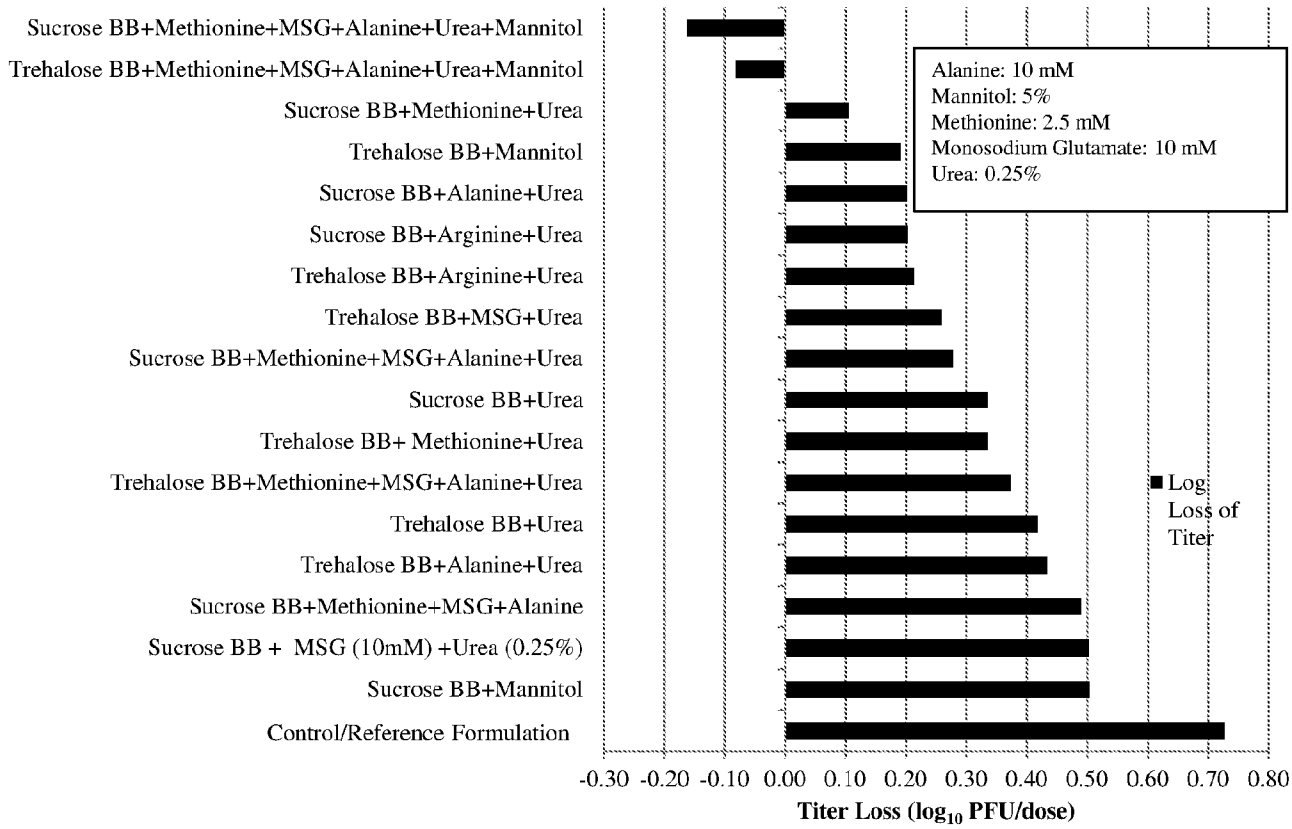

Potency Loss after 5 weeks at 25°C
Sucrose BB+Methionine+MSG+Alanine+Urea+Mannitol
Trehalose BB+Methionine+MSG+Alanine+Urea+Mannitol
Sucrose BB+Methionine+Urea
Trehalose BB+Mannitol
Sucrose BB+Alanine+Urea
Sucrose BB+Arginine+Urea
Trehalose BB+Arginine+Urea
Trehalose BB+MSG+Urea
Sucrose BB+Methionine+MSG+Alanine+Urea
Sucrose BB+Urea
Trehalose BB+ Methionine+Urea
Trehalose BB+Methionine+MSG+Alanine+Urea
Trehalose BB+Urea
Trehalose BB+Alanine+Urea
Sucrose BB+Methionine+MSG+Alanine
Sucrose BB + MSG (10mM) +Urea (0.25%)
Sucrose BB+Mannitol
Control/Reference Formulation
Alanine: 10 mM
Mannitol: 5%
Methionine: 2.5 mM
Monosodium Glutamate: 10 mM
Urea: 0.25%
Log Loss of Titer
-0.30 -0.20 -0.10 0.00 0.10 0.20 0.30 0.40 0.50 0.60 0.70 0.80
Titer Loss (log10 PFU/dose)

FIG. 1

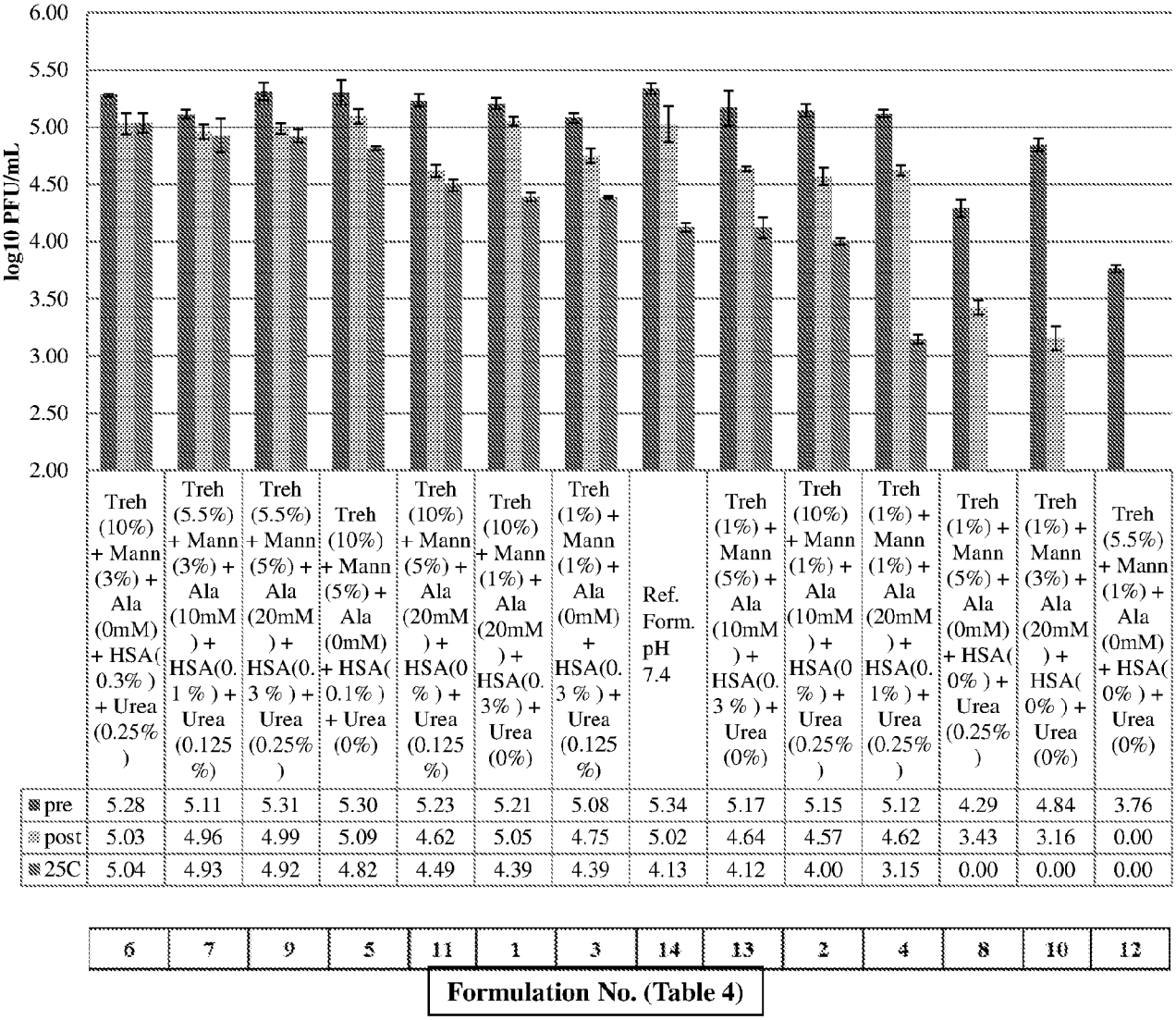
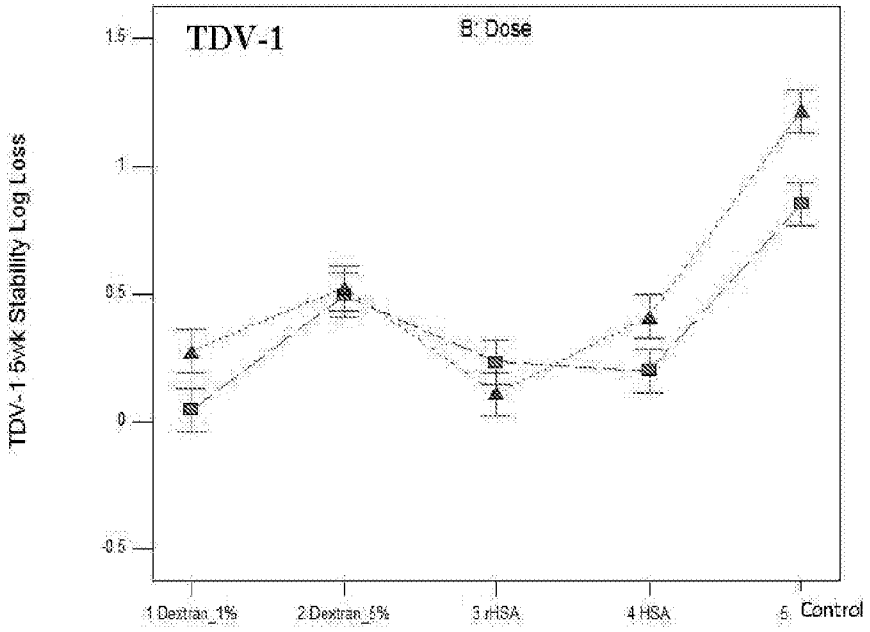
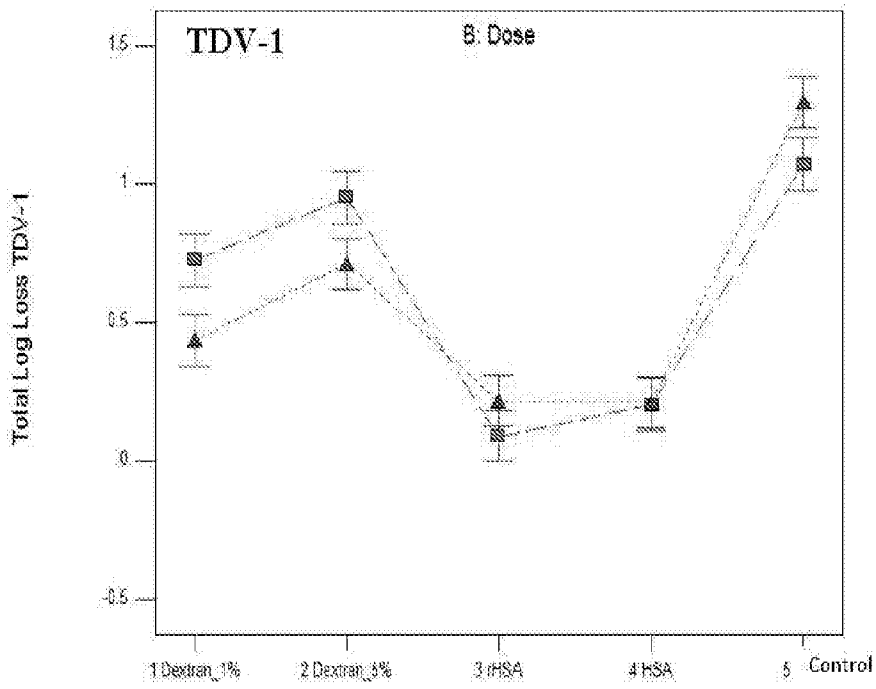

