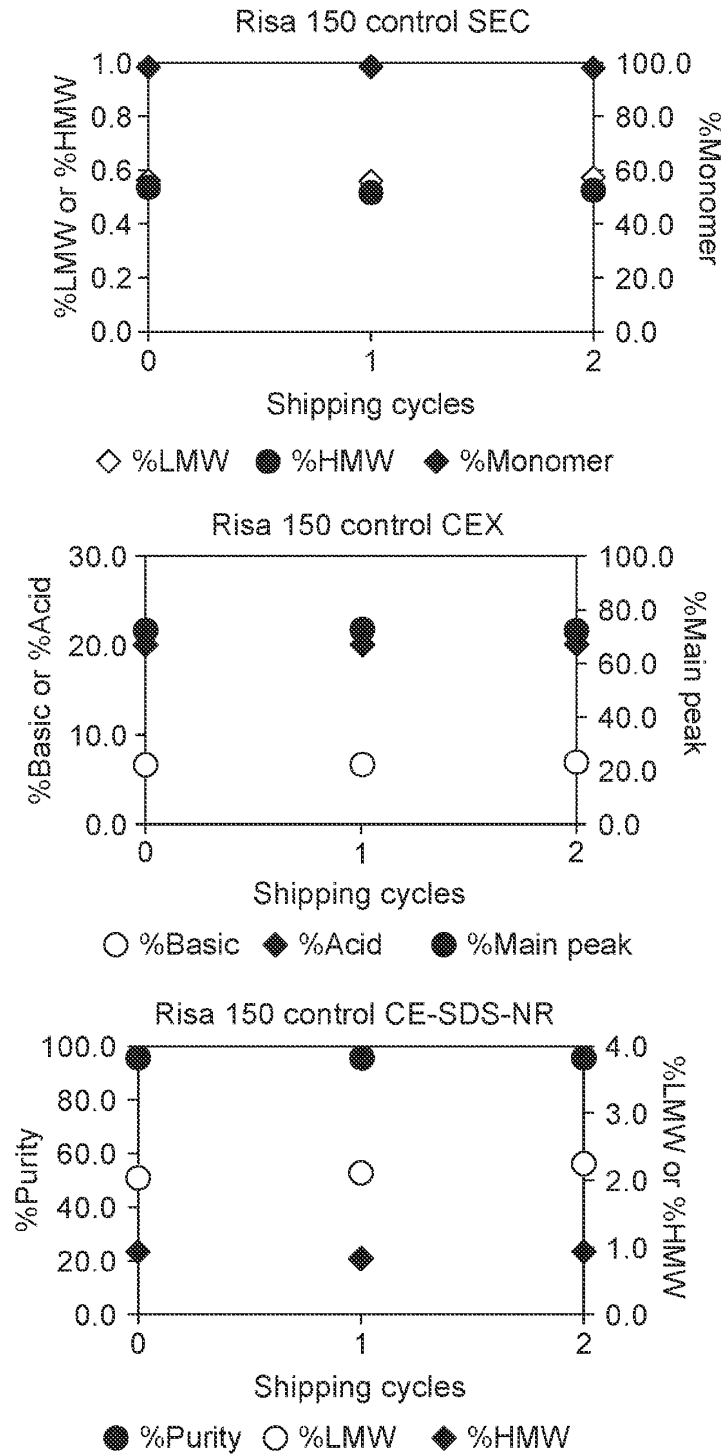


FIG. 12C

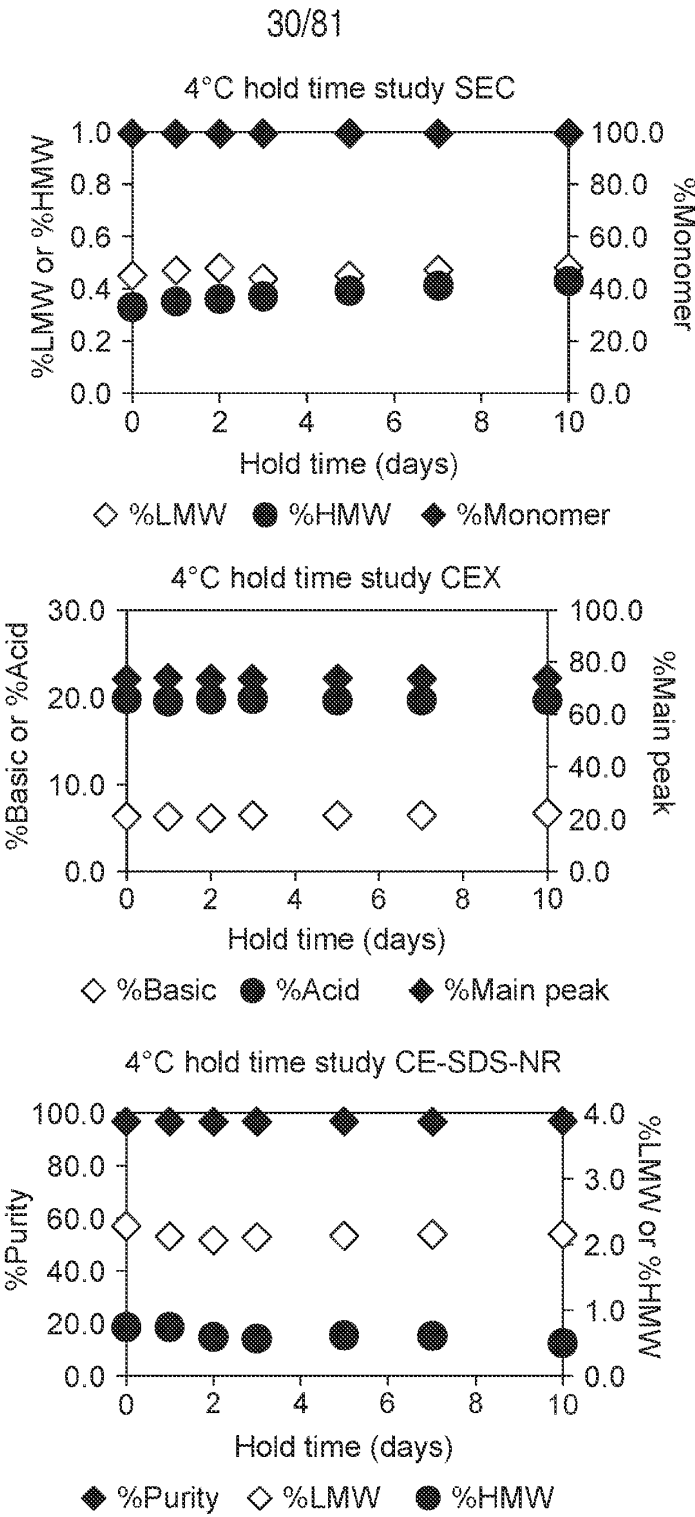


FIG. 13A

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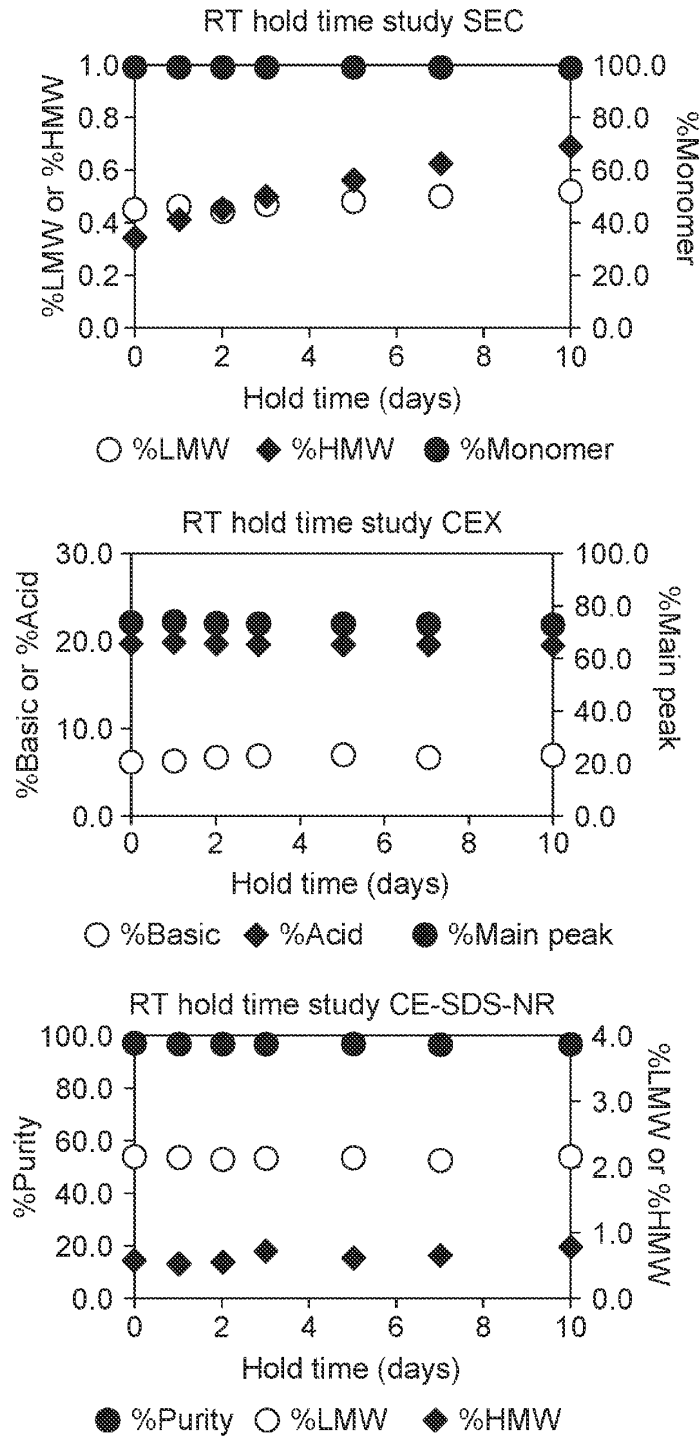


FIG. 13B

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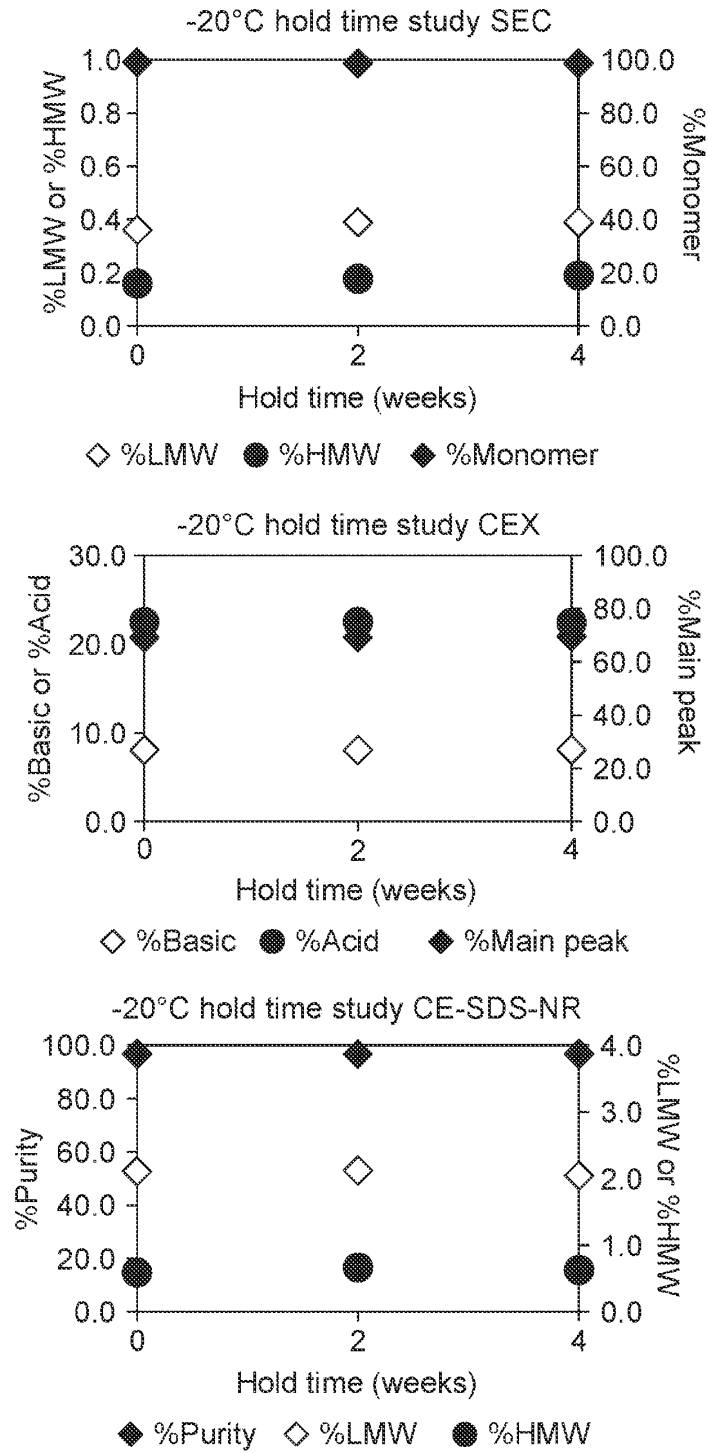


FIG. 13C

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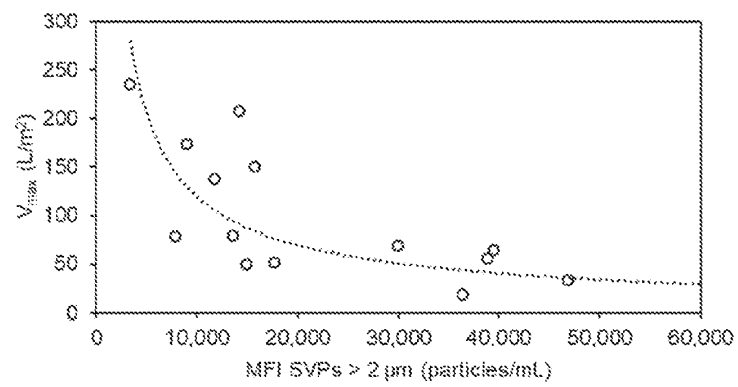


FIG. 14

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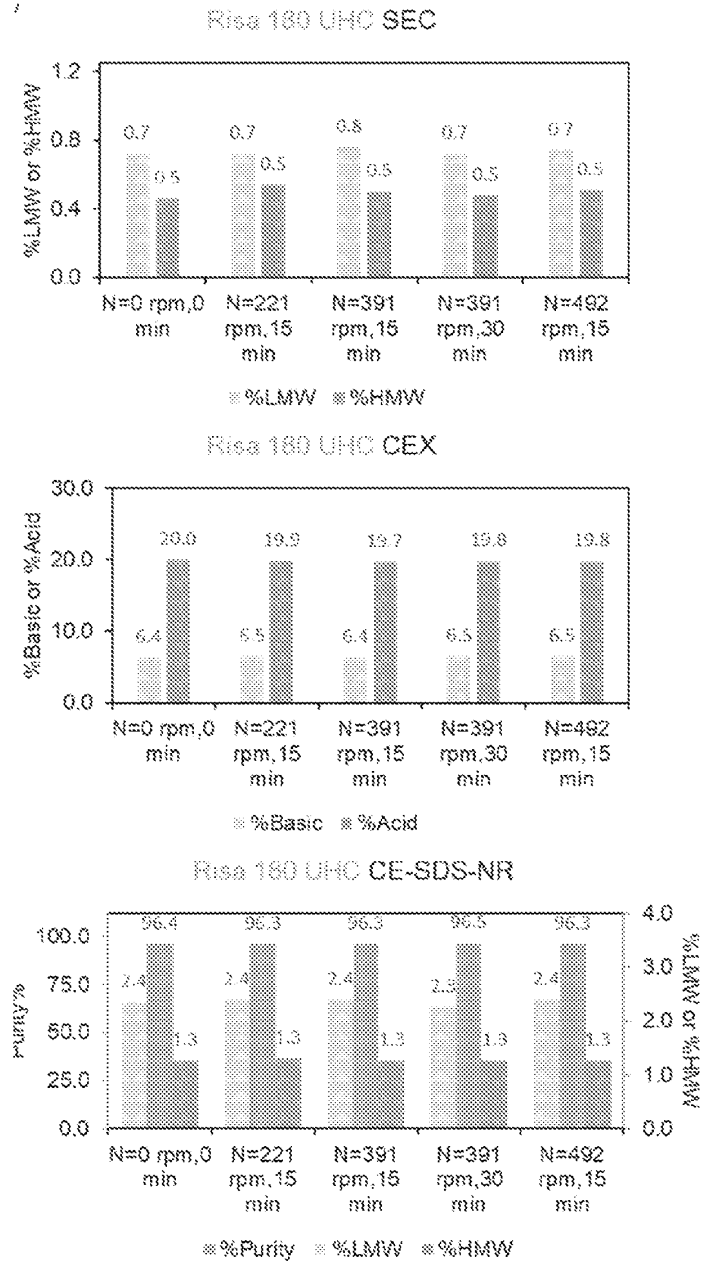