6.00
5.50
5.00
4.50
4.00
3.50
3.00
2.50
2.00
log10 PFU/mL
Treh (10%) + Mann (3%) + Ala (0mM) + HSA(0.3%) + Urea (0.25%)
Treh (5.5%) + Mann (3%) + Ala (10mM) + HSA(0. 1 %) + Urea (0.125 %)
Treh (5.5%) + Mann (5%) + Ala (20mM) + HSA(0. 3 %) + Urea (0.25%)
Treh (10%) + Mann (5%) + Ala (0mM) + HSA(0.1%) + Urea (0%)
Treh (10%) + Mann (5%) + Ala (20mM) + HSA(0 %) + Urea (0.125 %)
Treh (10%) + Mann (1%) + Ala (20mM) + HSA(0. 3%) + Urea (0%)
Treh (1%) + Mann (1%) + Ala (0mM) + HSA(0. 3 %) + Urea (0.125 %)
Ref. Form. pH 7.4
Treh (1%) + Mann (5%) + Ala (10mM) + HSA(0. 3 %) + Urea (0%)
Treh (10%) + Mann (1%) + Ala (10mM) + HSA(0 %) + Urea (0.25%)
Treh (1%) + Mann (1%) + Ala (20mM) + HSA(0. 1%) + Urea (0.25%)
Treh (1%) + Mann (5%) + Ala (0mM) + HSA(0%) + Urea (0.25%)
Treh (1%) + Mann (3%) + Ala (20mM) + HSA(0%) + Urea (0%)
Treh (5.5%) + Mann (1%) + Ala (0mM) + HSA(0%) + Urea (0%)
pre 5.28 5.11 5.31 5.30 5.23 5.21 5.08 5.34 5.17 5.15 5.12 4.29 4.84 3.76
post 5.03 4.96 4.99 5.09 4.62 5.05 4.75 5.02 4.64 4.57 4.62 3.43 3.16 0.00
25C 5.04 4.93 4.92 4.82 4.49 4.39 4.39 4.13 4.12 4.00 3.15 0.00 0.00 0.00
6 7 9 5 11 1 3 14 13 2 4 8 10 12
Formulation No. (Table 4)