FIG. 15A

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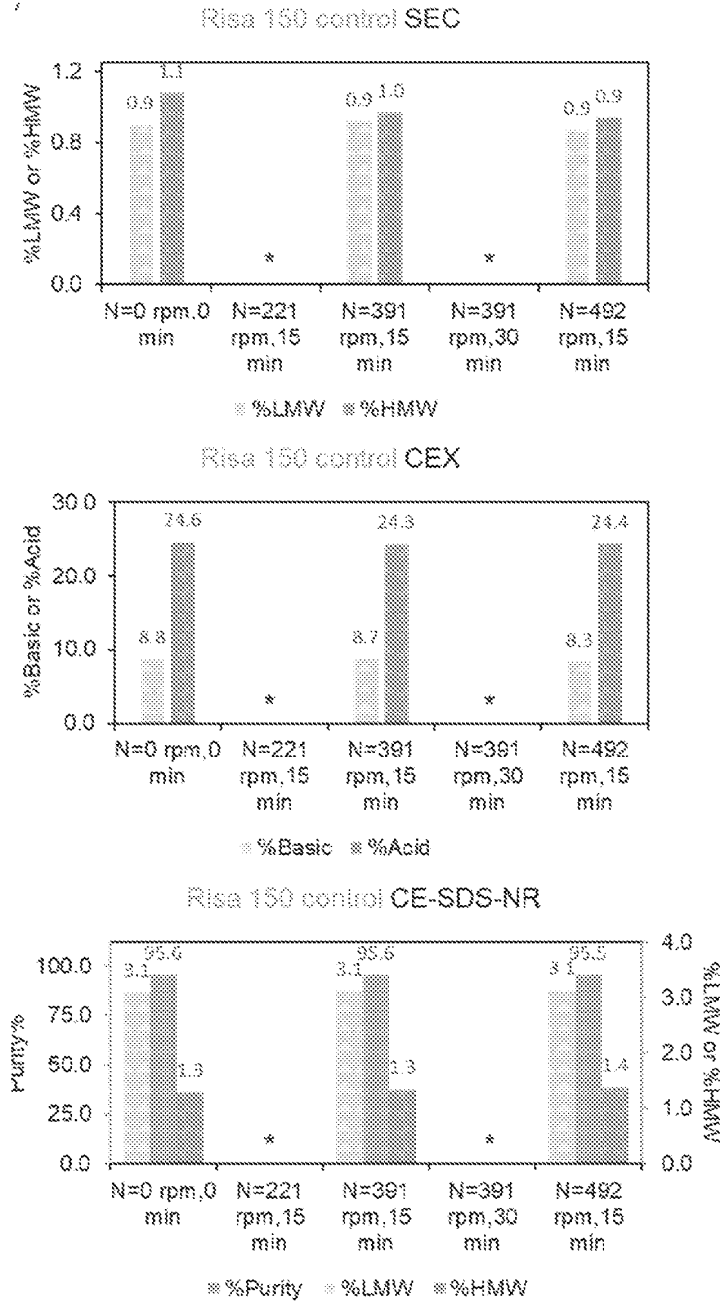


FIG. 15B

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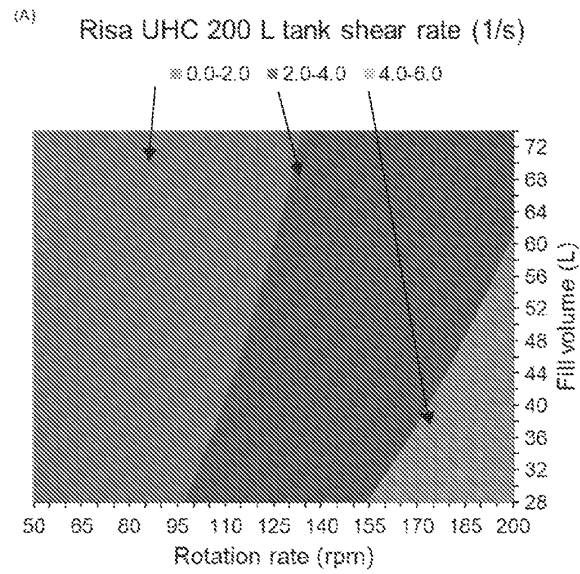


FIG. 16A

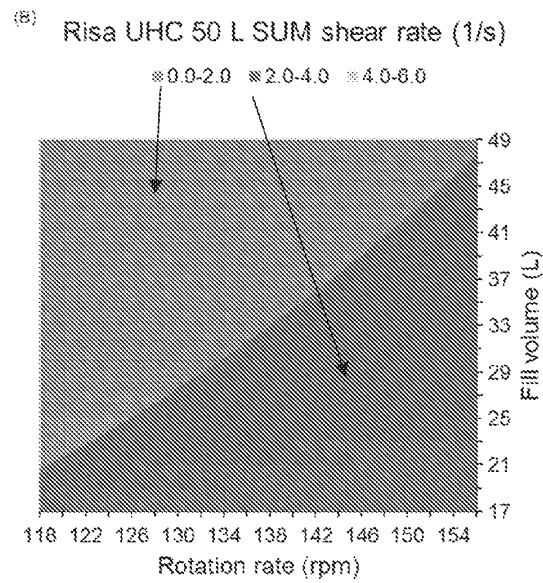


FIG. 16B

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At-scale shipping study and SDM validation MFI

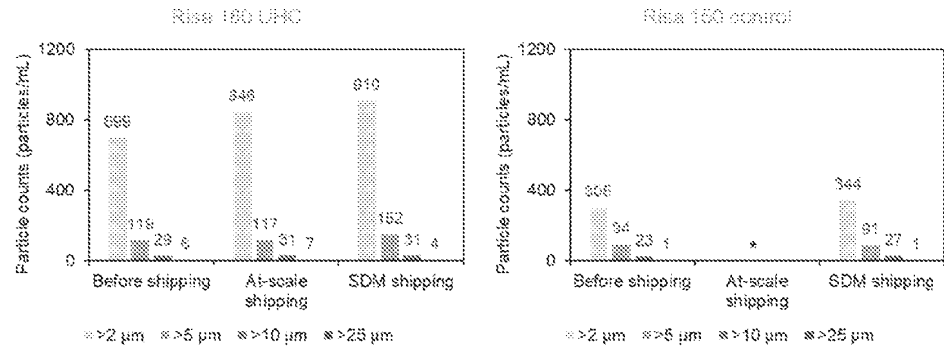


FIG. 17A

FIG. 17B

Worst-case shipping simulation

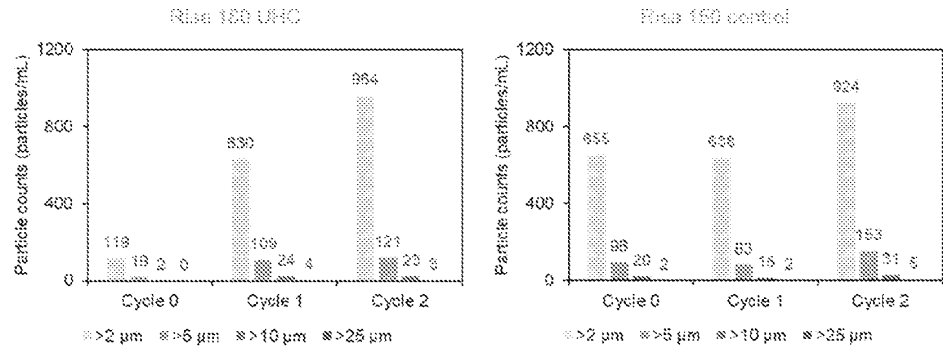


FIG. 17C

FIG. 17D

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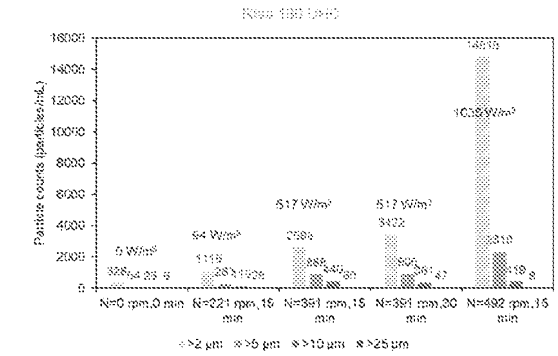


FIG. 18A

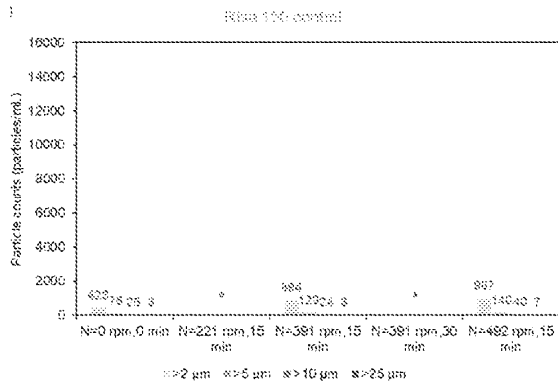


FIG. 18B

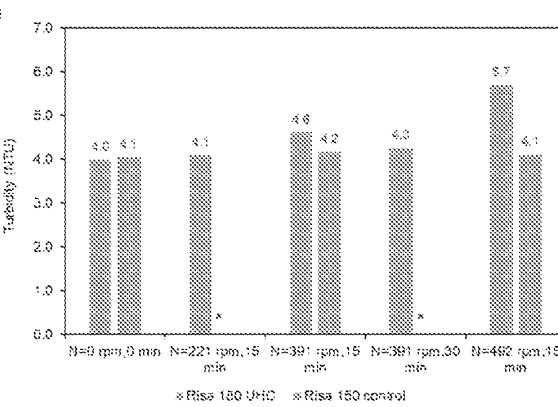


FIG. 18C

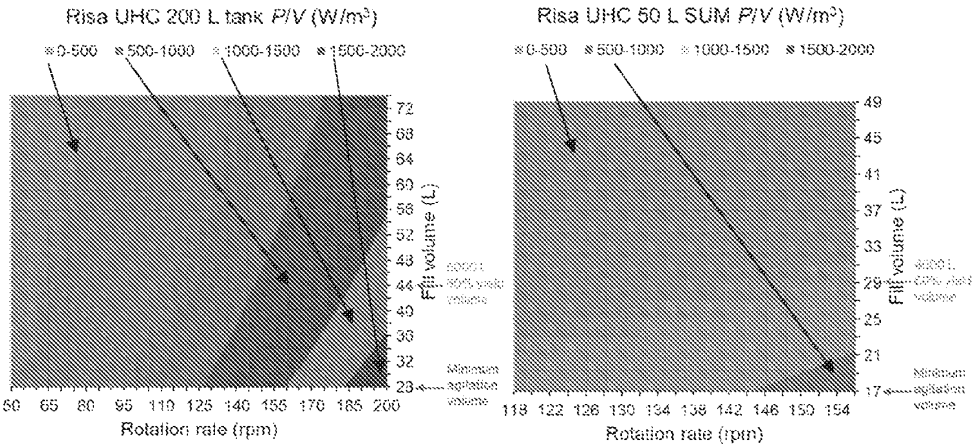


FIG. 19A

FIG. 19B

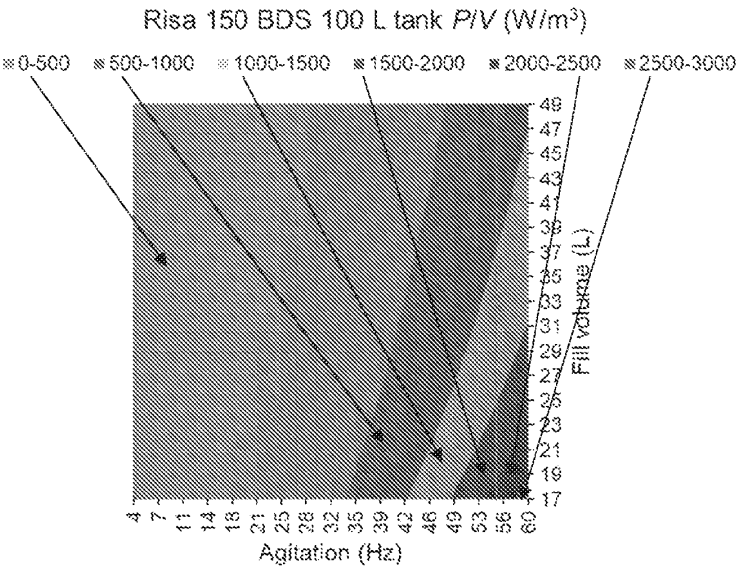


FIG. 20

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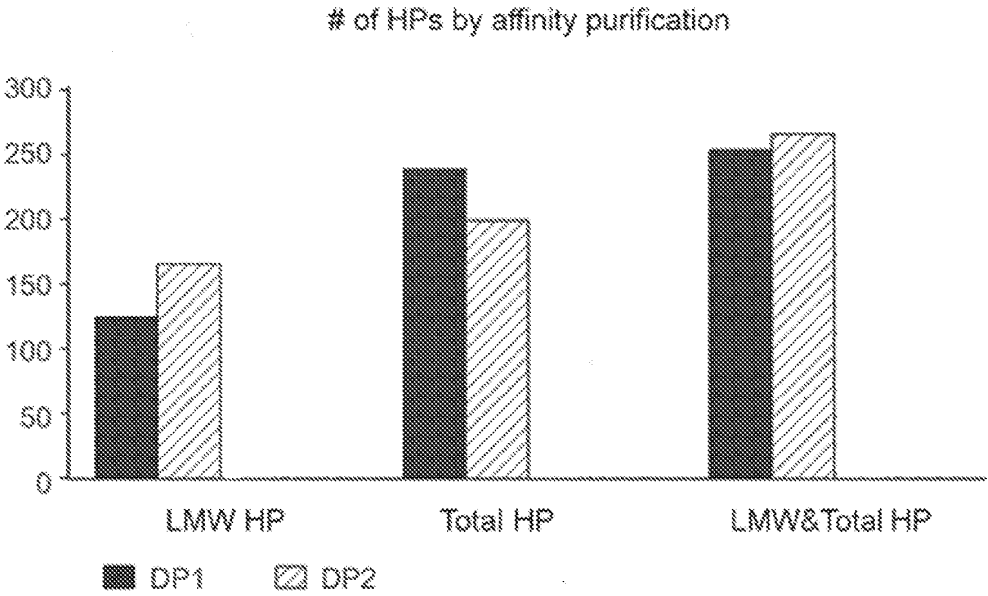


FIG. 21

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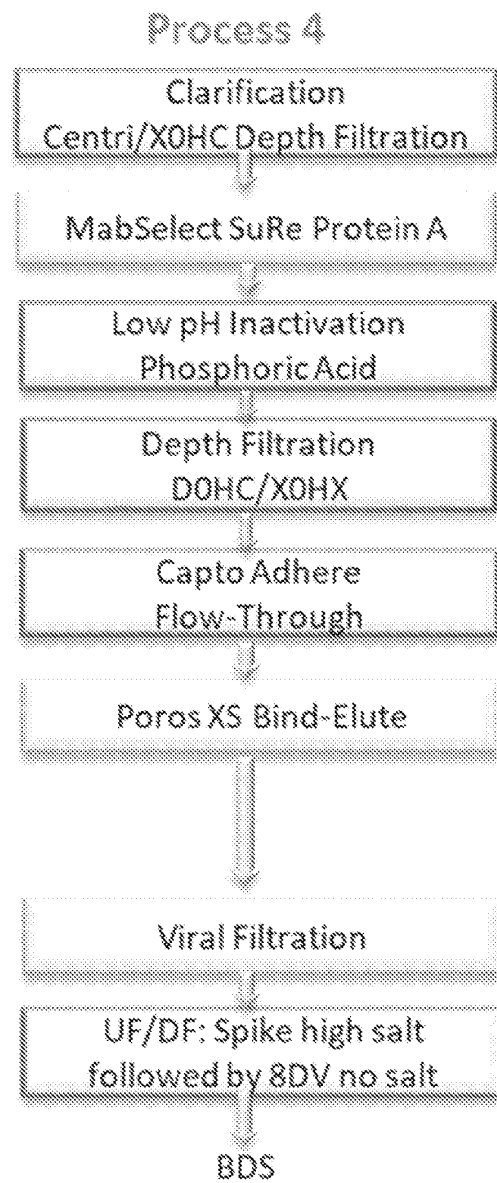


FIG. 22

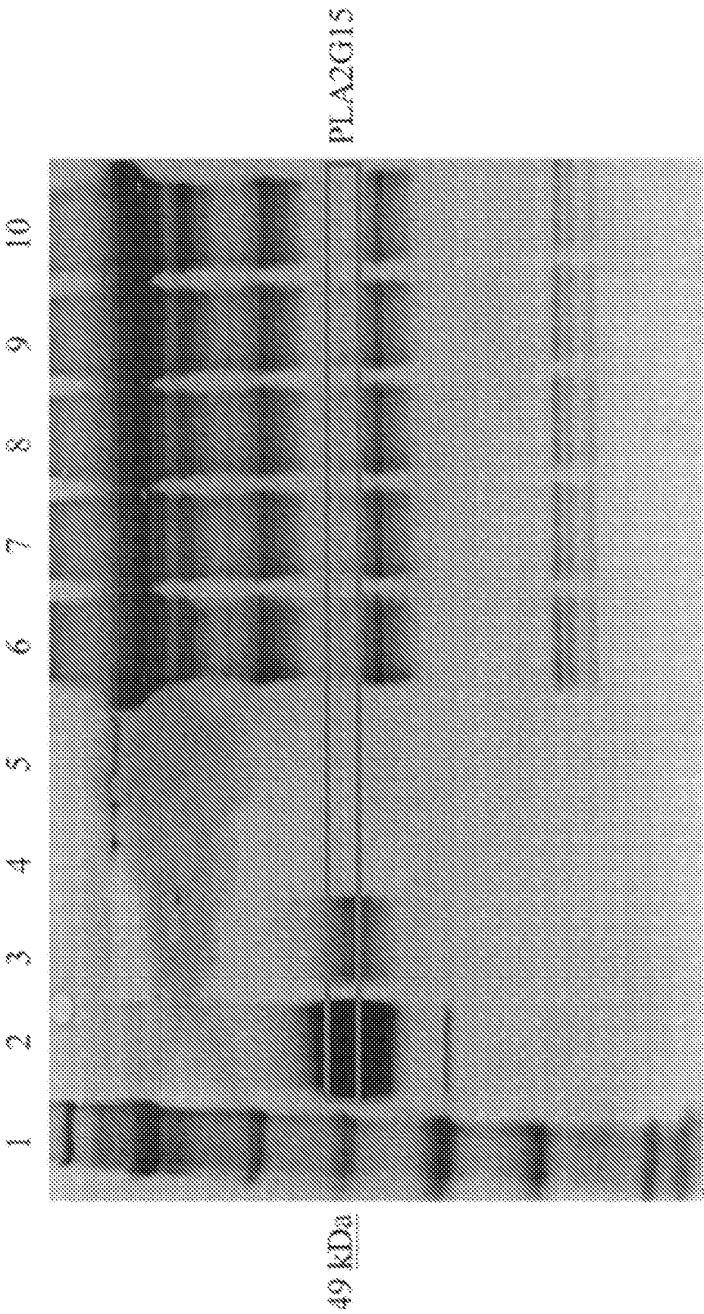


FIG. 23

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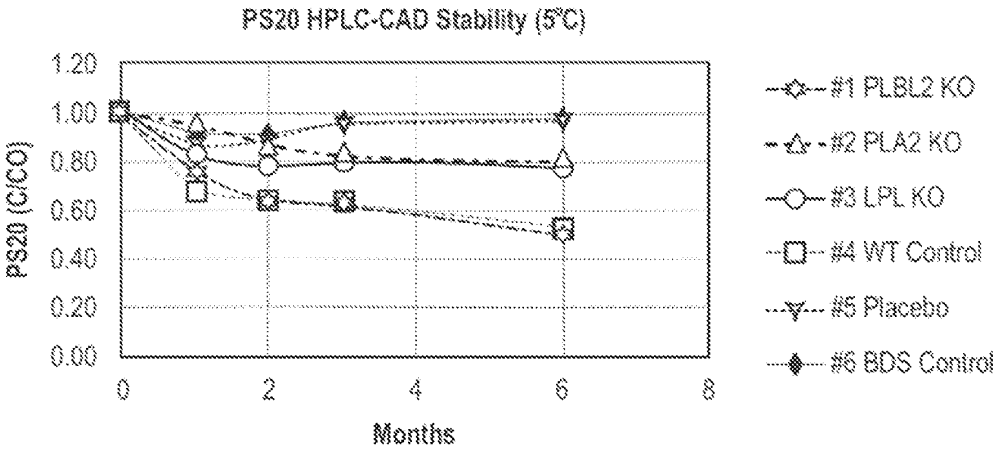