FIG. 2

3A

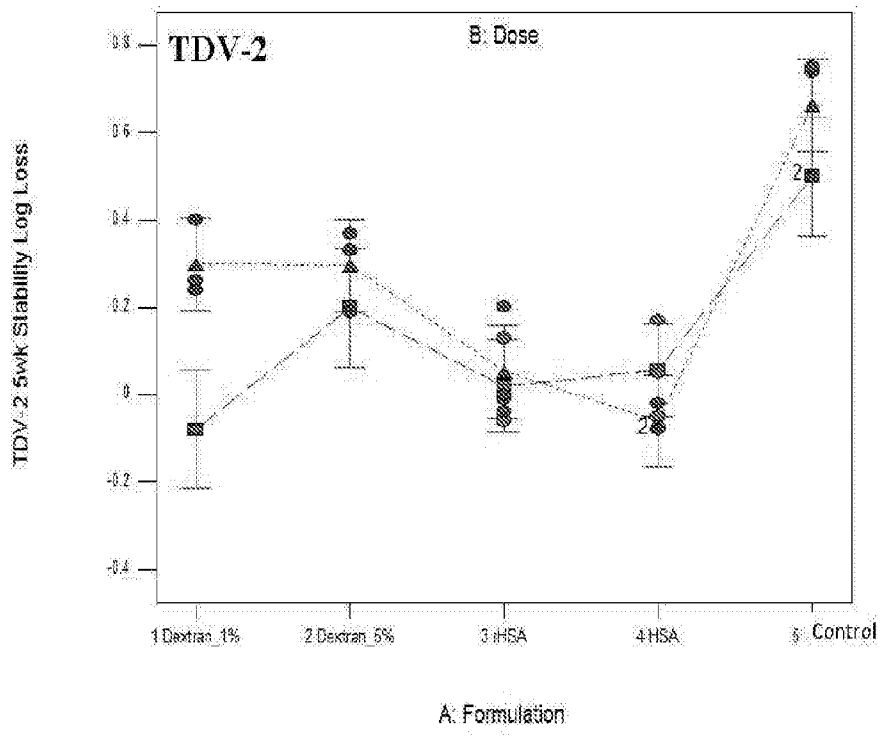


3B

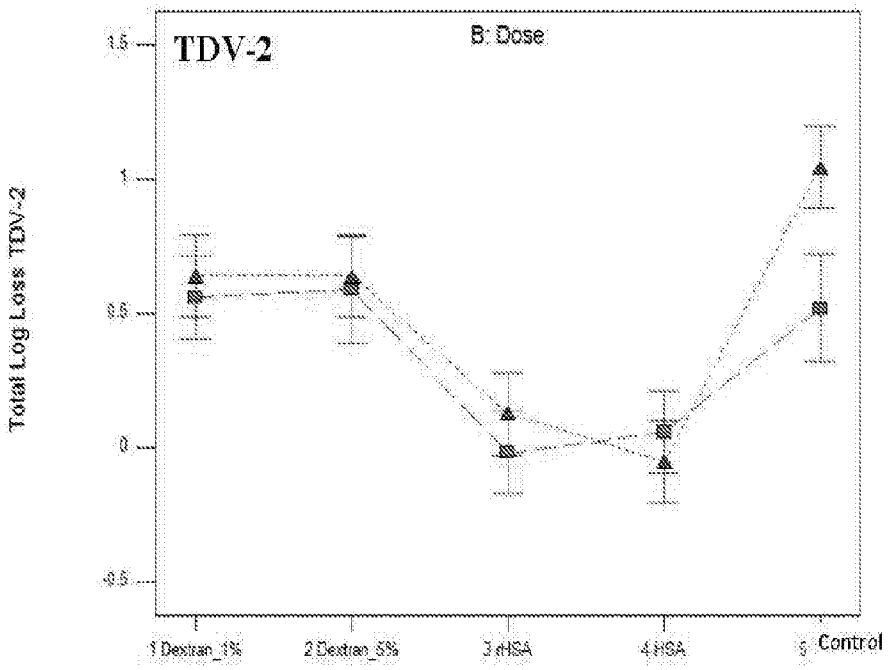


FIGS. 3A-3B

4A

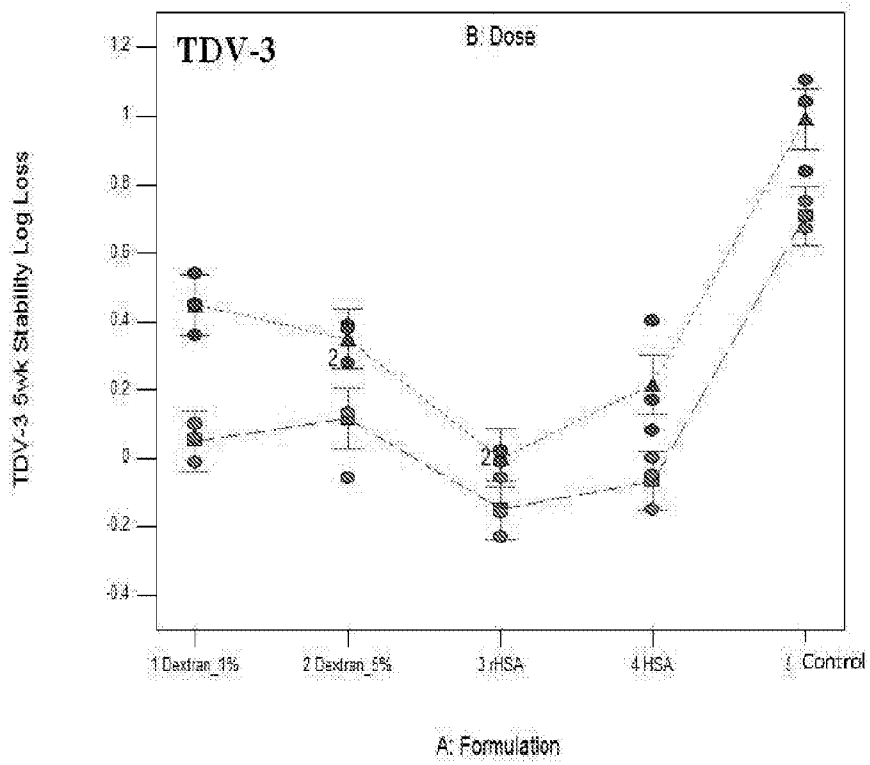


4B

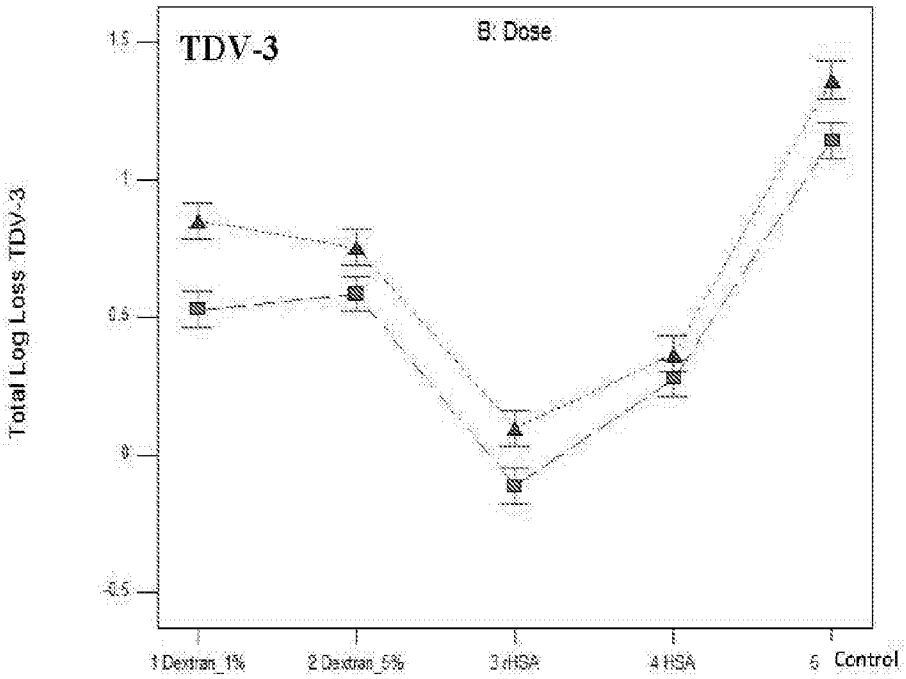


FIGS. 4A-4B

5A

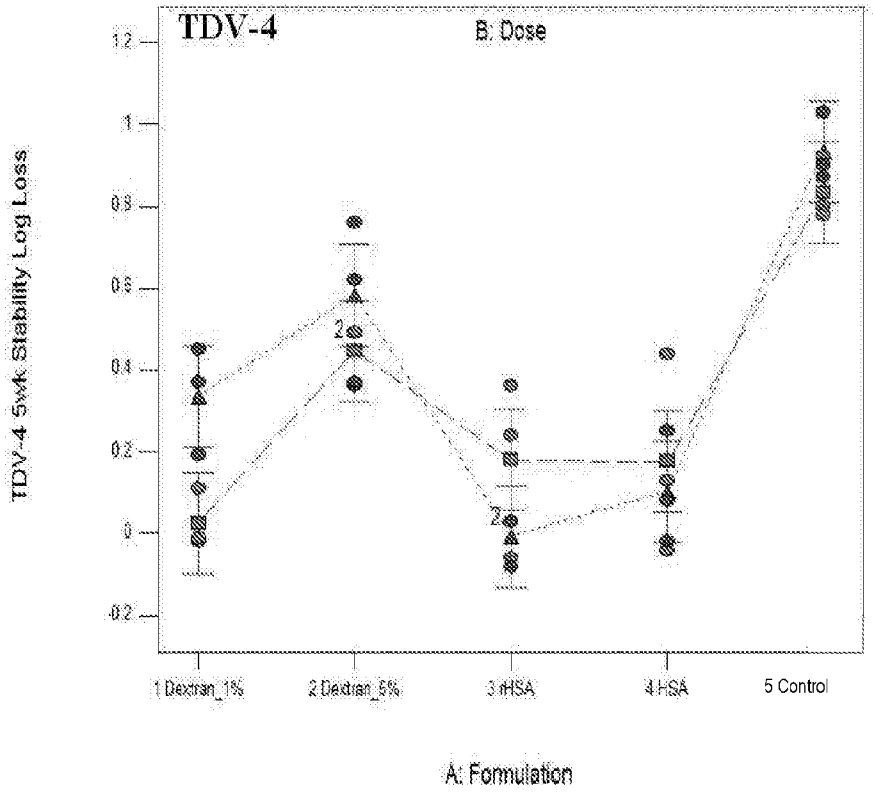


5B

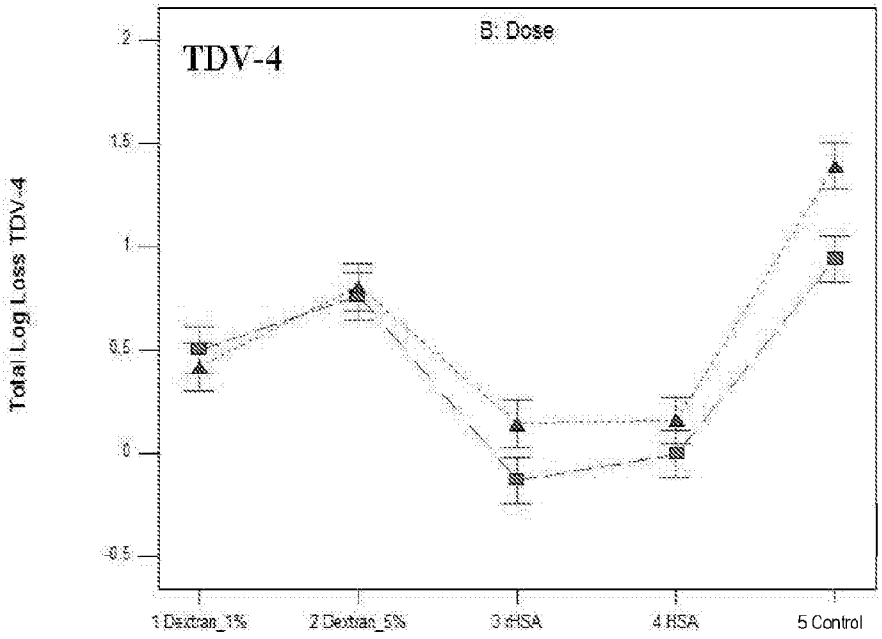


FIGS. 5A-5B

6A

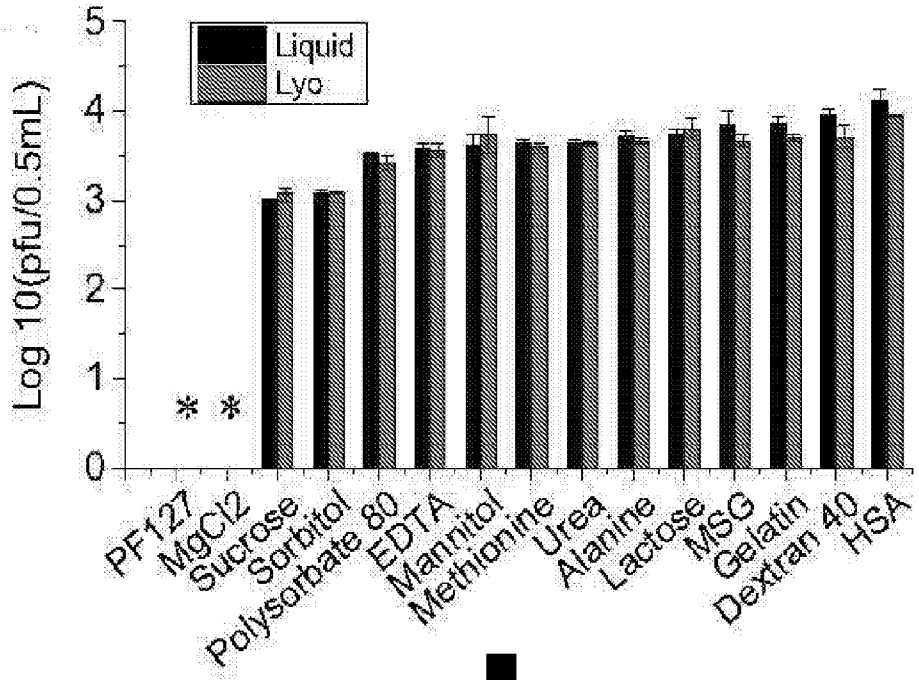


6B

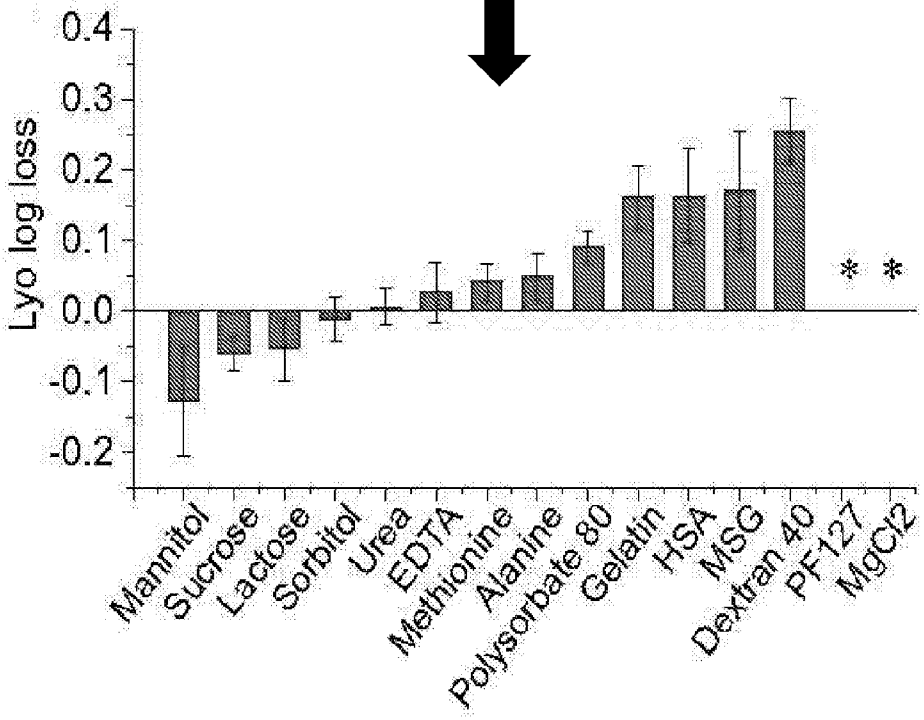


FIGS. 6A-6B

7A

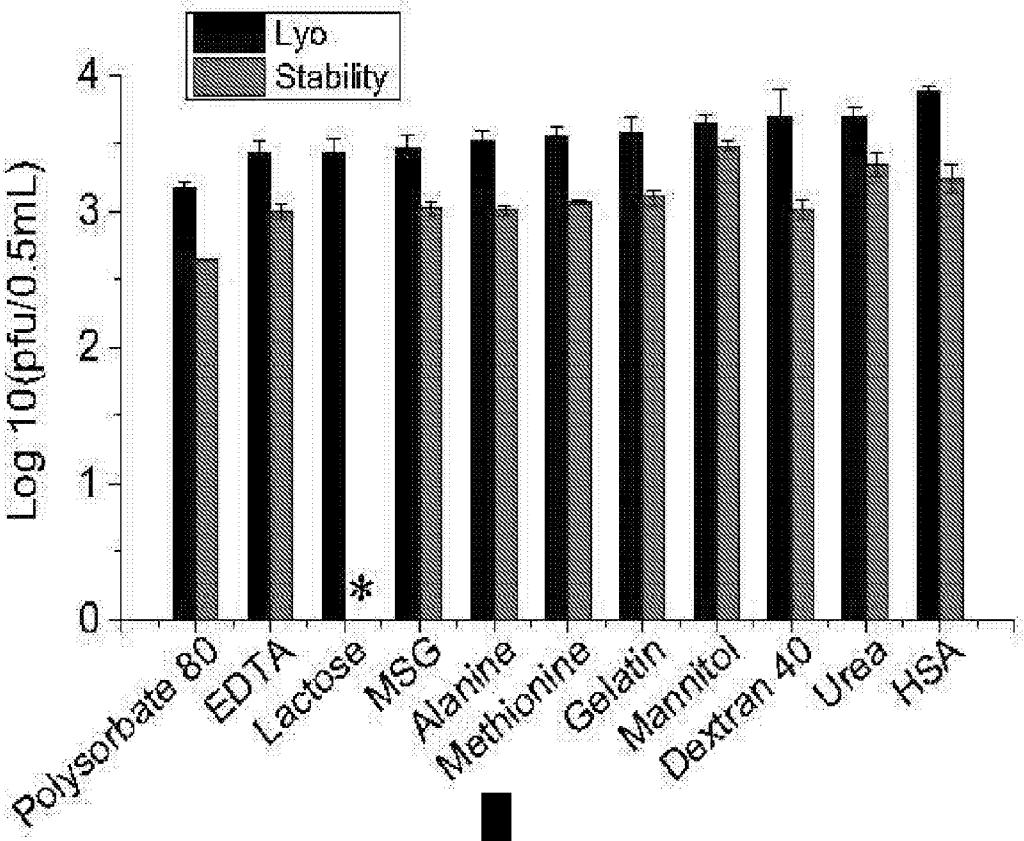


7B

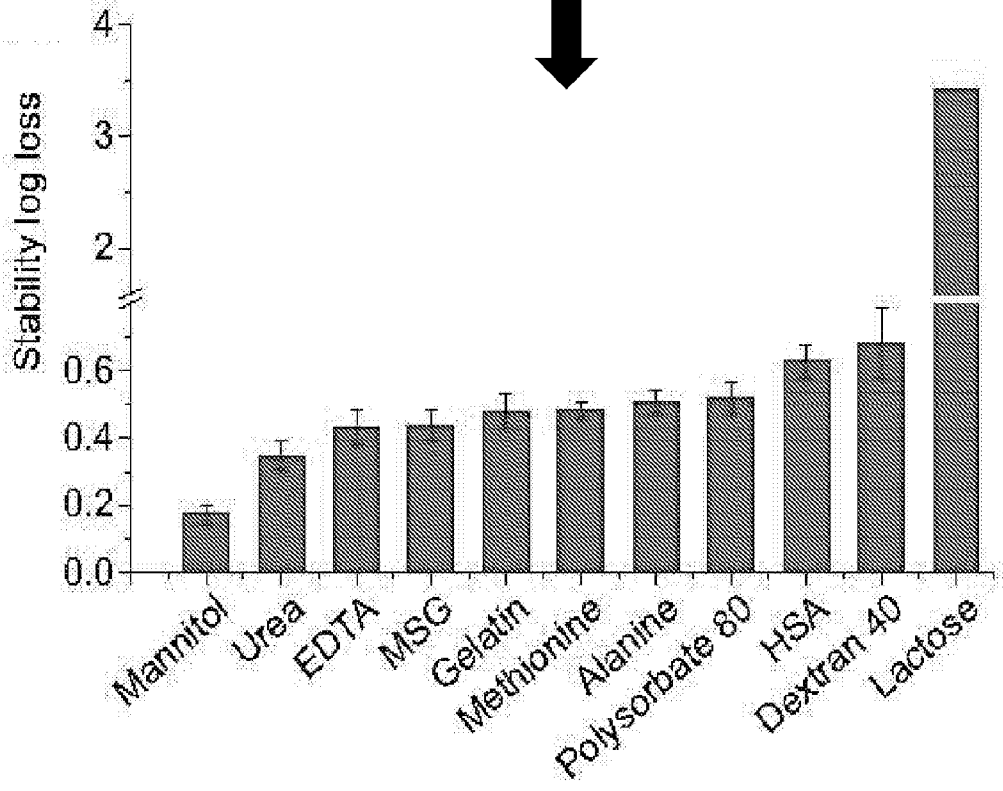


FIGS. 7A-7B

7C

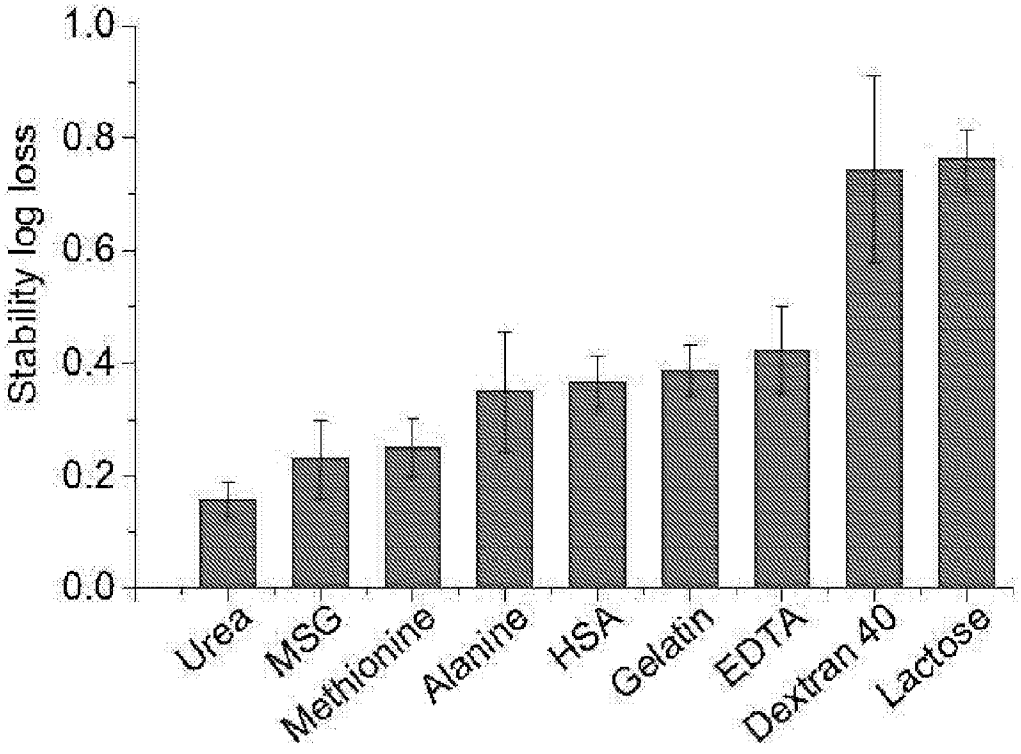


7D

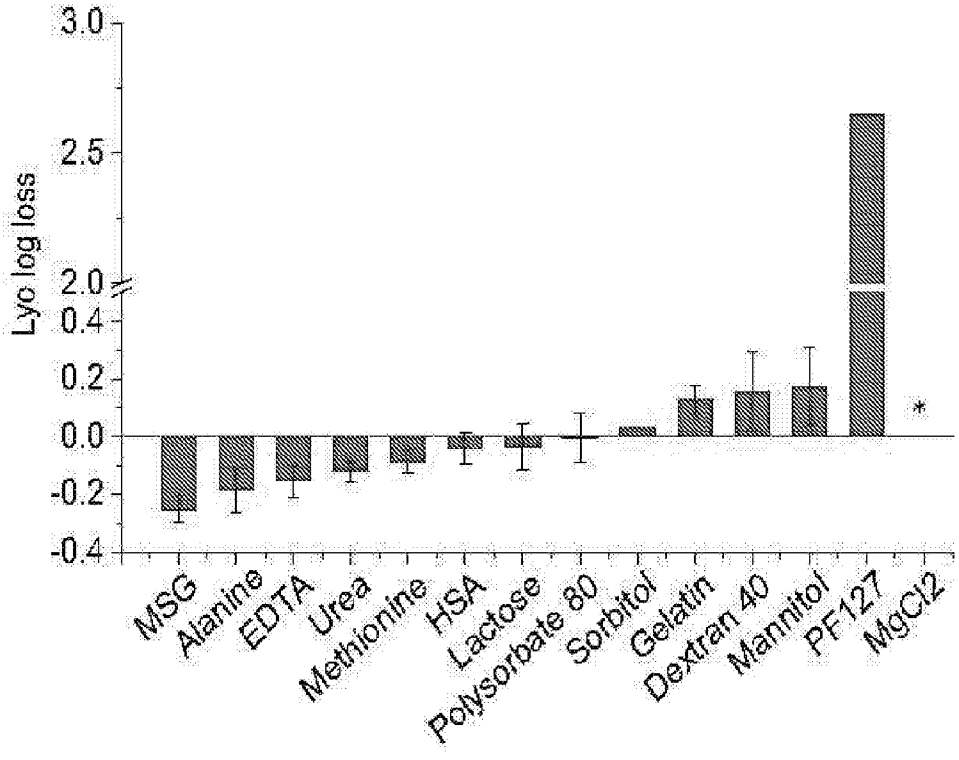


FIGS. 7C-7D

8A

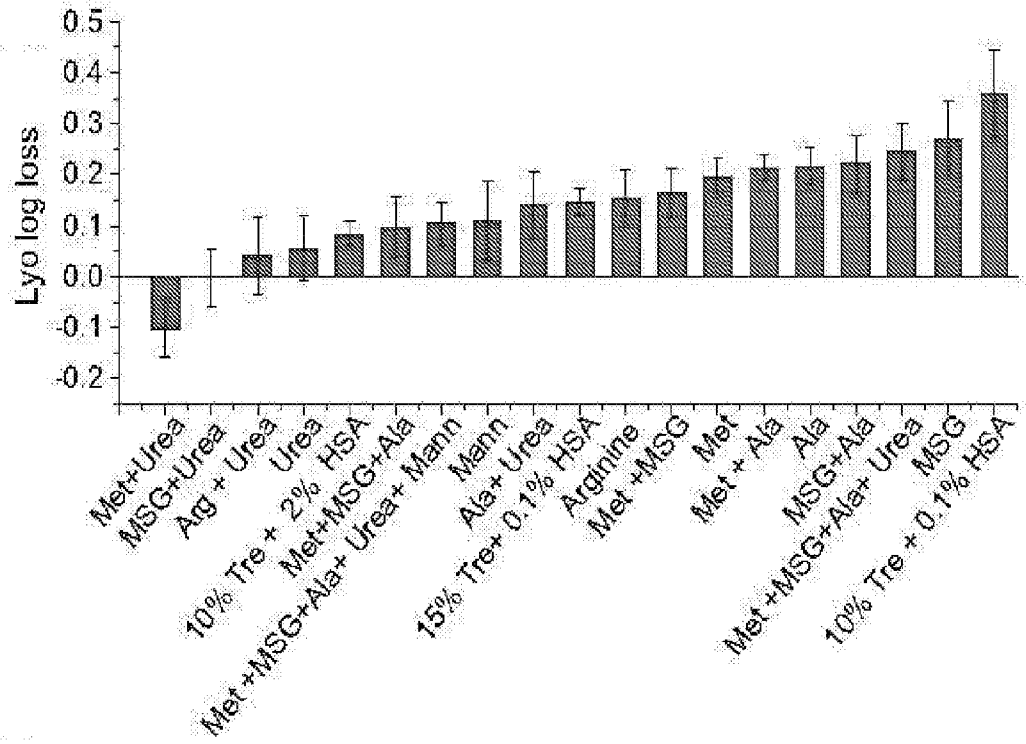


8B

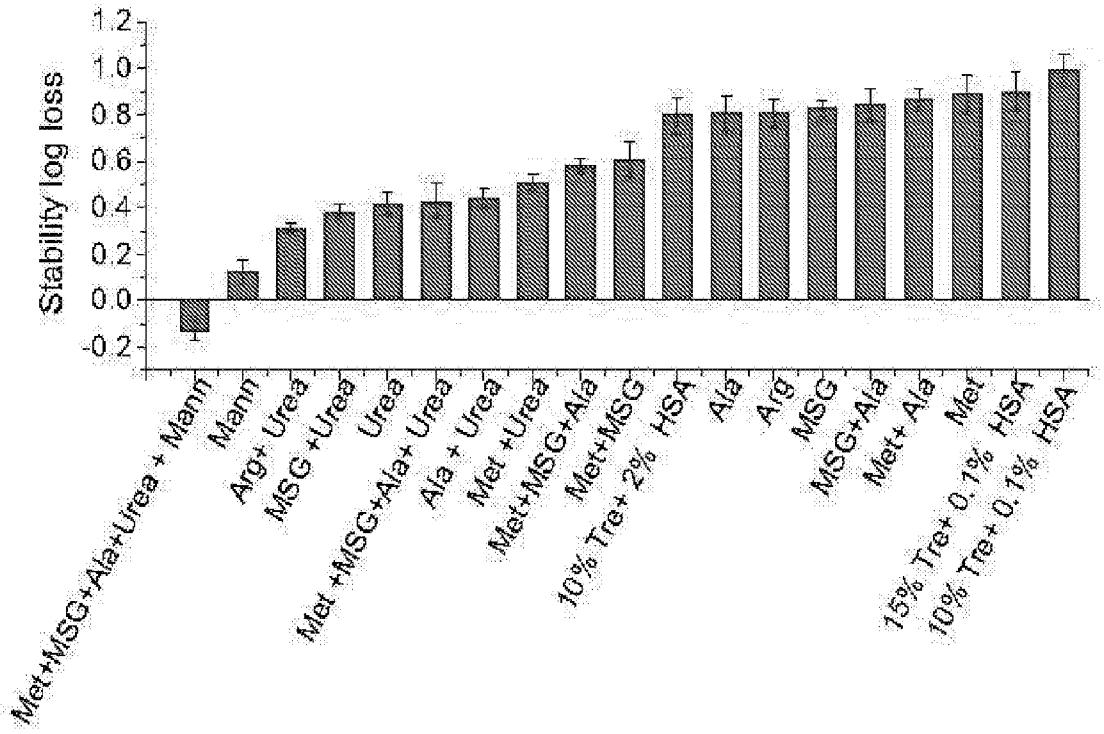


FIGS. 8A-8B

9A

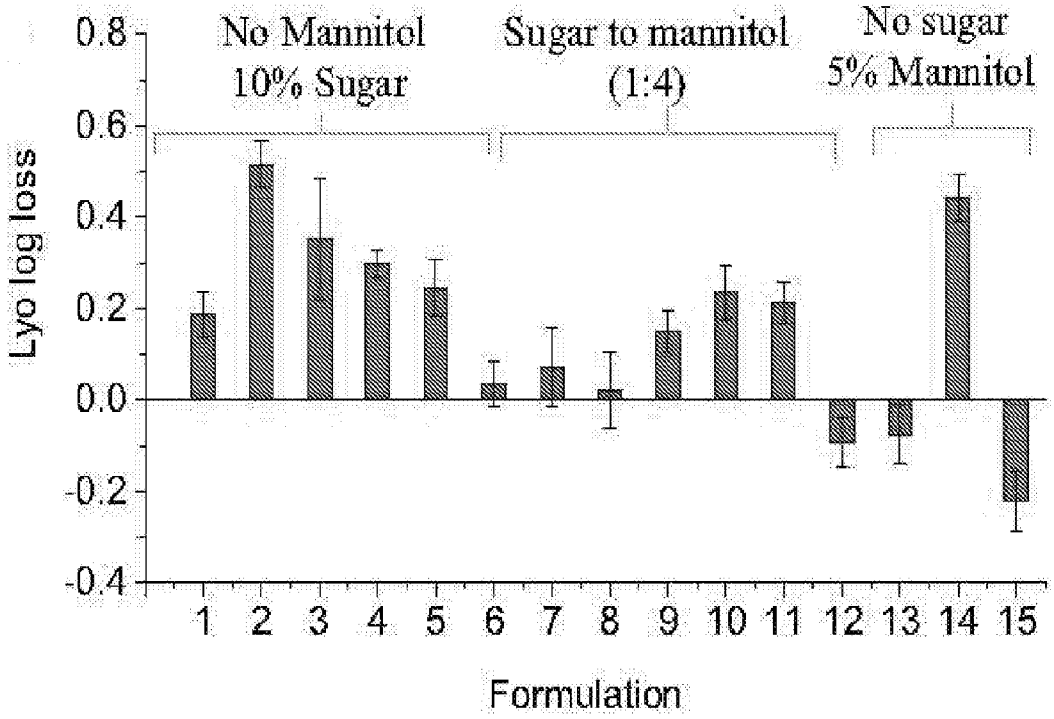


9B

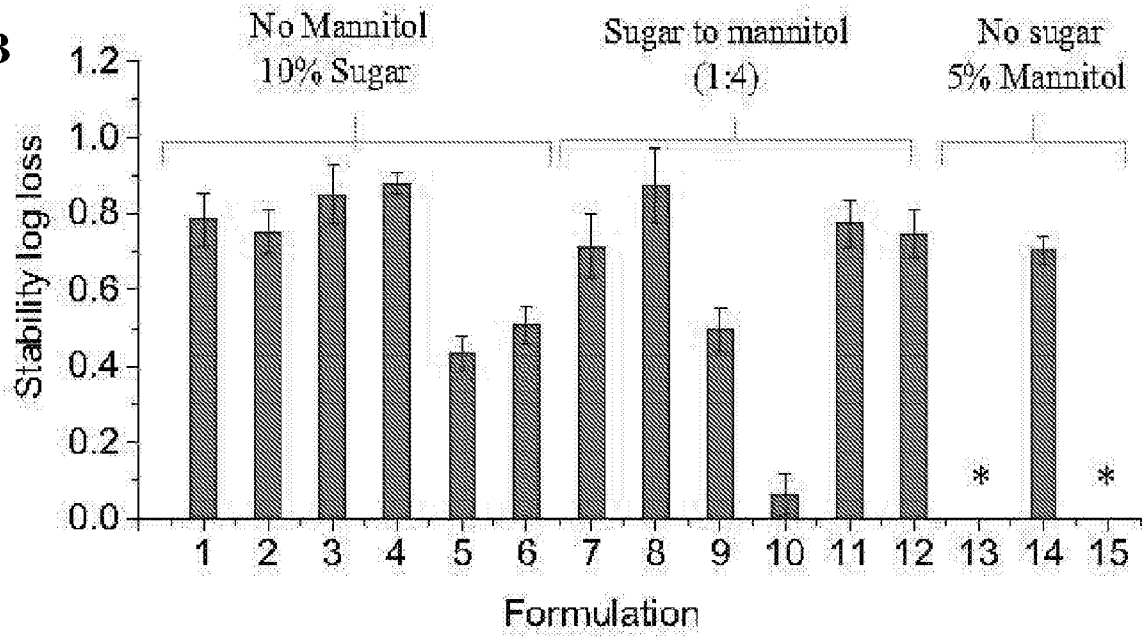


FIGS. 9A-9B

10A



10B



FIGS. 10A-10B

11A

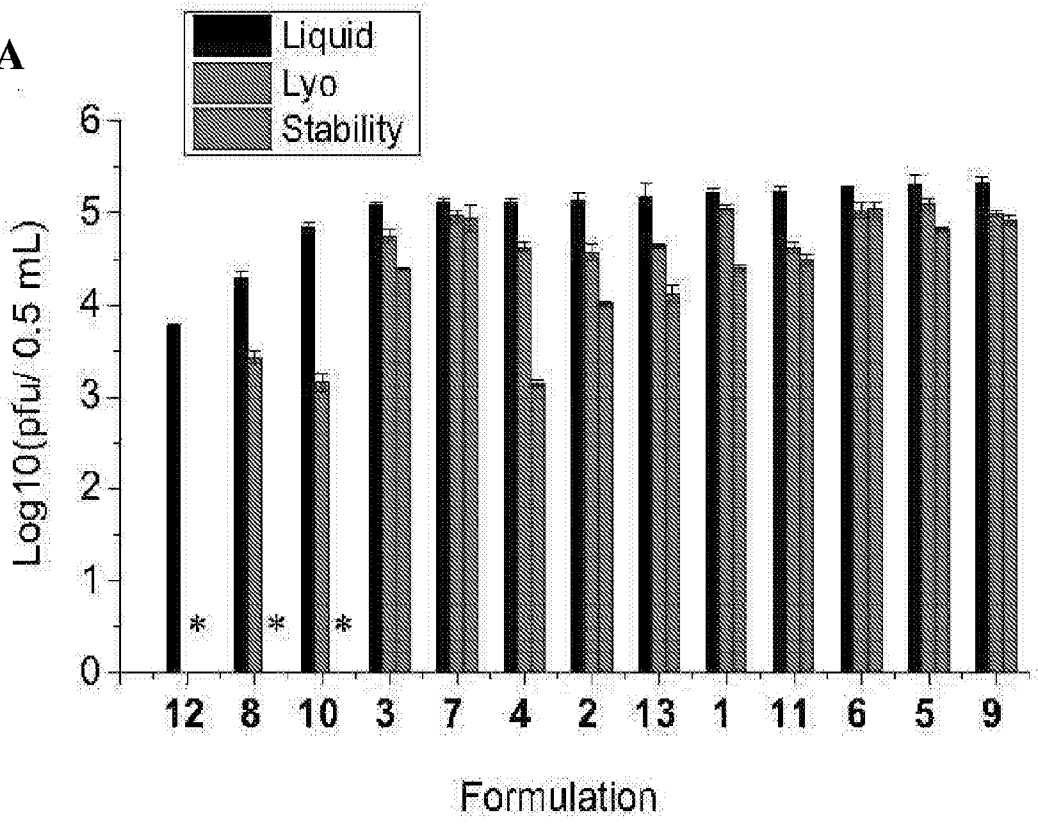
Term	Std Error	t Ratio	Prob>|t|