FIG. 24A

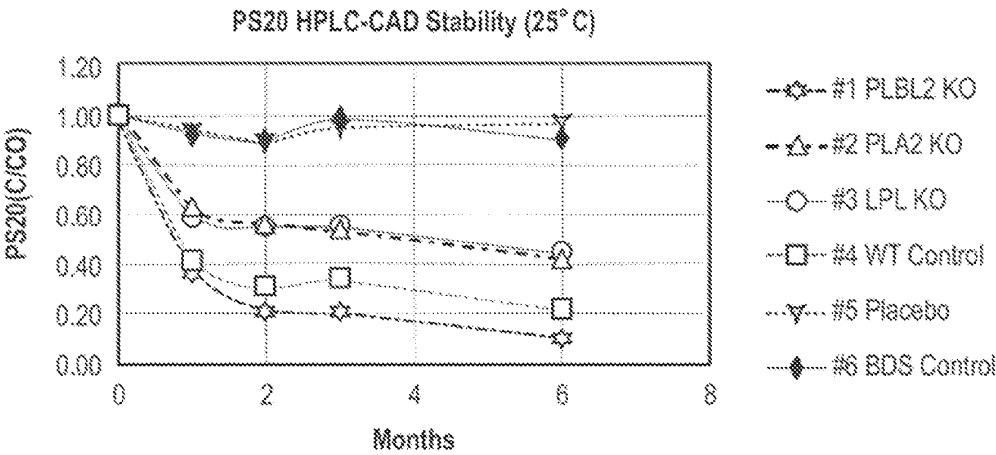


FIG. 24B

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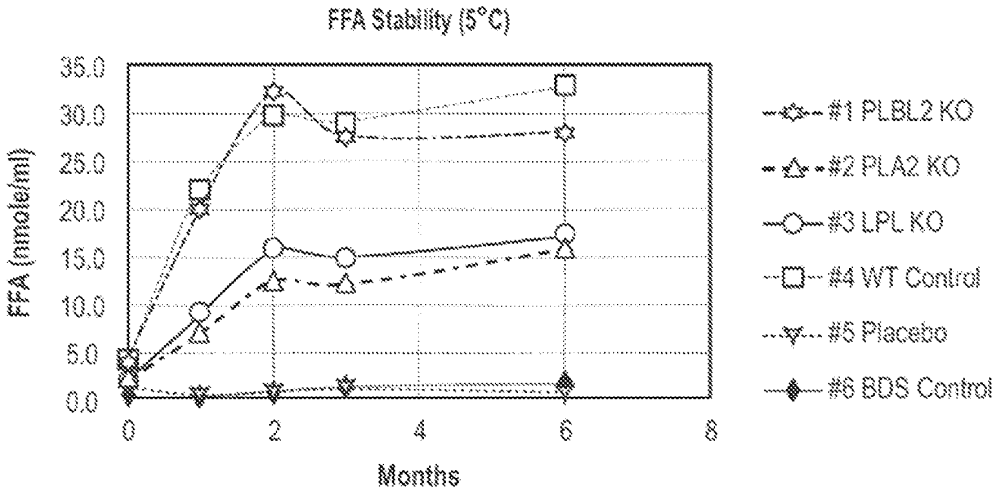


FIG. 24C

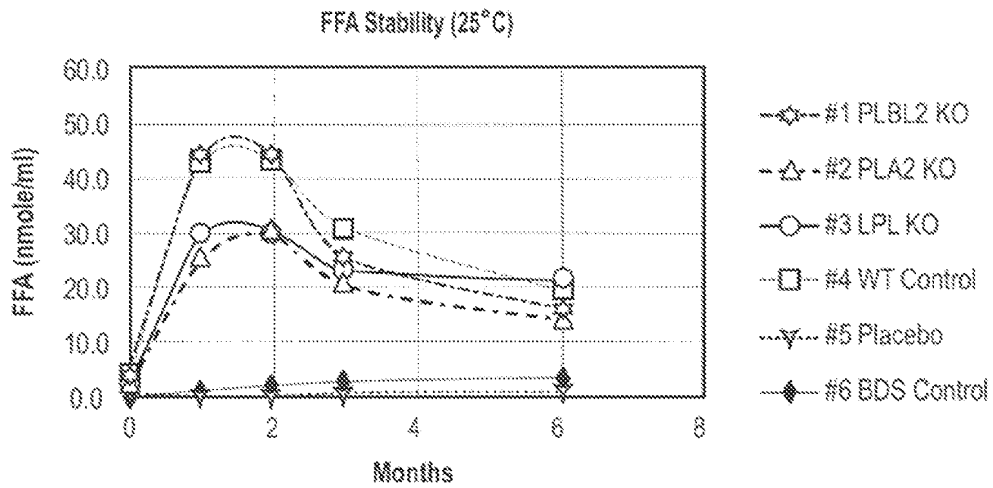


FIG. 24D

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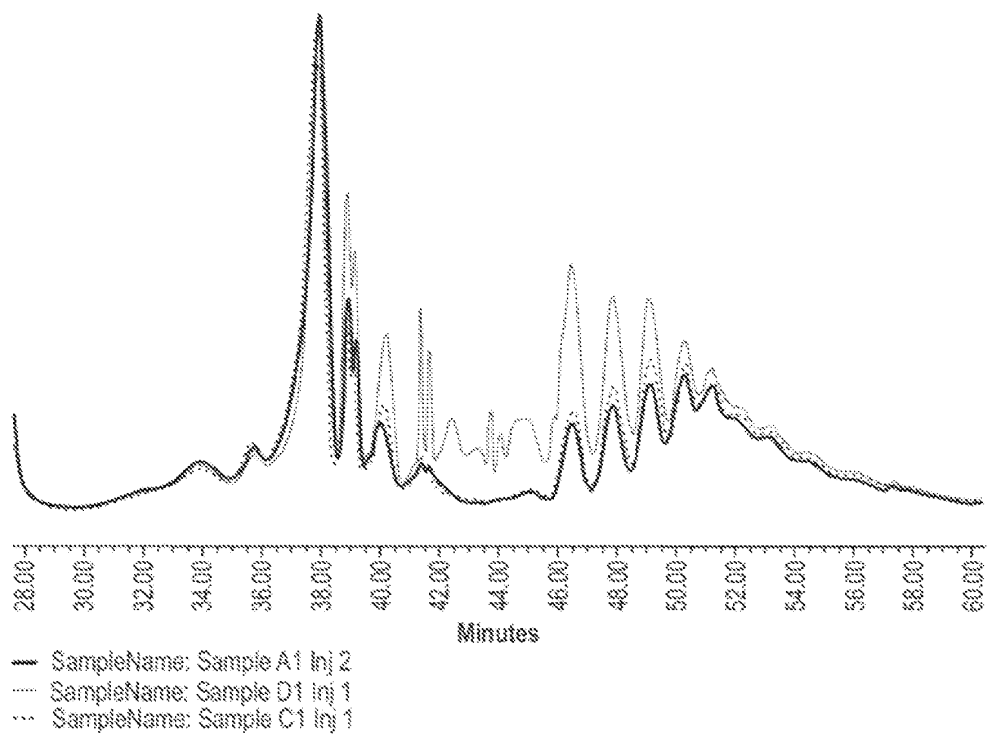


FIG. 25A

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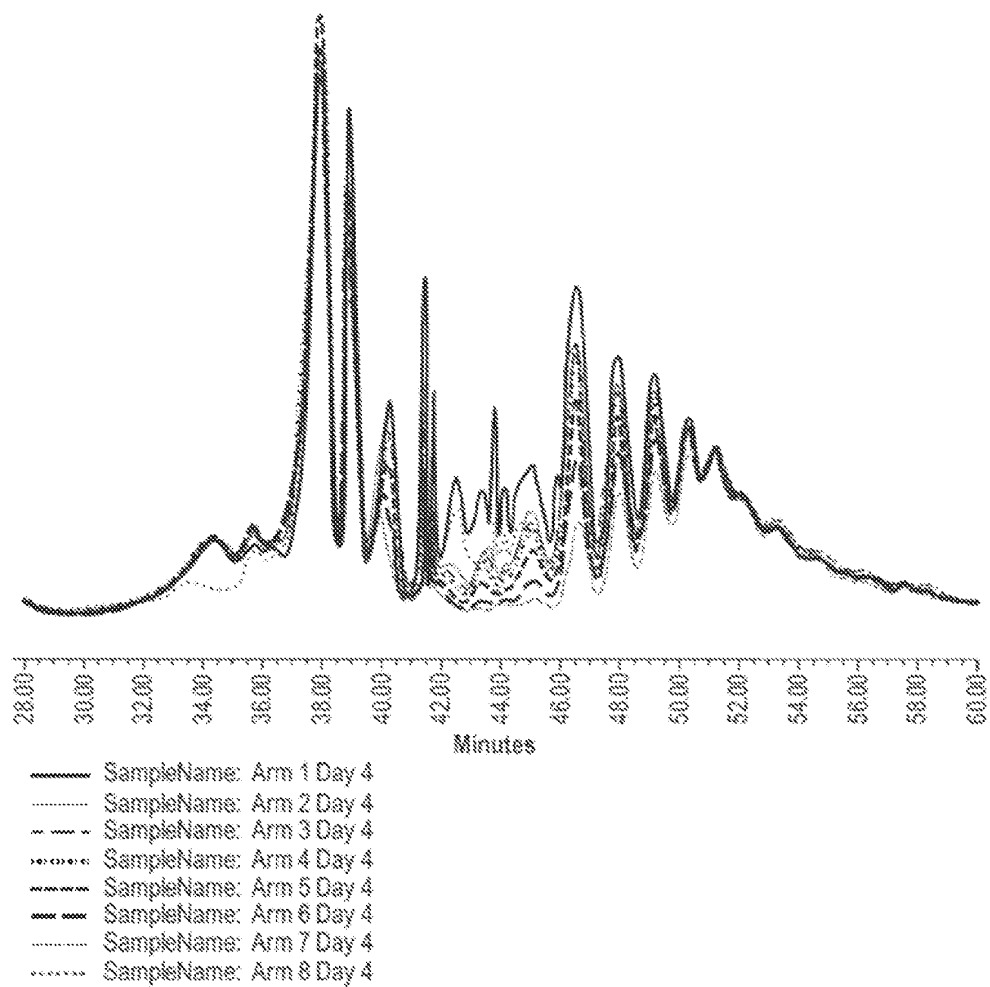


FIG. 25B

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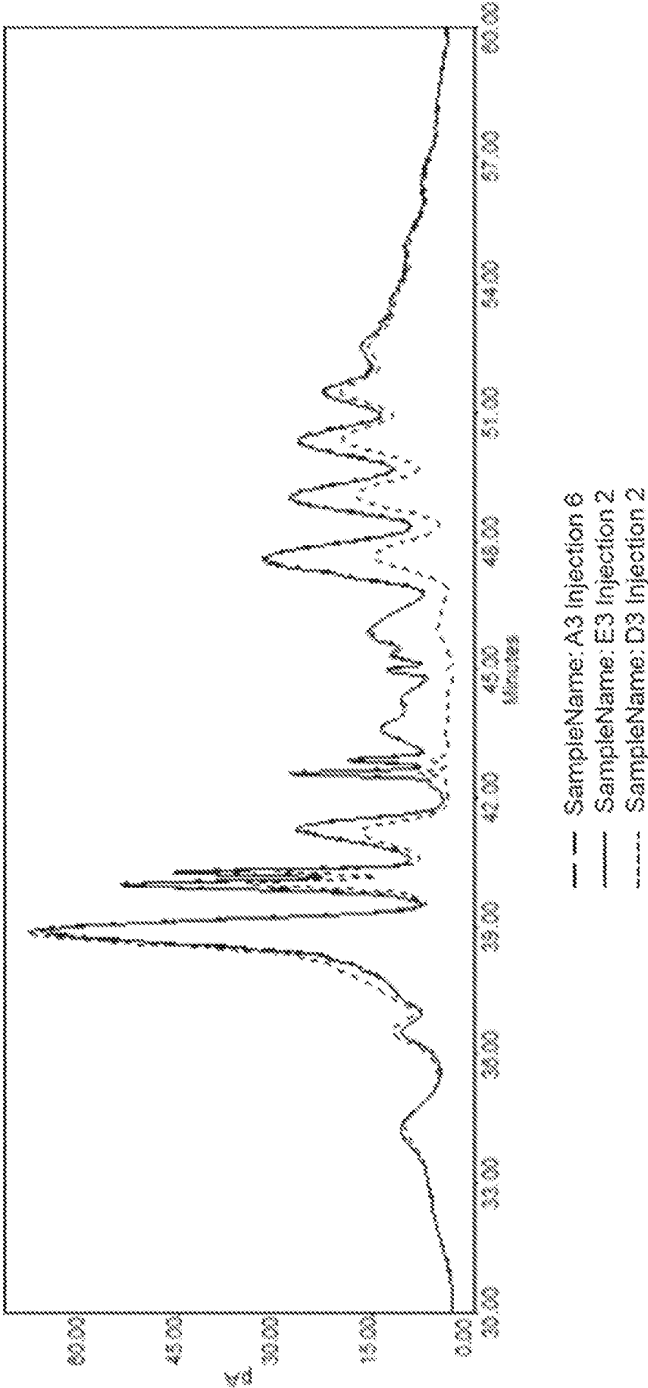


FIG. 26

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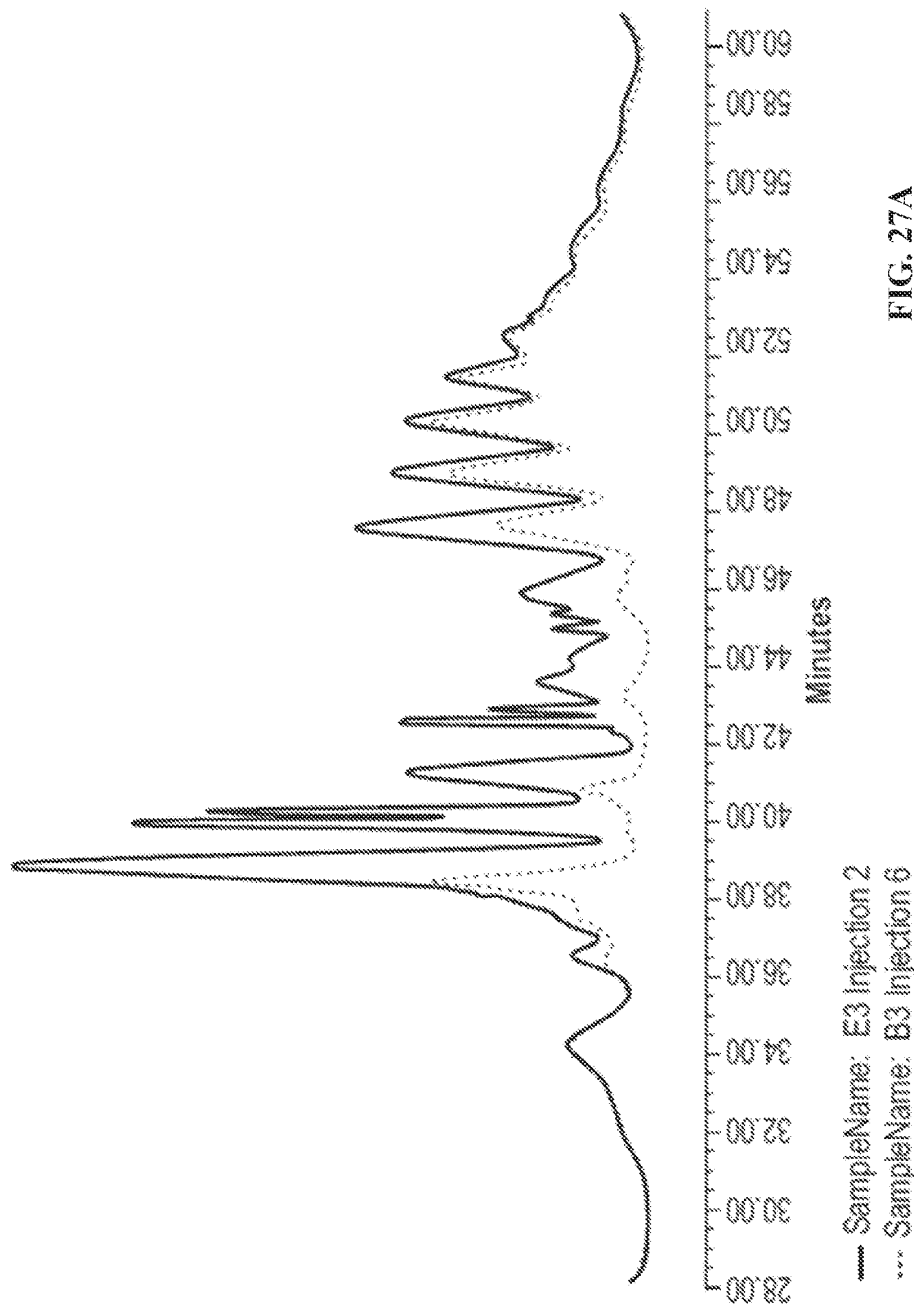
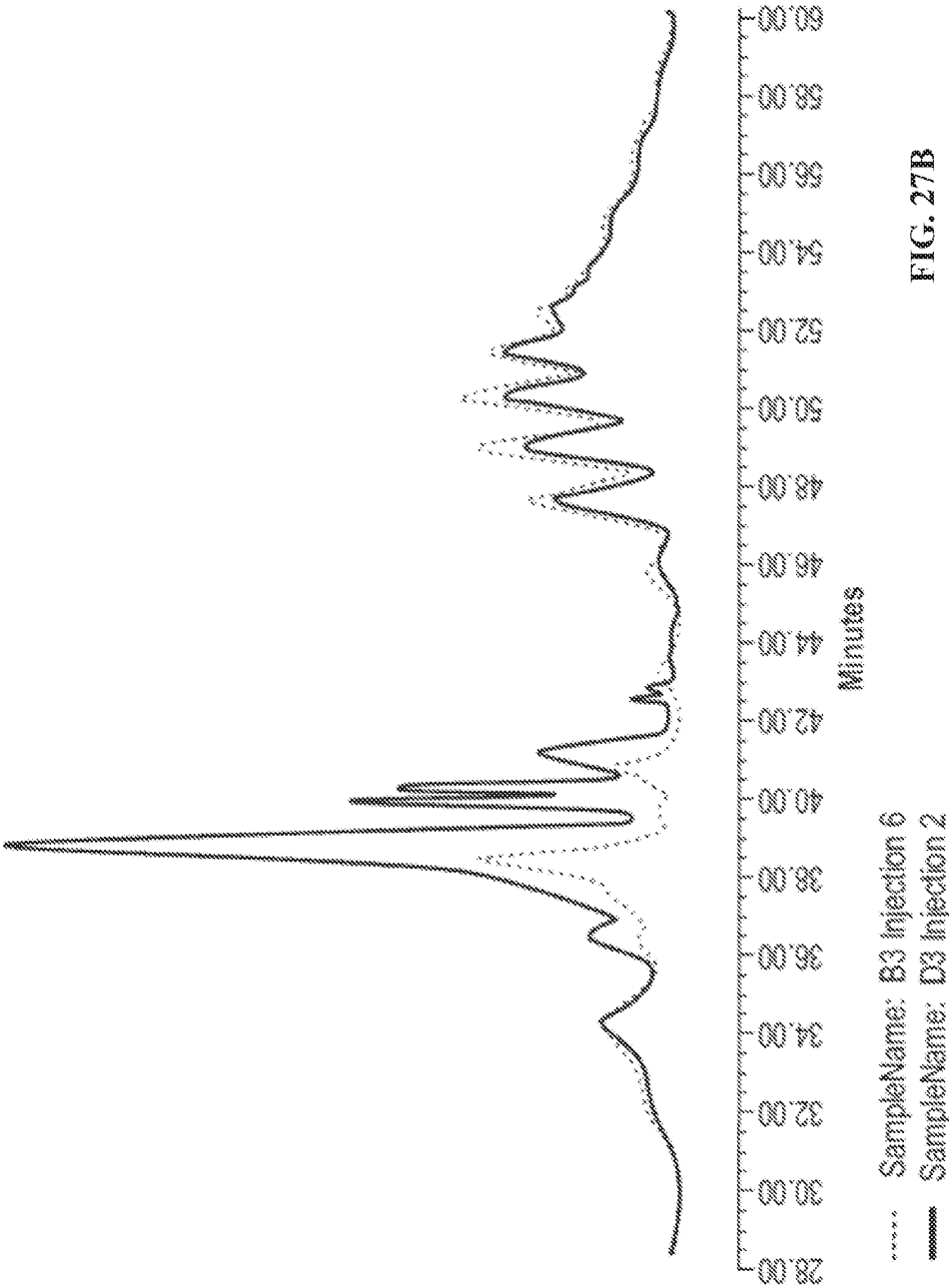