(HSA (%)-0.18986)*(HSA (%)-0.18986)	0.204587	-4.18	0.0001*
HSA (%)	0.342905	4.13	0.0001*
Urea (%)	0.136339	-3.59	0.0007*
Sucrose %	0.008072	-3.47	0.0010*
Mannitol (%)	0.07305	-2.86	0.0058*
(Mannitol (%)-0.85507)*(Mannitol (%)-0.85507)	0.022518	2.80	0.0069*
Trehalose %	0.00811	-2.56	0.0133*
Met (mM)	0.015594	-1.15	0.2546
Ala (mM)	0.003898	0.48	0.6298
MSG (mM)	0.003854	0.25	0.8004

11B

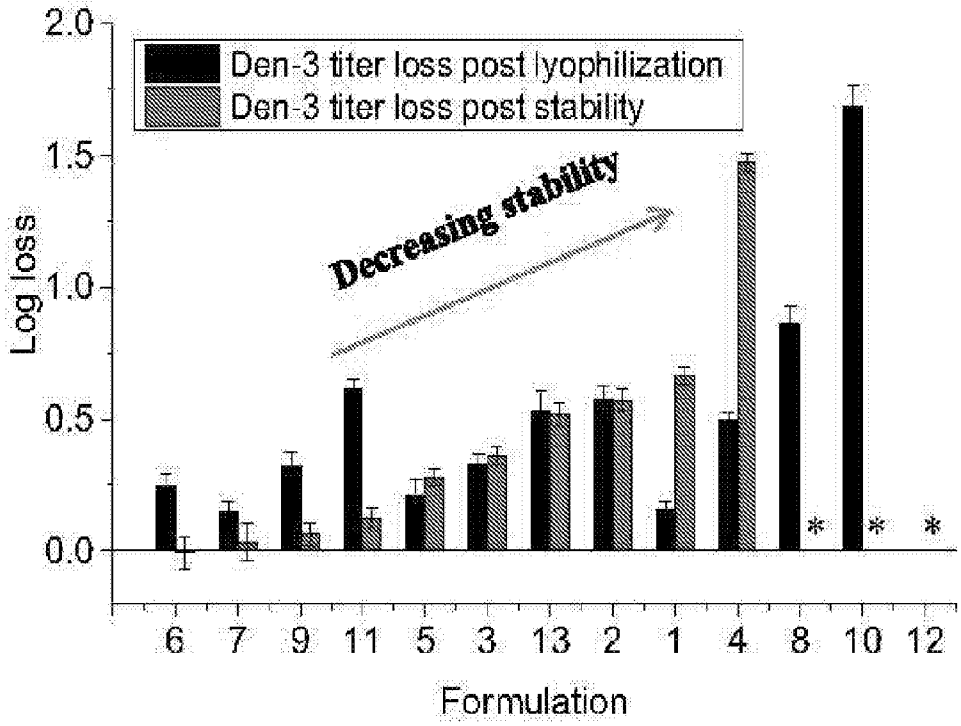
Term	Std Error	t Ratio	Prob>|t|
Urea (%)	0.165159	-7.11	<.0001*