FIG. 27A

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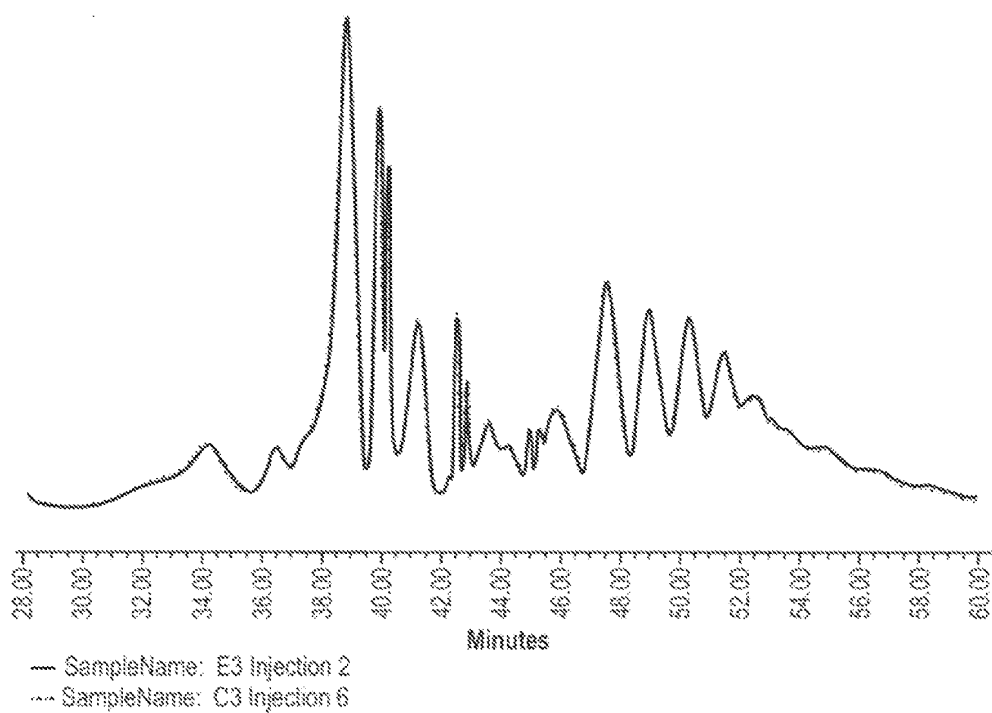


FIG. 28

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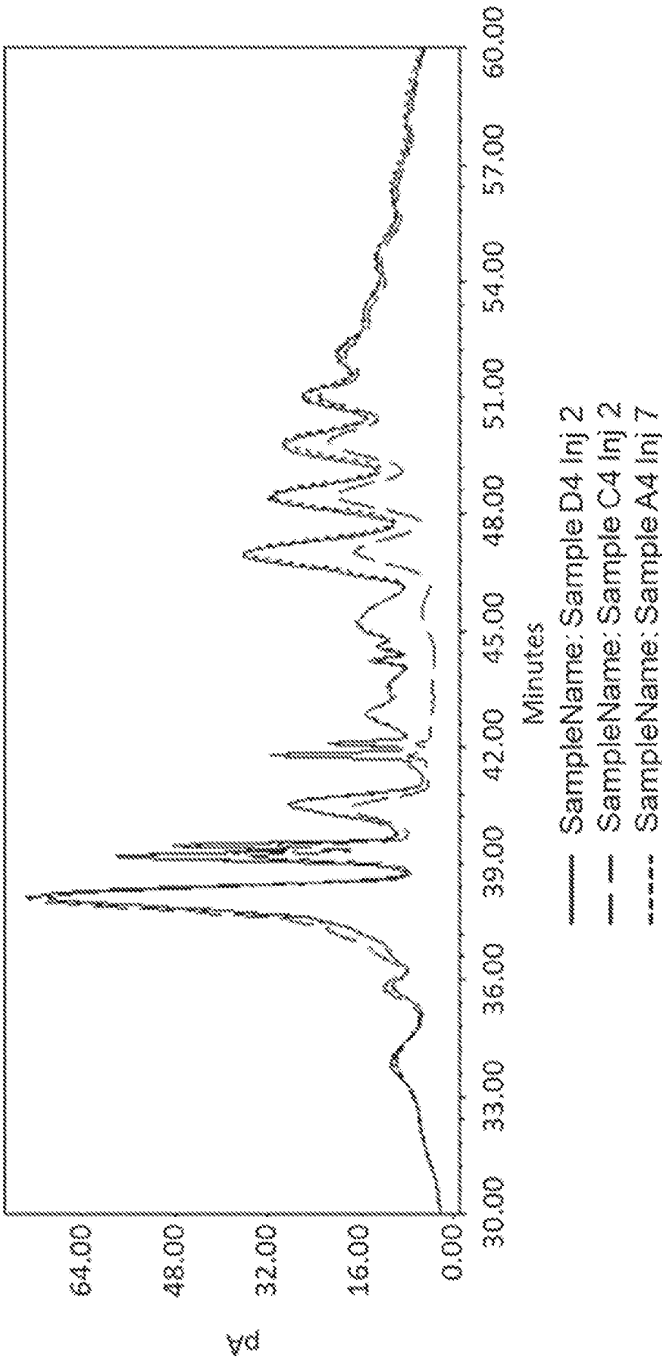


FIG. 29

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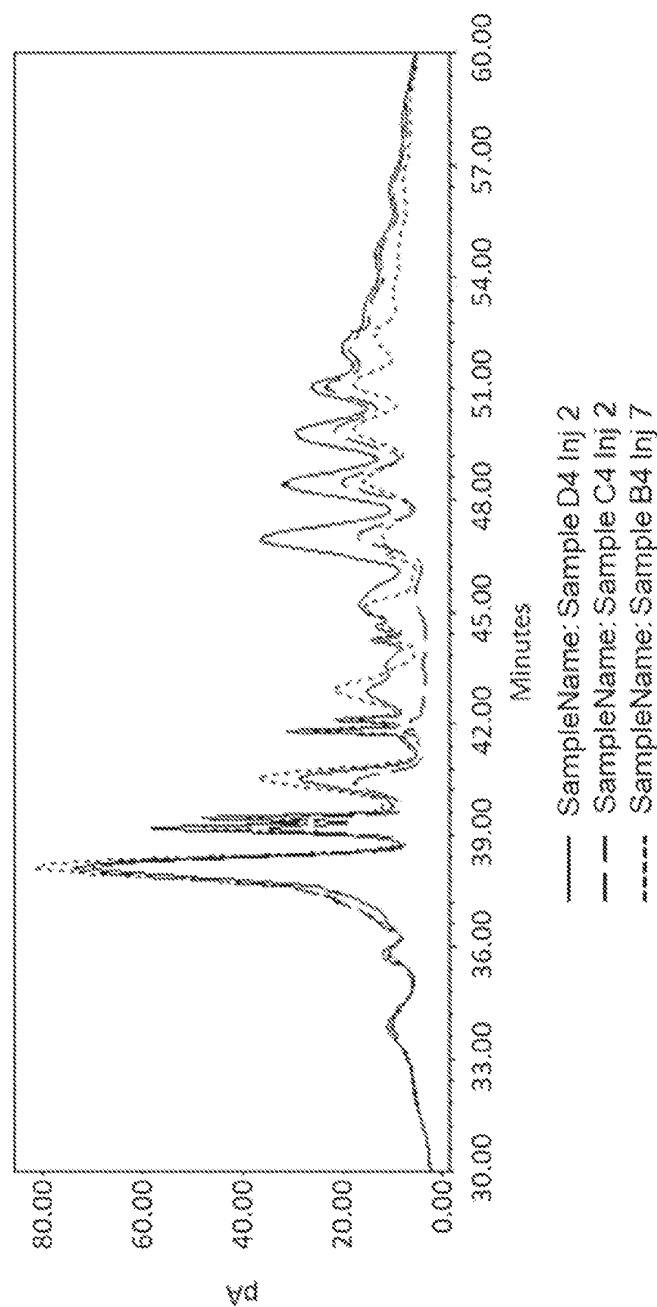


FIG. 30

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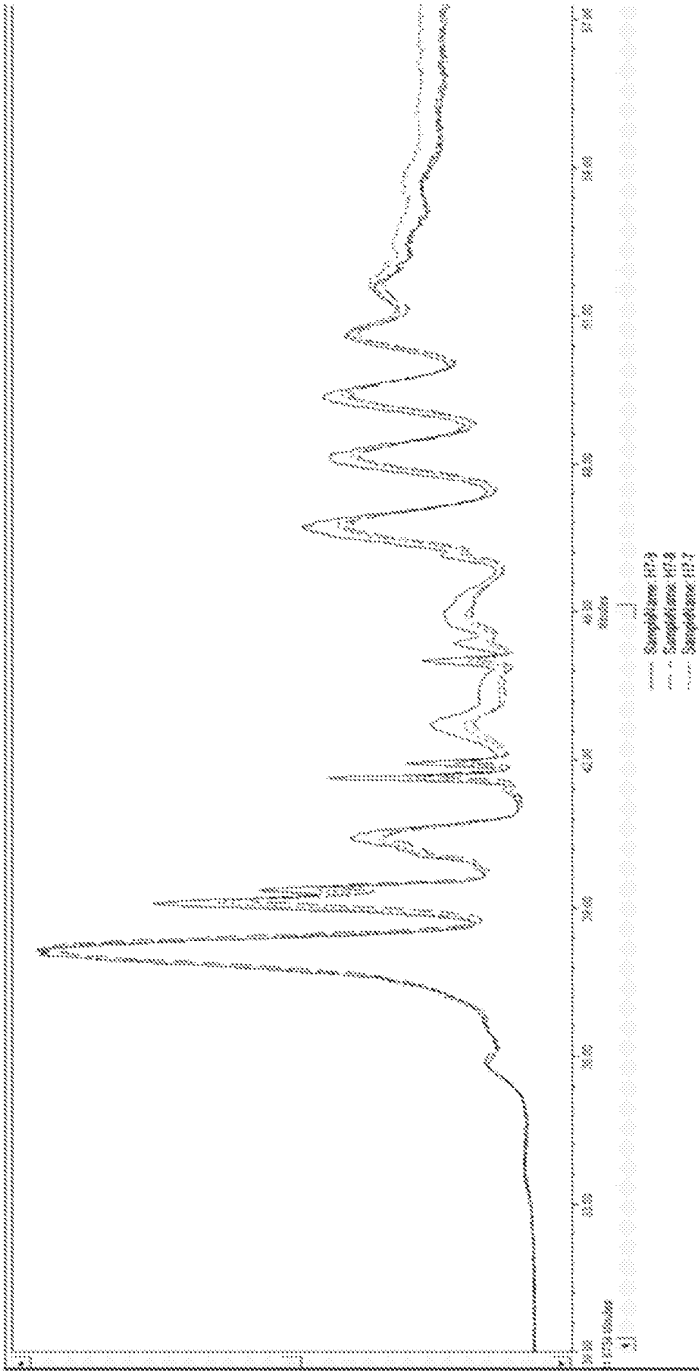


FIG. 31

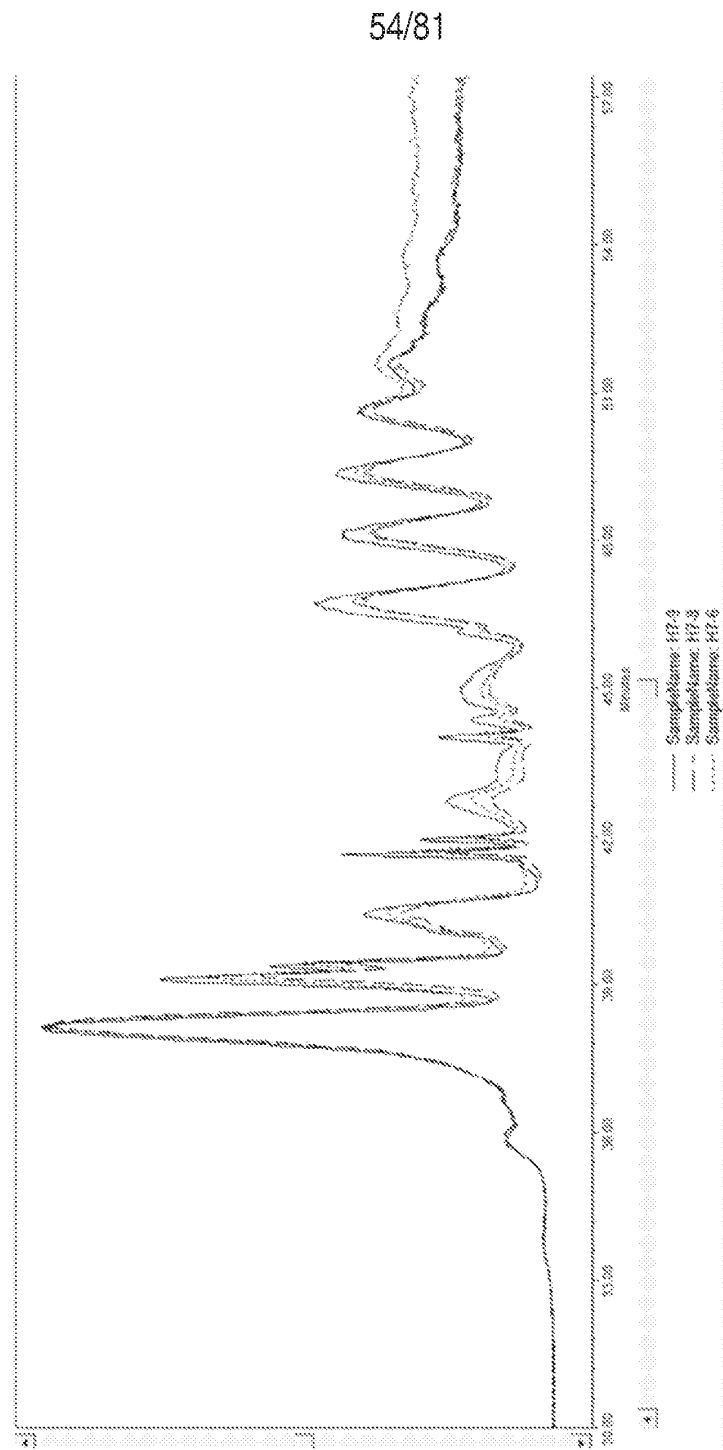


FIG. 32

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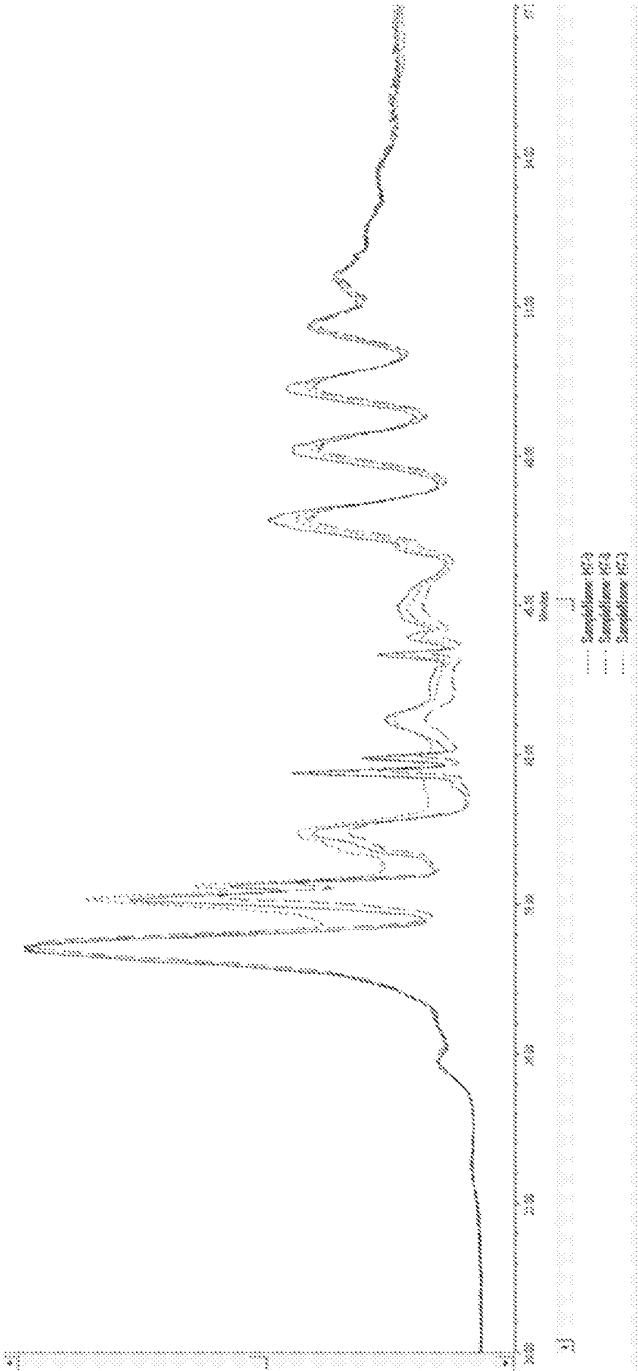


FIG. 33

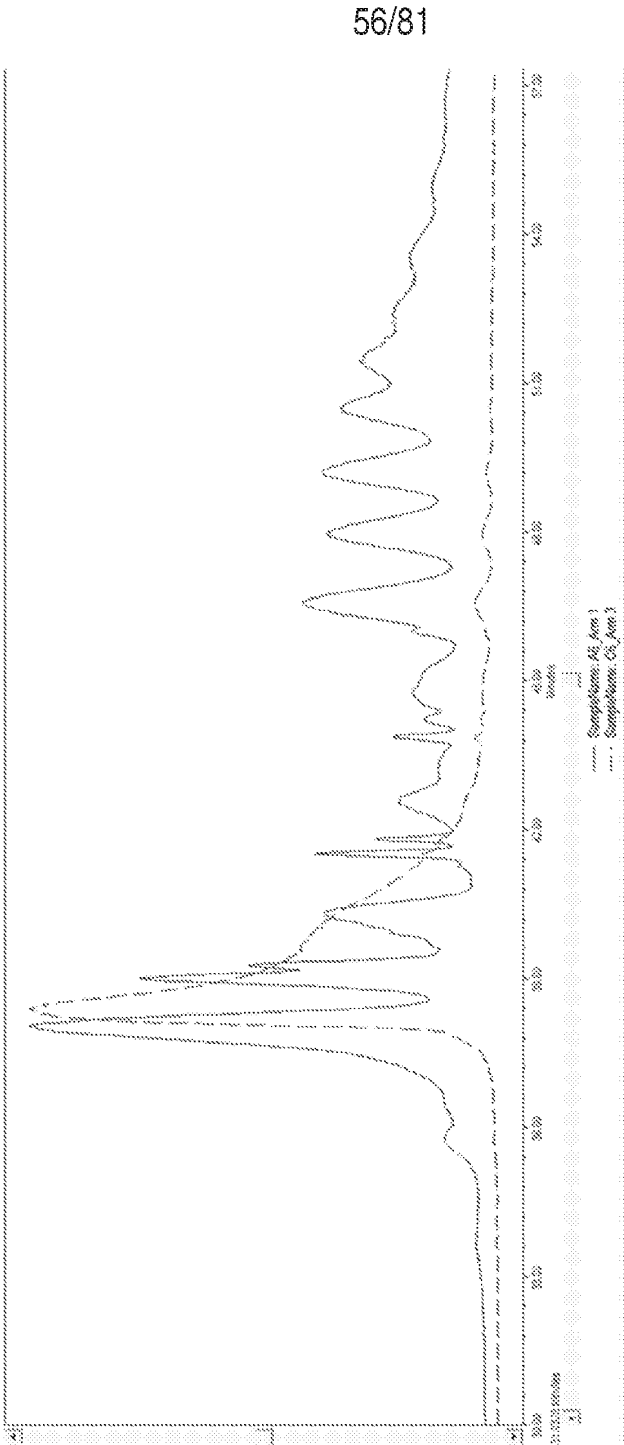


FIG. 34

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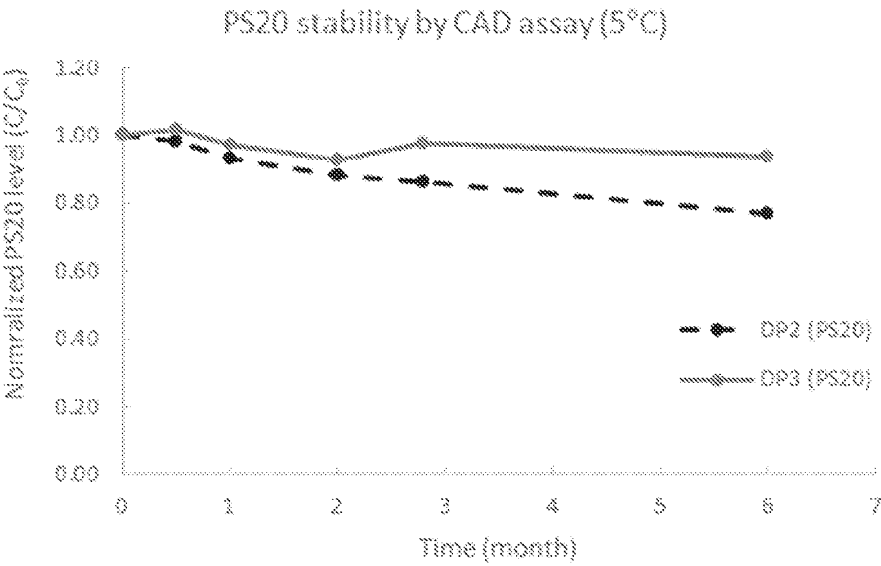


FIG. 35A

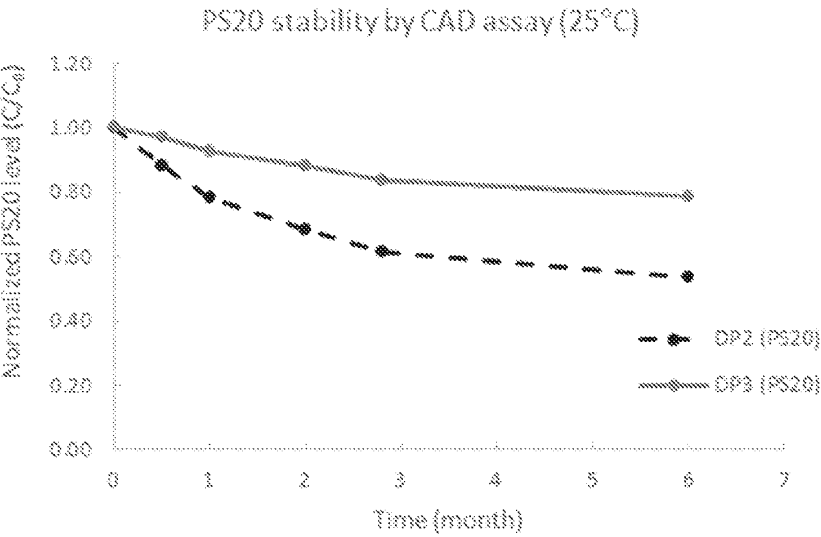


FIG. 35B

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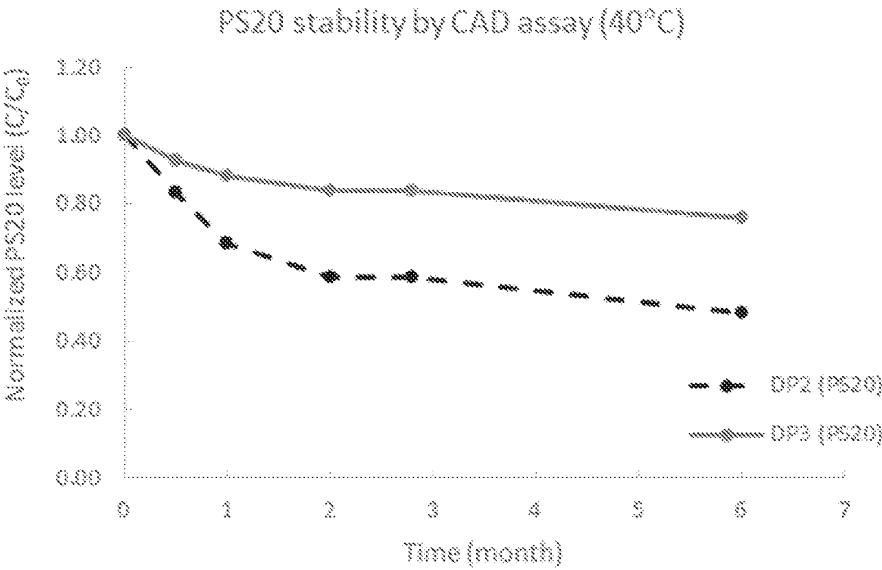


FIG. 35C

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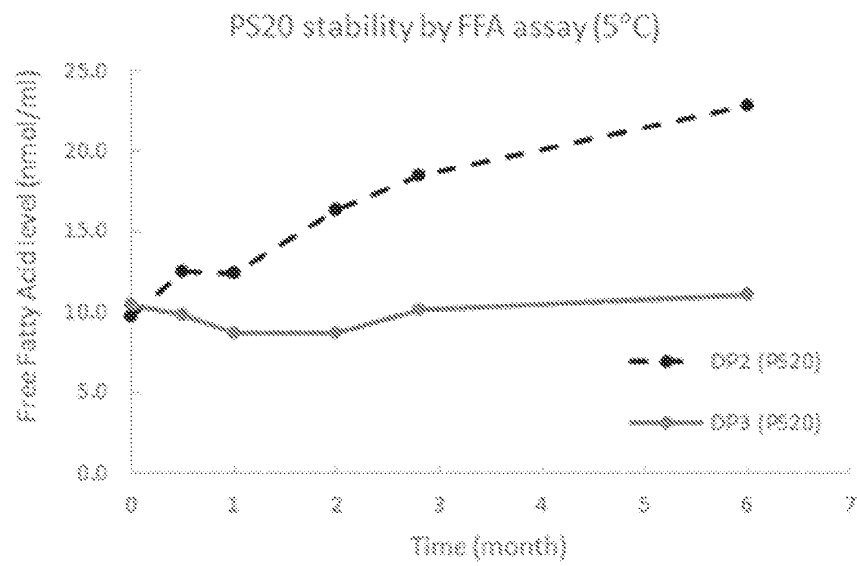


FIG. 36A

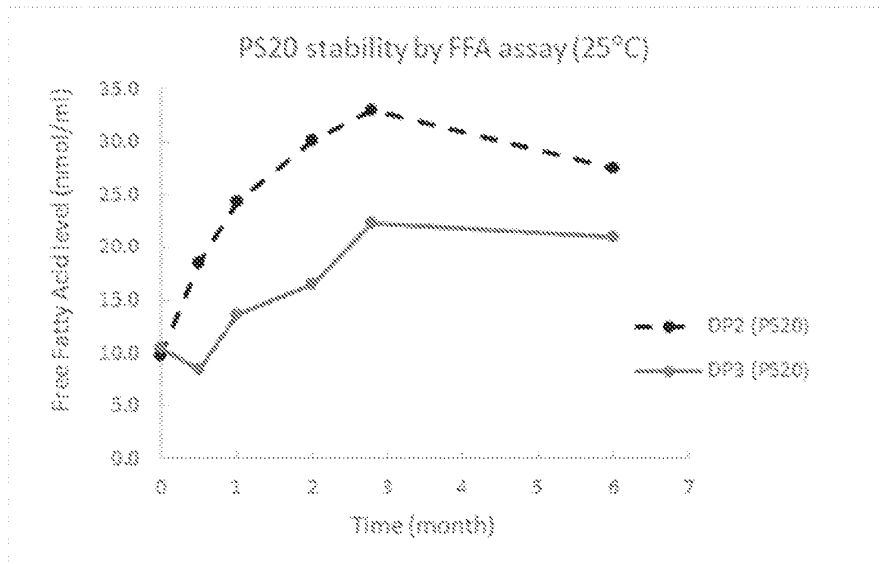


FIG. 36B

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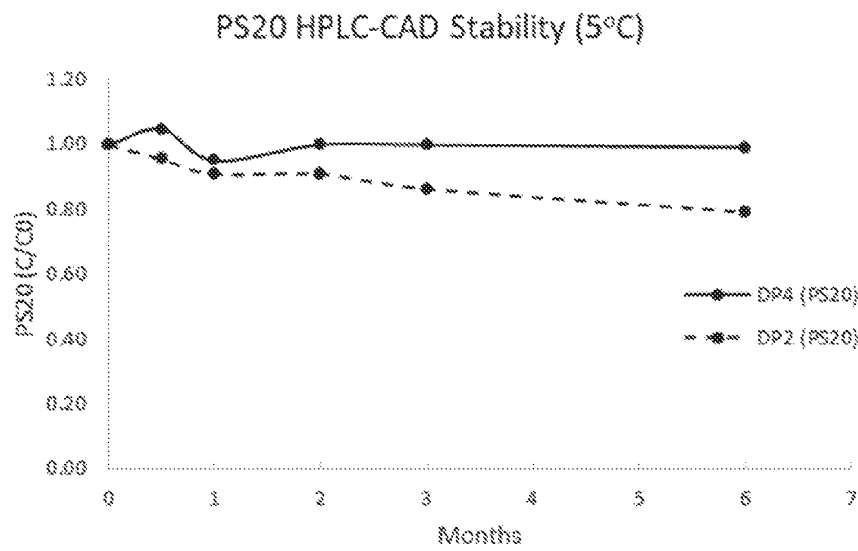


FIG. 37A

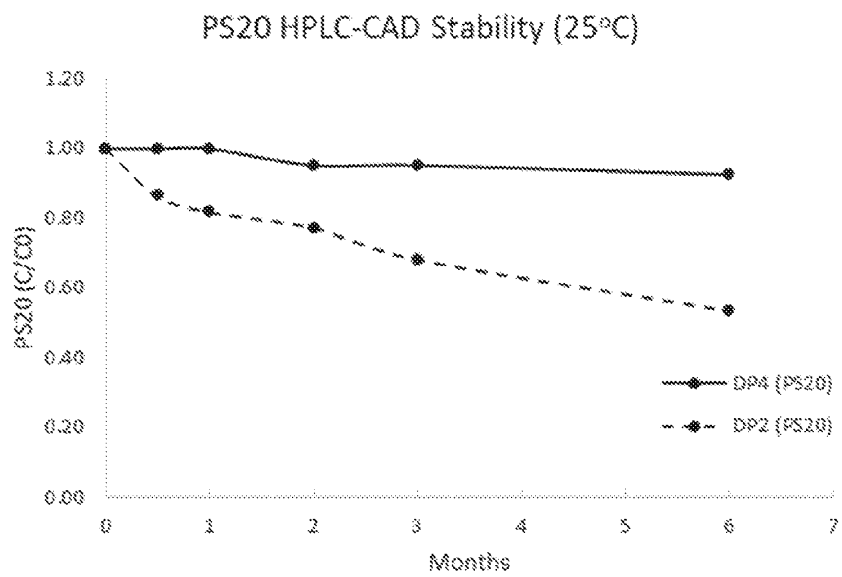


FIG. 37B

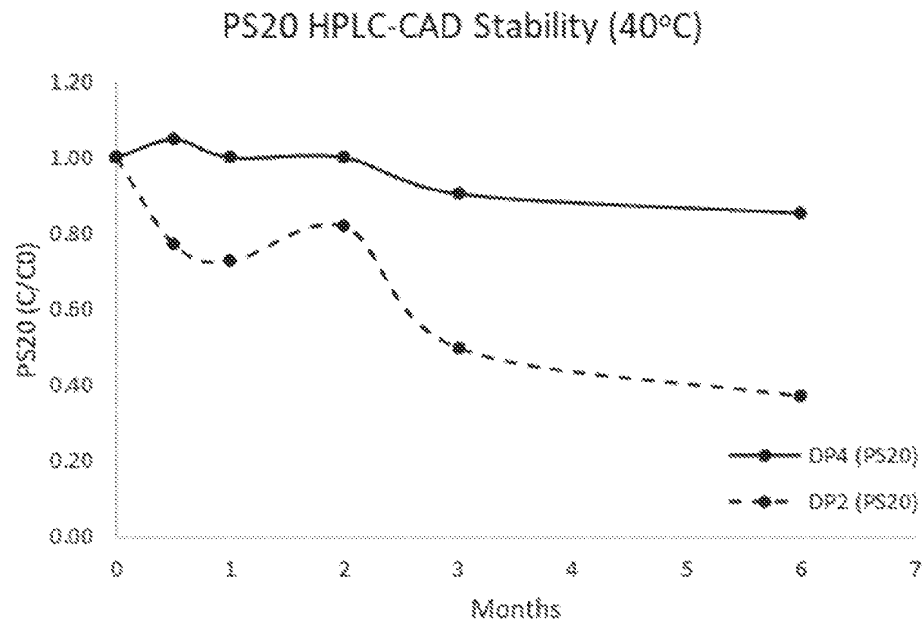


FIG. 37C

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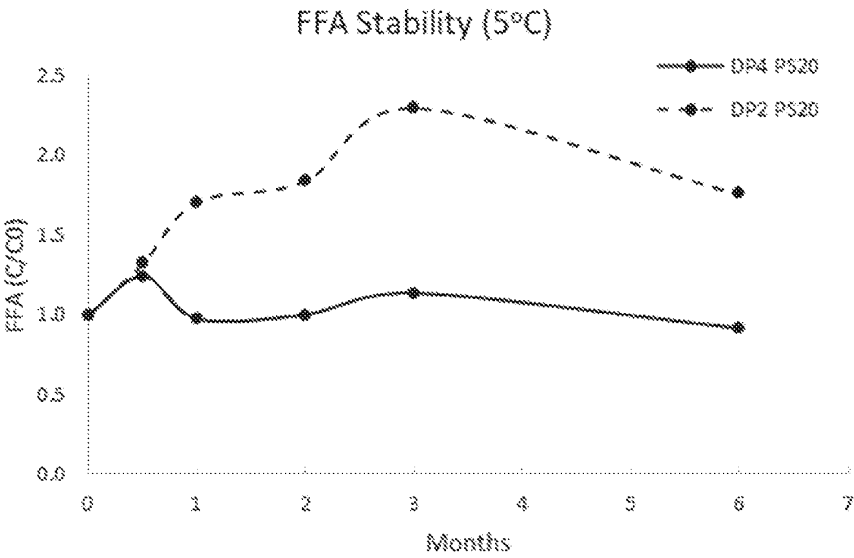