Mannitol (%)	0.01342	-5.49	<.0001*
(Trehalose %-4.81818)*(Urea (%)-0.07576)	0.06008	-3.92	0.0003*
(Trehalose %-4.81818)*(Mannitol (%)-0.81818)	0.003985	-2.95	0.0047*
(Sucrose %-4.51515)*(Urea (%)-0.07576)	0.060134	-2.85	0.0062*
HSA (%)	0.438094	2.23	0.0301*
(HSA (%)-0.19848)*(HSA (%)-0.19848)	0.263223	-2.13	0.0382*
Sucrose %	0.011029	-1.94	0.0584
(Sucrose %-4.51515)*(Mannitol (%)-0.81818)	0.004138	-1.80	0.0780
Ala (mM)	0.004622	-1.05	0.2971
Trehalose %	0.011031	-1.00	0.3208
Met (mM)	0.018489	-0.59	0.5555
MSG (mM)	0.004657	-0.33	0.7418

FIGS. 11A-11B

12A



12B



FIGS. 12A-12B

12C

Log10 Lyo Drop Model Summary of fit: R^2=0.79

Term	Std Error	t Ratio	Prob>|t|
HSA (%)(0,0.3)	0.18675	-3.04	0.0189*
Mannitol (%)*Urea	0.218268	2.75	0.0285*
Mannitol (%)*HSA (%)	0.215885	2.62	0.0342*
Urea(0,0.25)	0.189131	-2.22	0.0615
Mannitol (%)(1,5)	0.189131	-1.28	0.2428

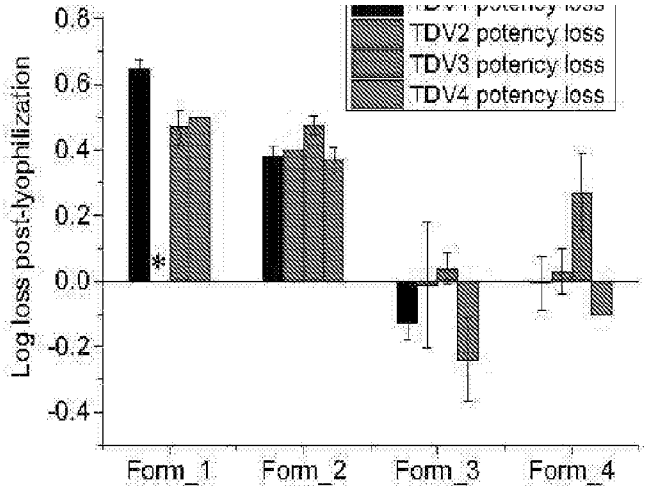
Log10 drop 5 weeks at 25°C Model Summary of fit R^2=0.89