FIG. 38A

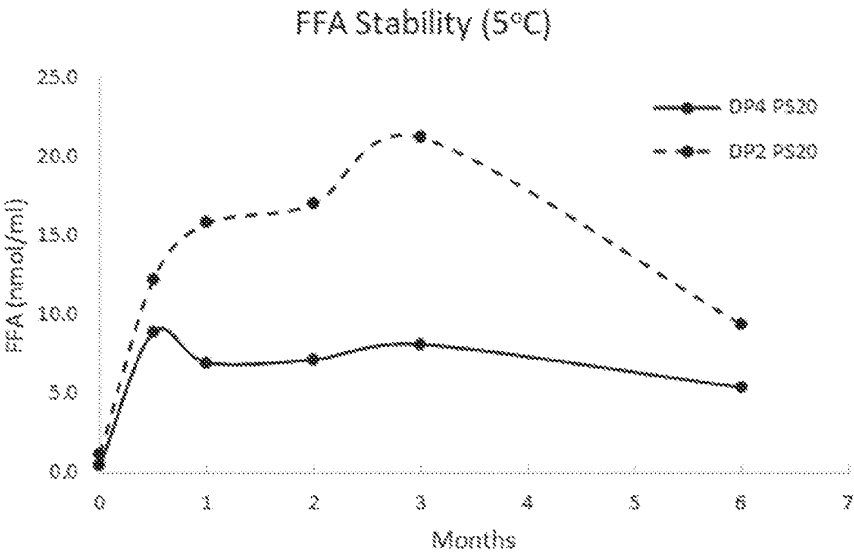


FIG. 38B

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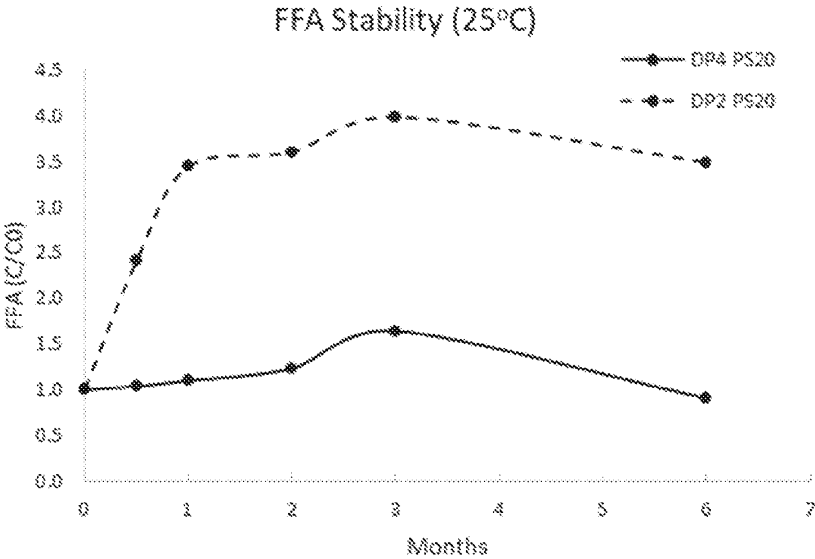


FIG. 38C

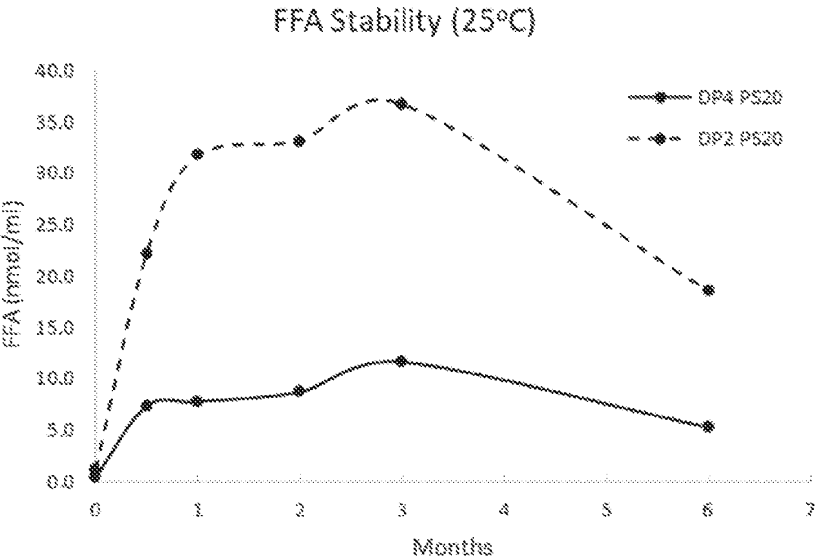
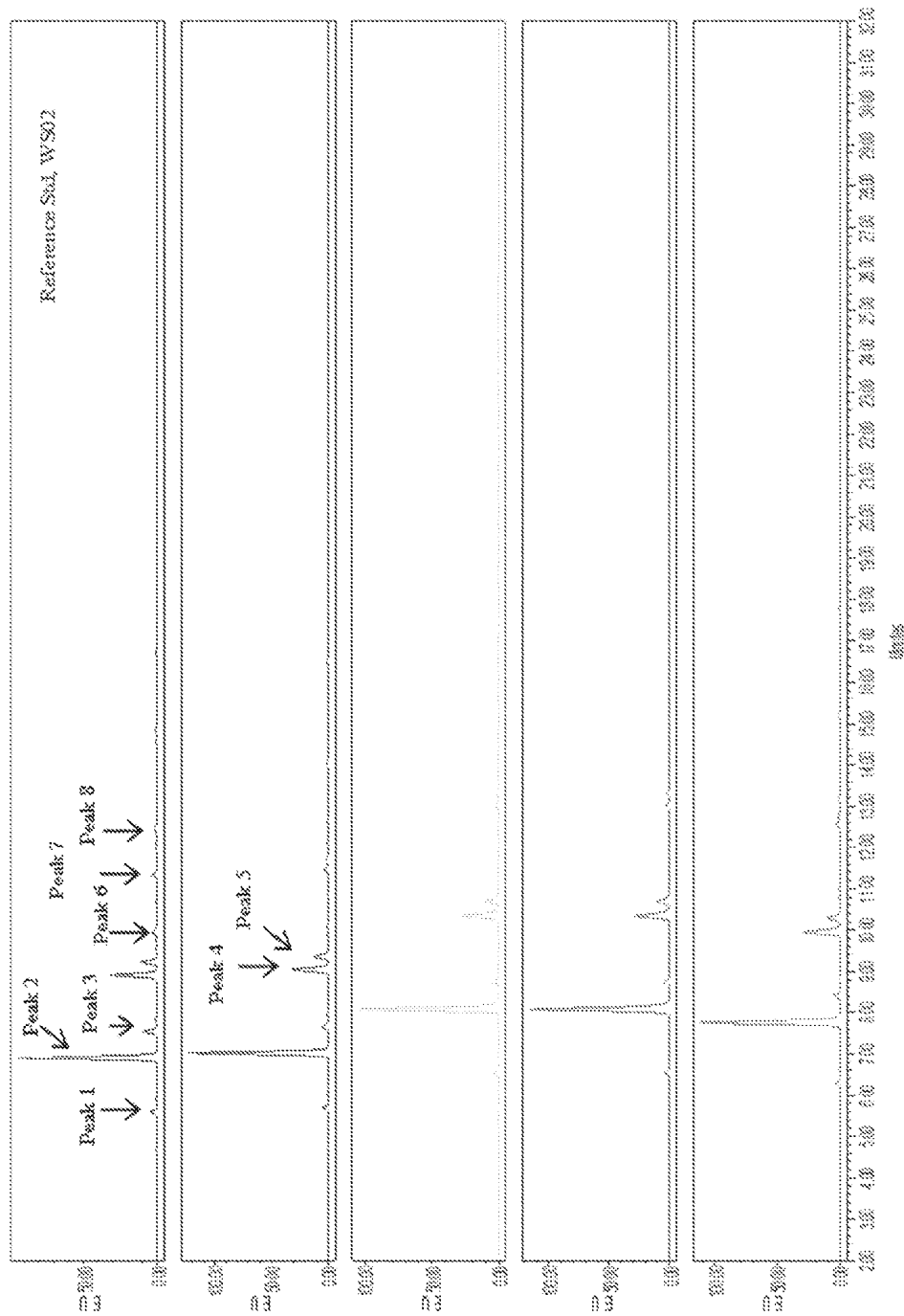


FIG. 38D



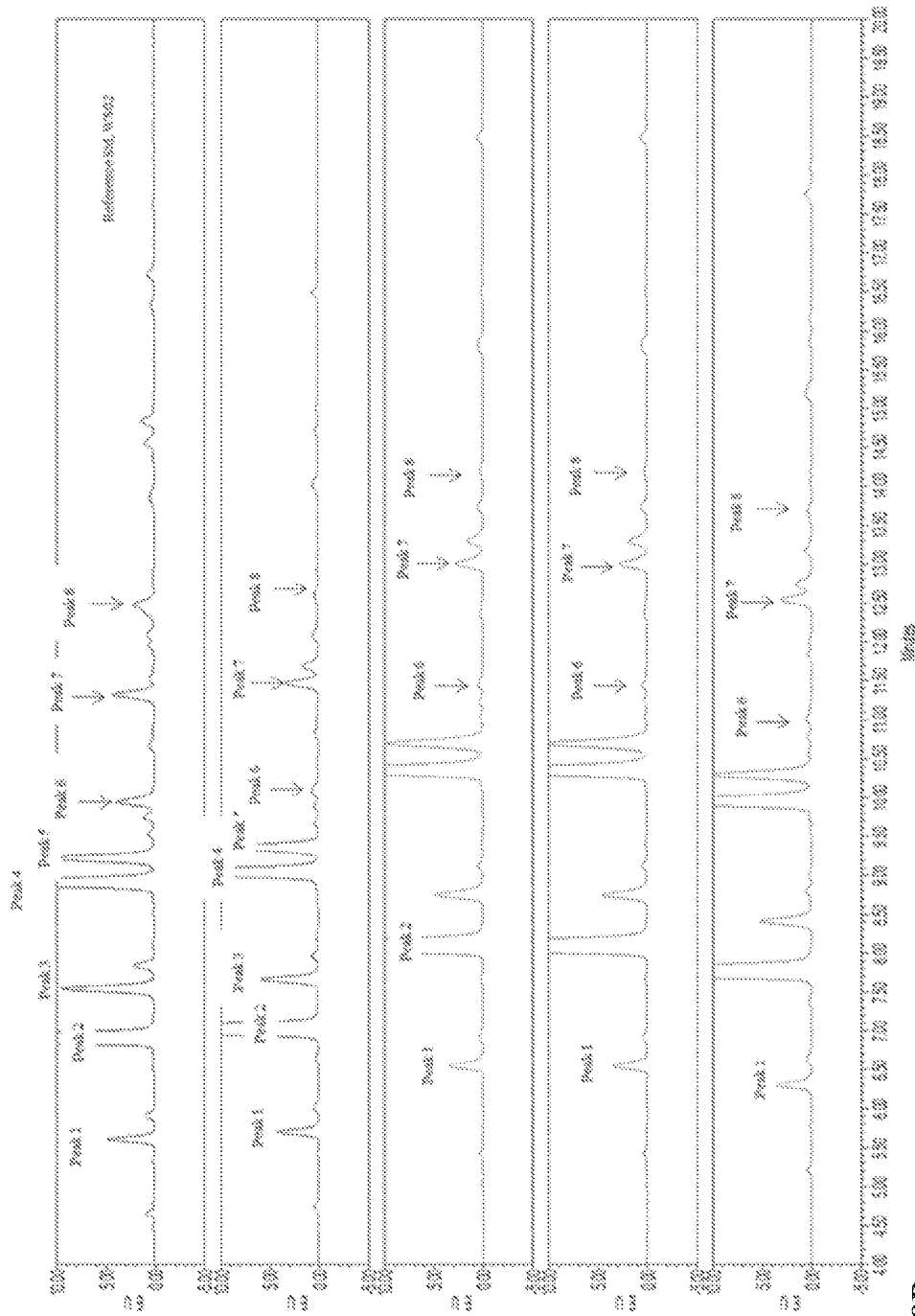


FIG. 39B

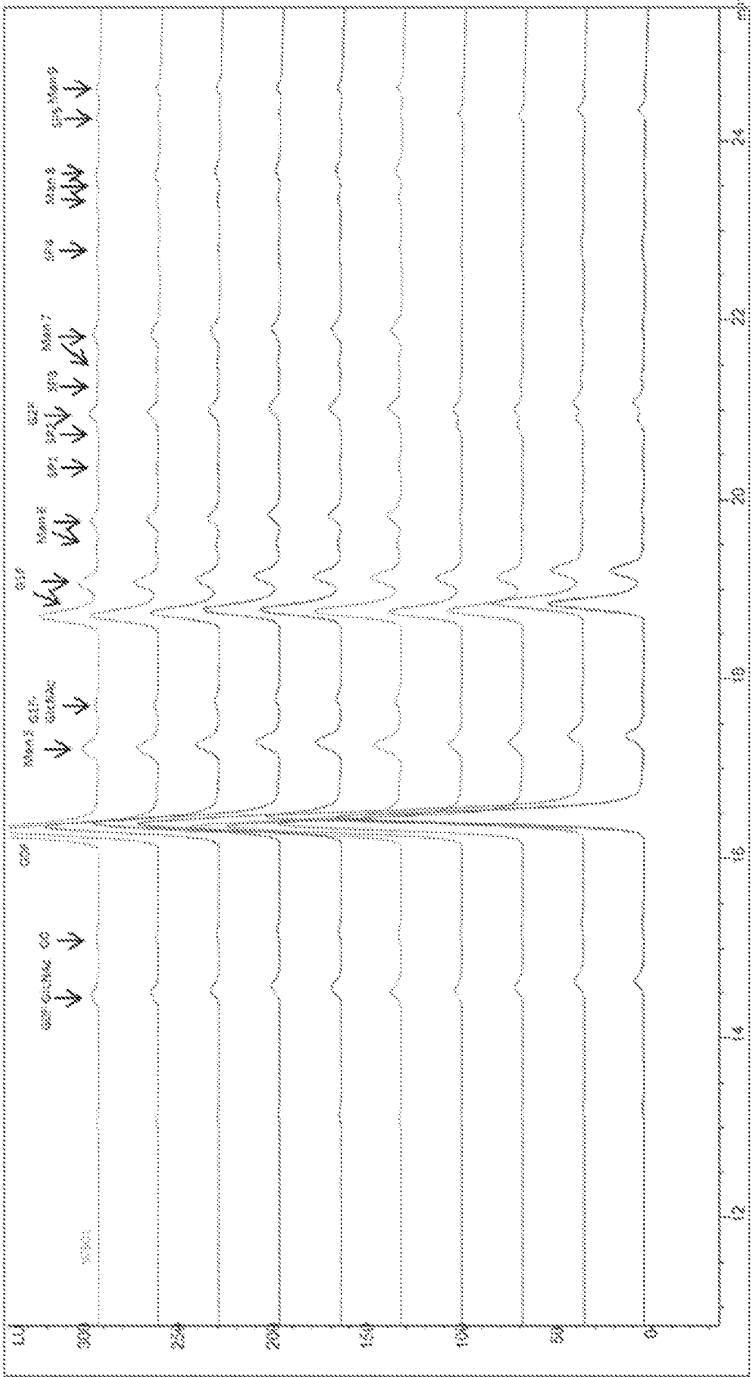


FIG. 40

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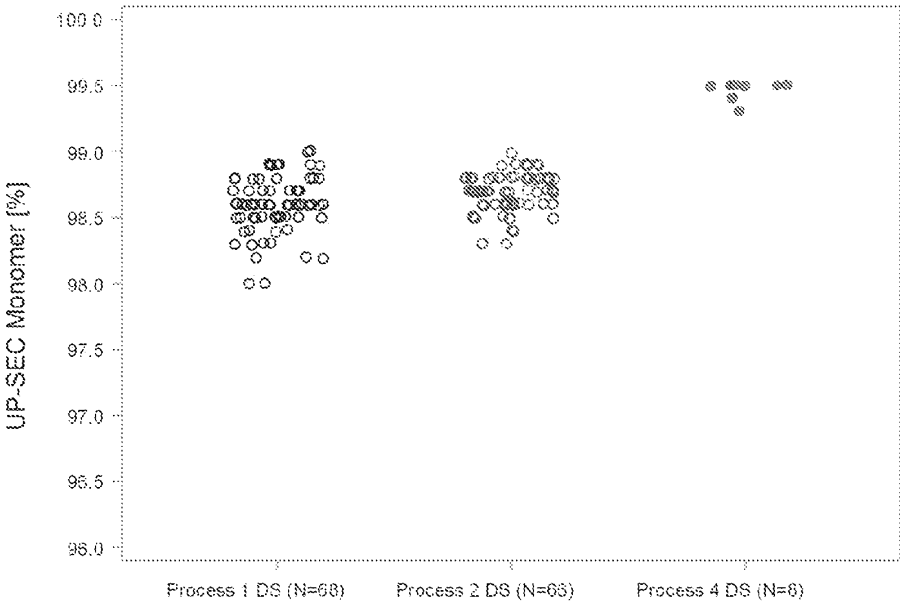


FIG. 41A

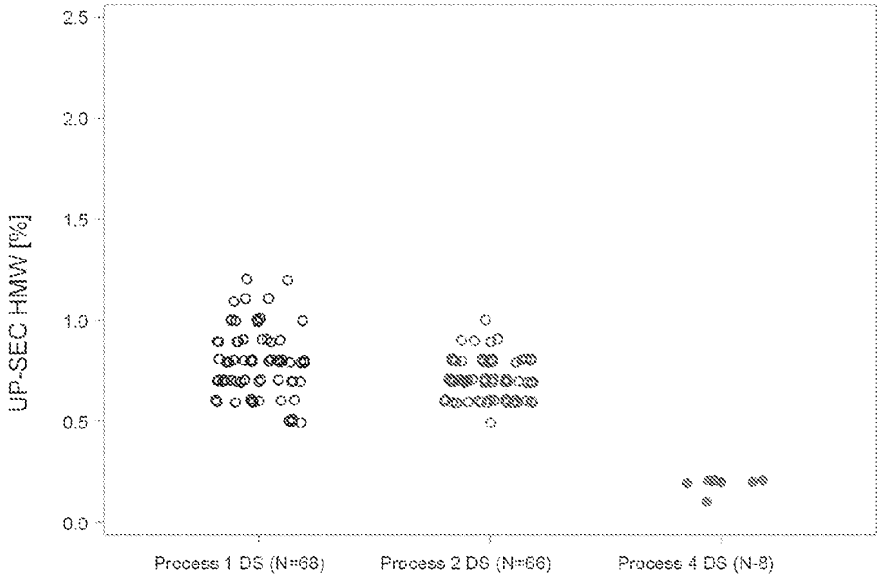


FIG. 41B

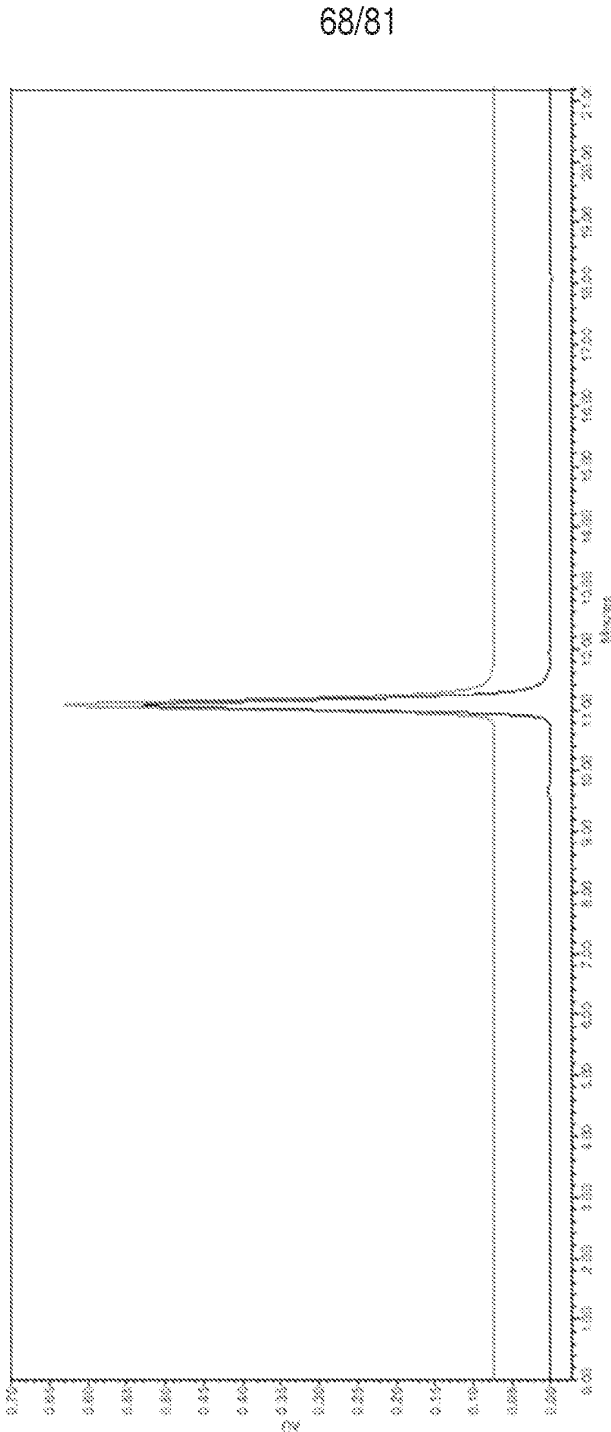


FIG. 41C

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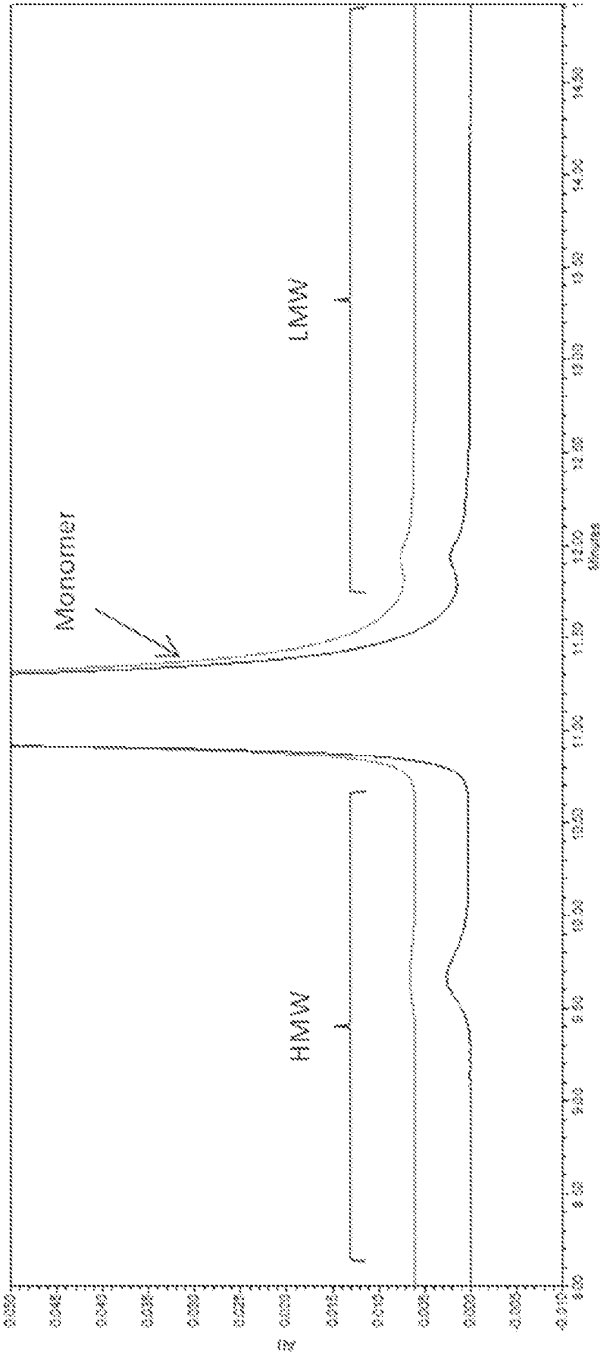


FIG. 41D

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FIG. 42A

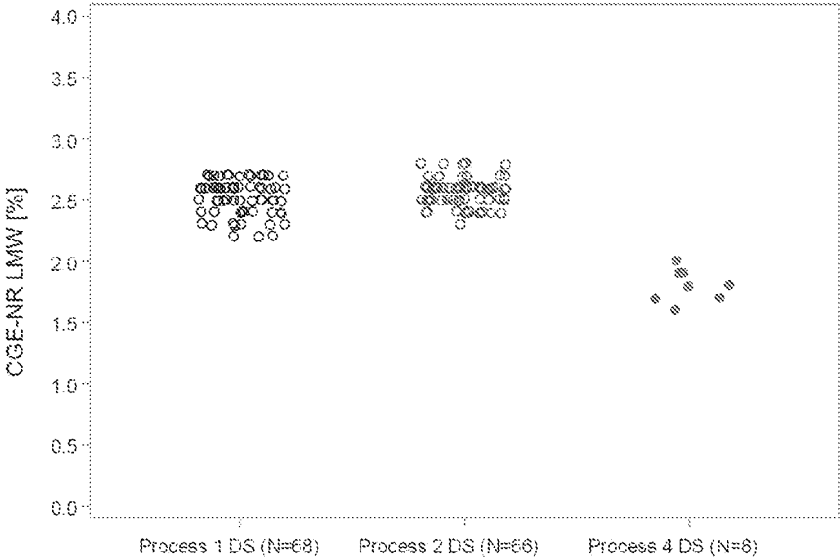


FIG. 42B

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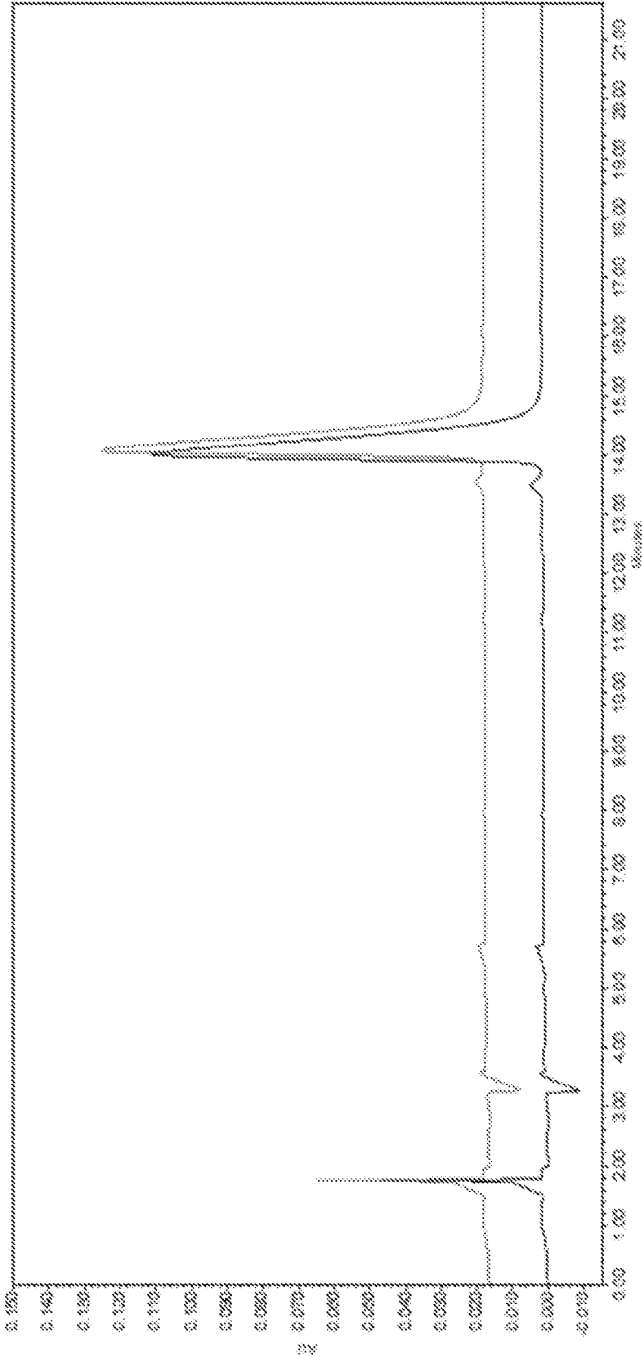


FIG. 42C

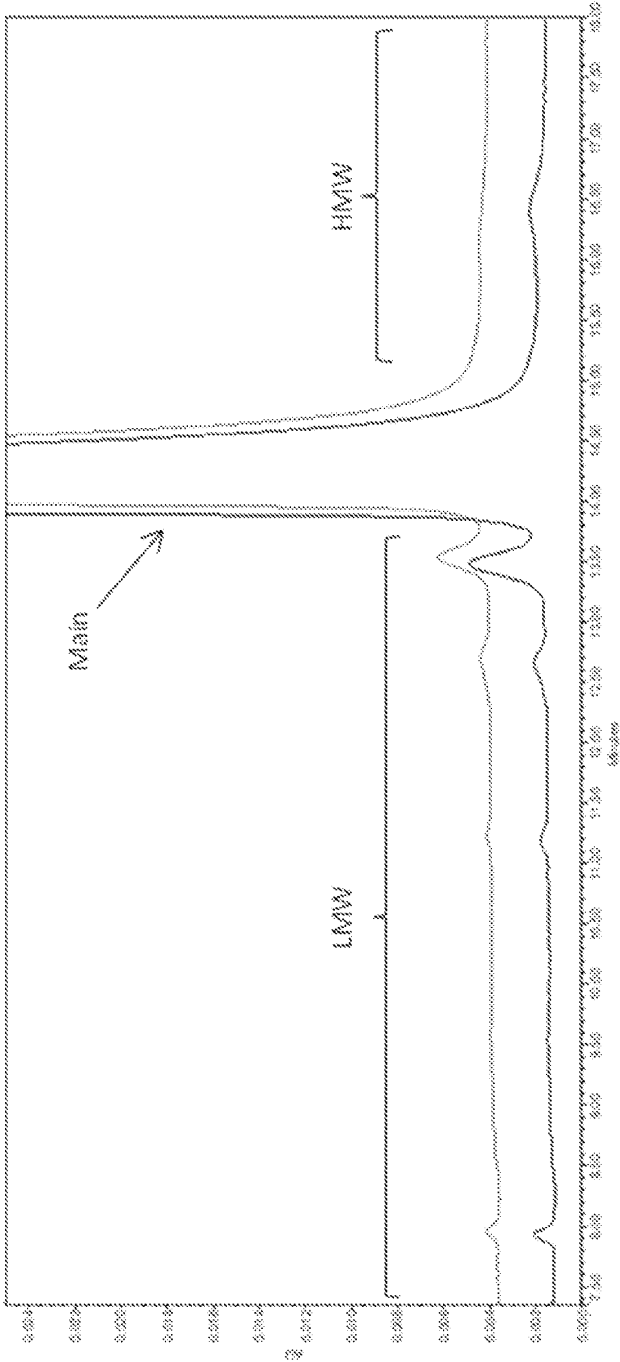


FIG. 42D

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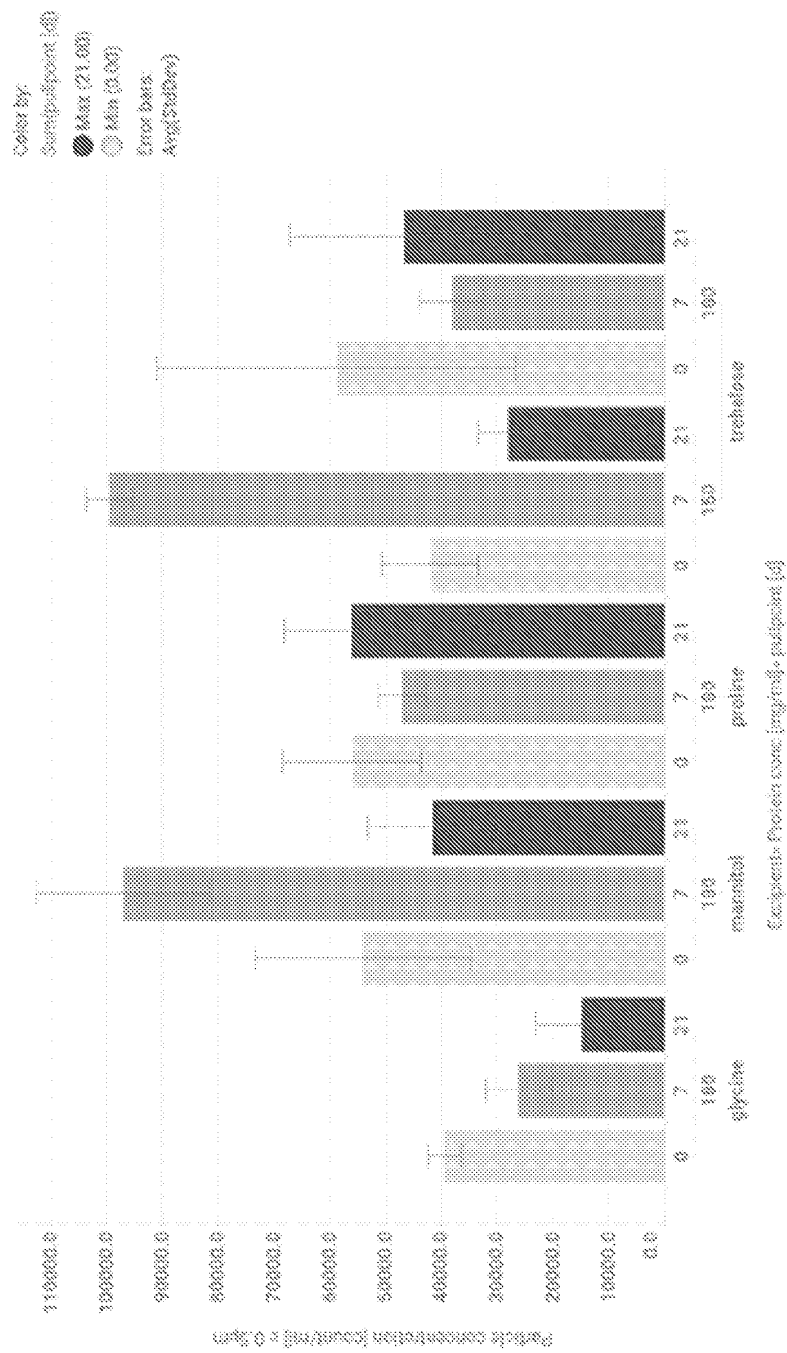


FIG. 43

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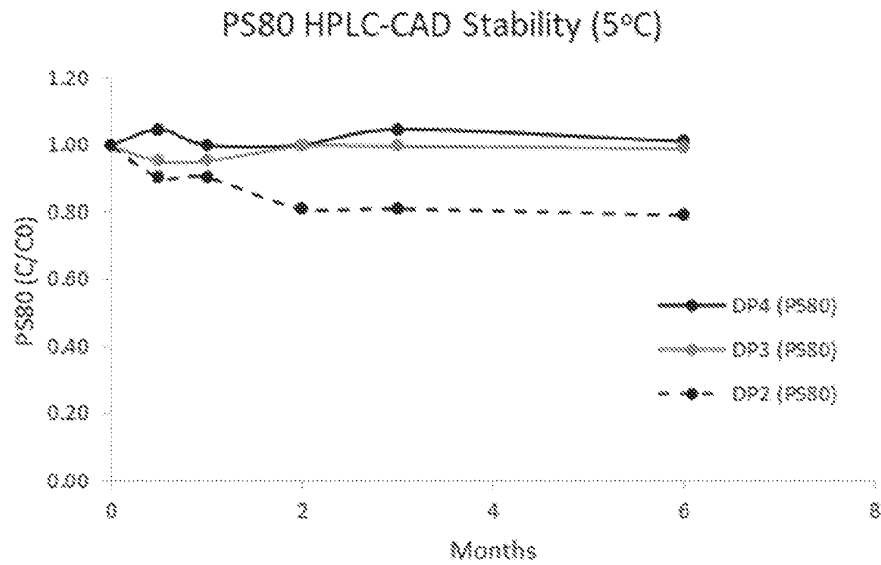


FIG. 44A

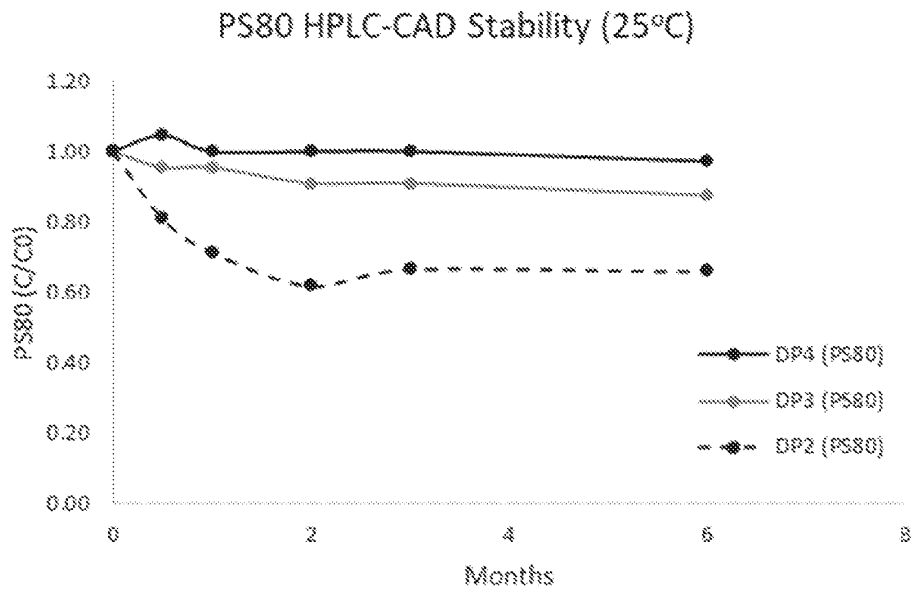


FIG. 44B

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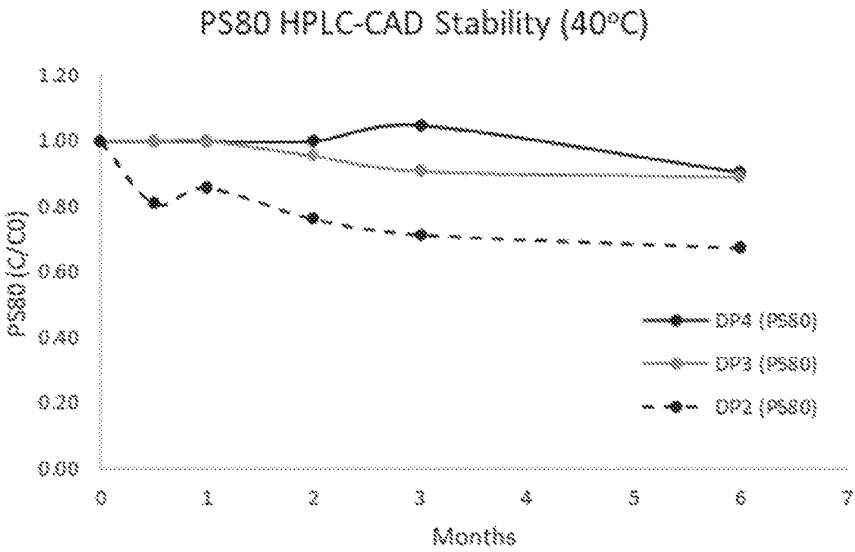


FIG. 44C

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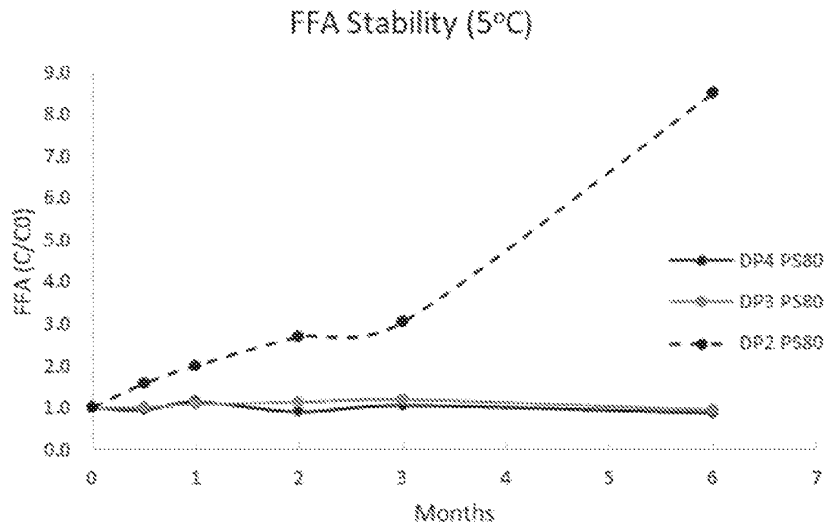


FIG. 45A

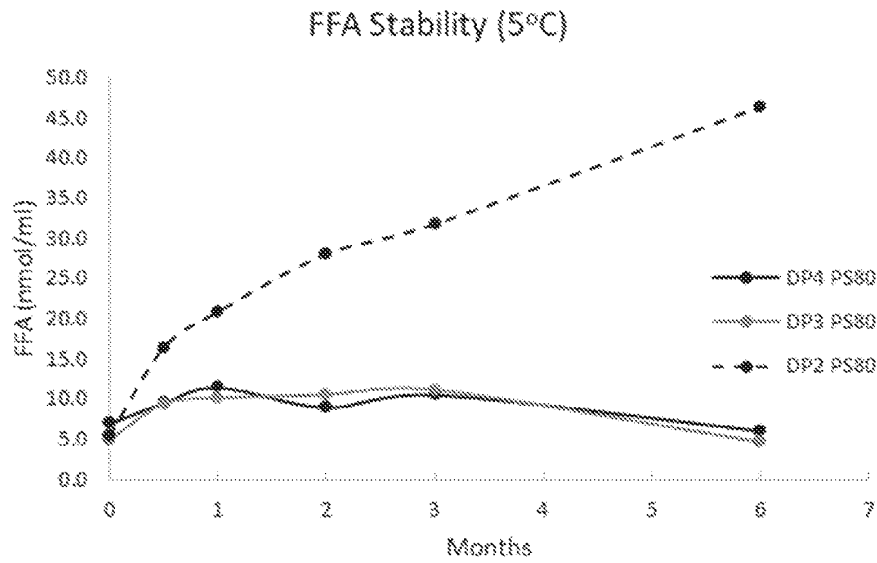


FIG. 45B

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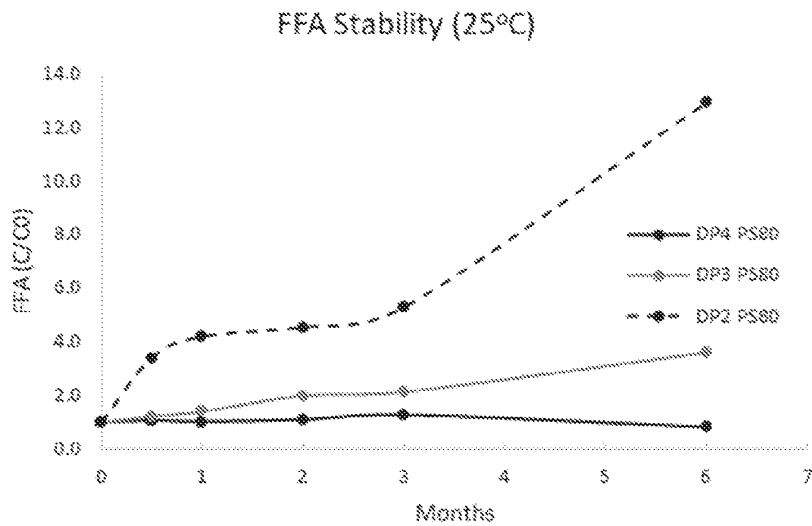


FIG. 45C

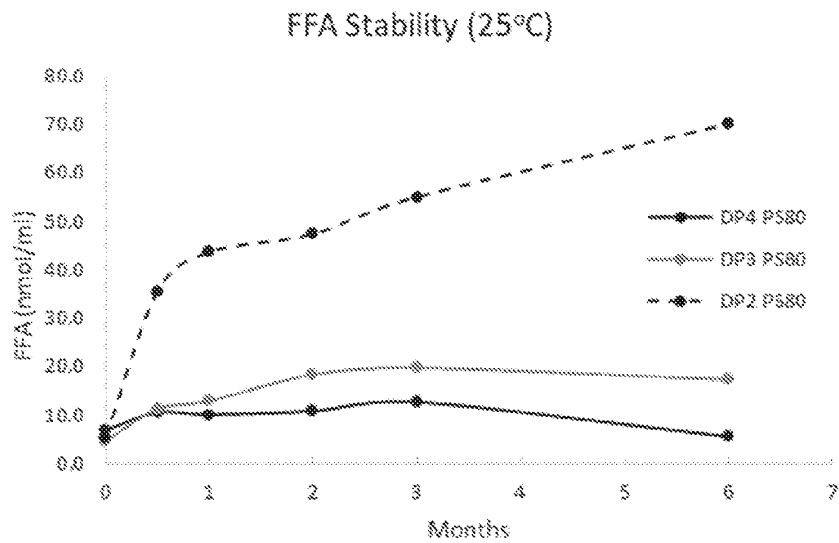


FIG. 45D

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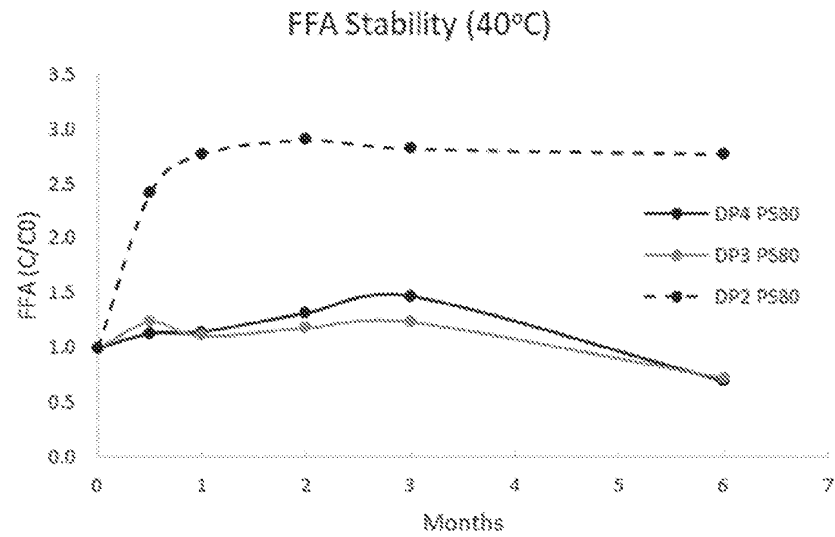


FIG. 45E

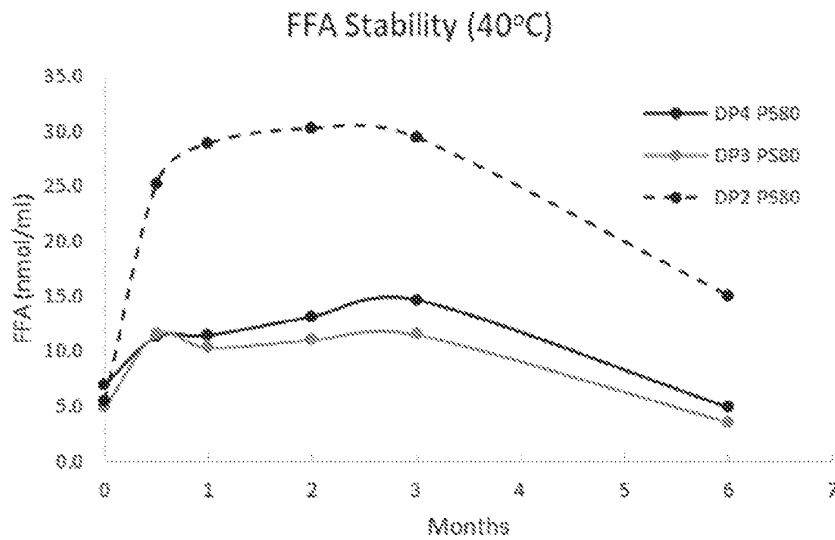


FIG. 45F

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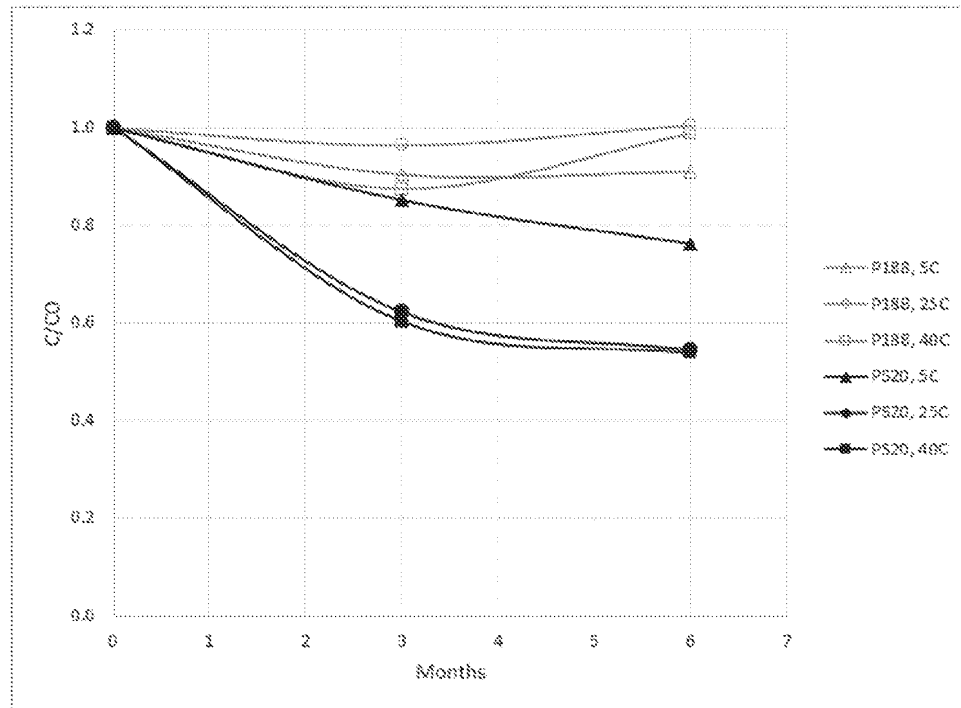


FIG. 46

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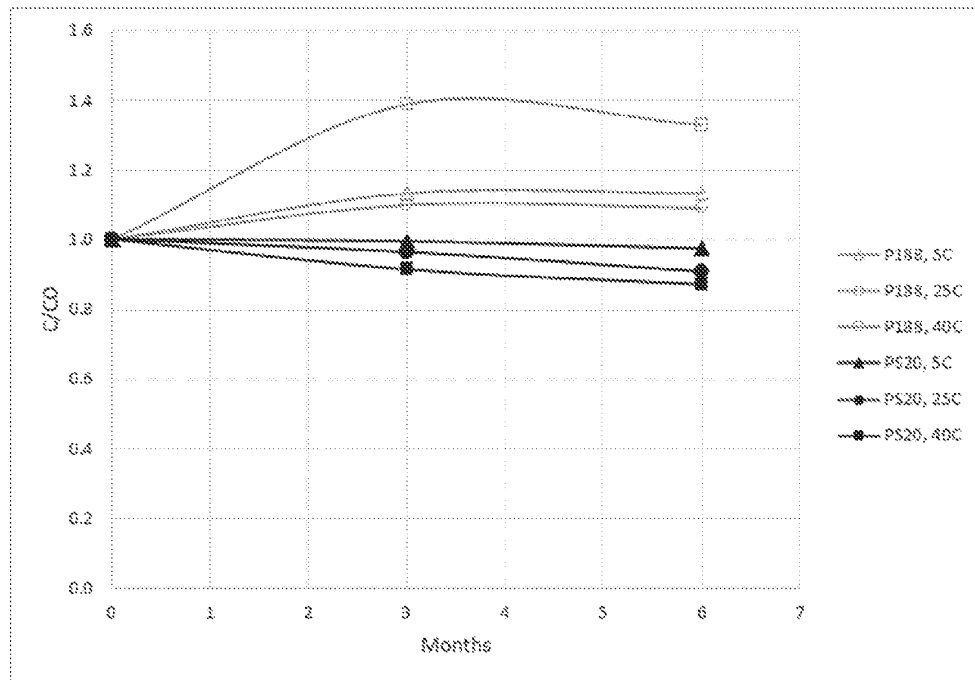


FIG. 47

Assay	Excipient Temperature Time (Month)	P188						P530					
		-80°C		5°C		25°C		40°C		-80°C		5°C	
		0	3	6	0.15	0.13	0.15	0.17	0.15	0	0.21	0.24	0.22
[P188], mg/mL	CMC2 150	0.12	0.15	0.15	0.15	0.17	0.15	0.17	0.15				
	CMC2 150 HIC	0.12	0.13	0.13	0.13	0.13	0.16	0.16	0.16				
	CMC2 150									0.21	0.18	0.15	0.12
[P520], mg/mL	CMC2 150 HIC									0.25	0.24	0.22	0.20
	CMC2 150		1.7			2.7		4.4	0.7		1.7		5.3
	CMC2 150 HIC			1.4		2.3		5.8	0.5		1.3		5.5
%HMW	CMC2 150			25.1		33.8		57.6	24.9		25.1		71.4
	CMC2 150 HIC			24.6		33.3		70.2	34.7		24.6		74.2
	CMC2 150			6.5		10.0		10.9	7.5		8.2		10.1
%BPG	CMC2 150 HIC			8.3		11.2		11.0	6.7		7.8		10.5
	CMC2 150			2.5		4.0		10.0	2.9		2.9		15.1
	CMC2 150 HIC			2.7		4.8		15.2	2.5		2.8		15.5

FIG. 48