Term	Std Error	t Ratio	Prob>|t|
Trehalose %(1,10)	0.15198	-4.51	0.0020*
Trehalose %*HSA (%)	0.167607	4.08	0.0035*
HSA (%)(0,0.3)	0.149696	-3.63	0.0067*
Trehalose %*Trehalose %	0.315586	3.31	0.0106*

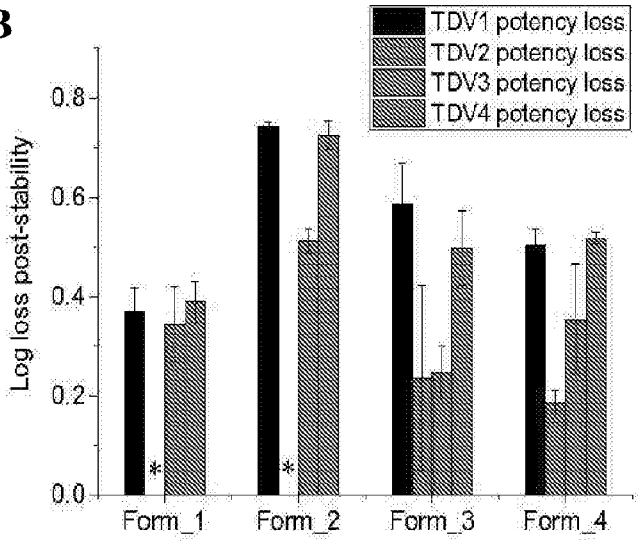
Log10 Total Loss Model Summary of fit R^2=0.99

Term	Std Error	t Ratio	Prob>|t|
HSA (%)(0,0.3)	0.087618	-13.22	<.0001*
Trehalose %(1,10)	0.087923	-10.21	<.0001*
HSA (%)*HSA (%)	0.210133	6.46	0.0007*
Trehalose %*HSA (%)	0.109792	5.88	0.0011*
Urea(0,0.25)	0.087923	-3.82	0.0087*
Urea*Urea	0.207974	3.32	0.0160*

FIG. 12C



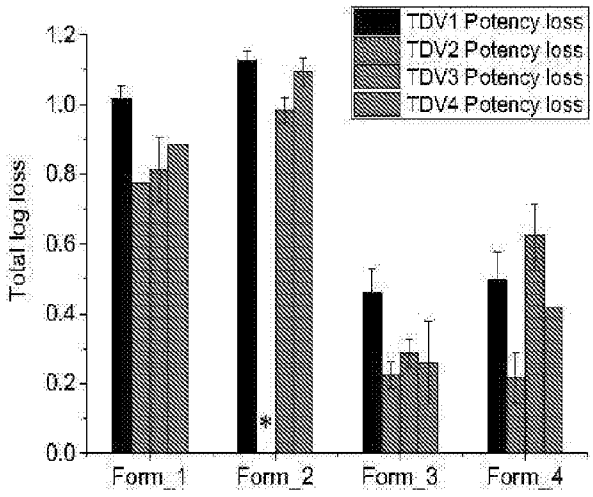
13B



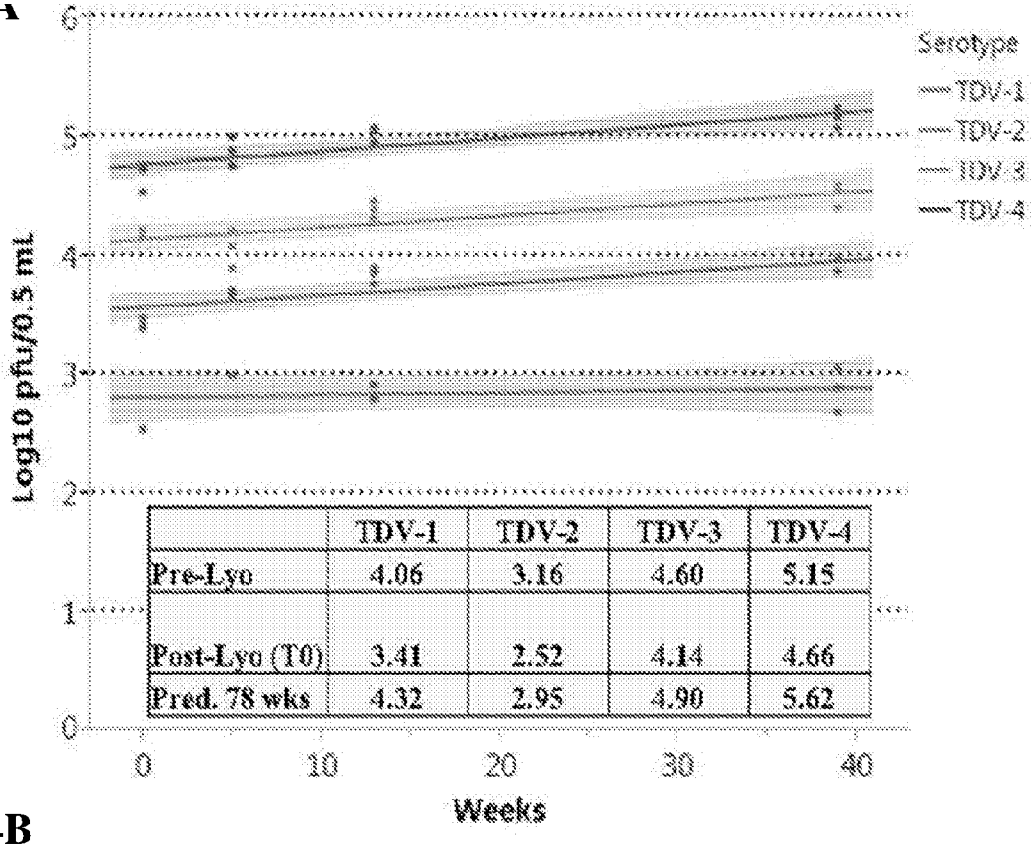
13C

FIGS. 13A-13C

(d)

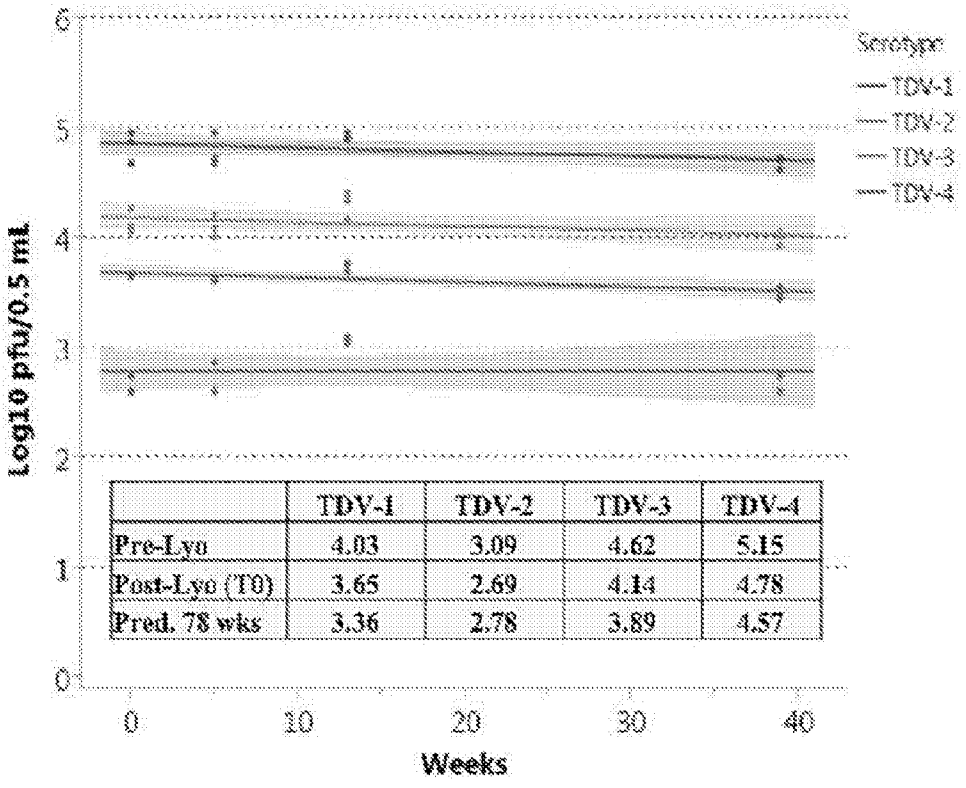


14A



	TDV-1	TDV-2	TDV-3	TDV-4
Pre-Lyo	4.06	3.16	4.60	5.15
Post-Lyo (T0)	3.41	2.52	4.14	4.66
Pred. 78 wks	4.32	2.95	4.90	5.62

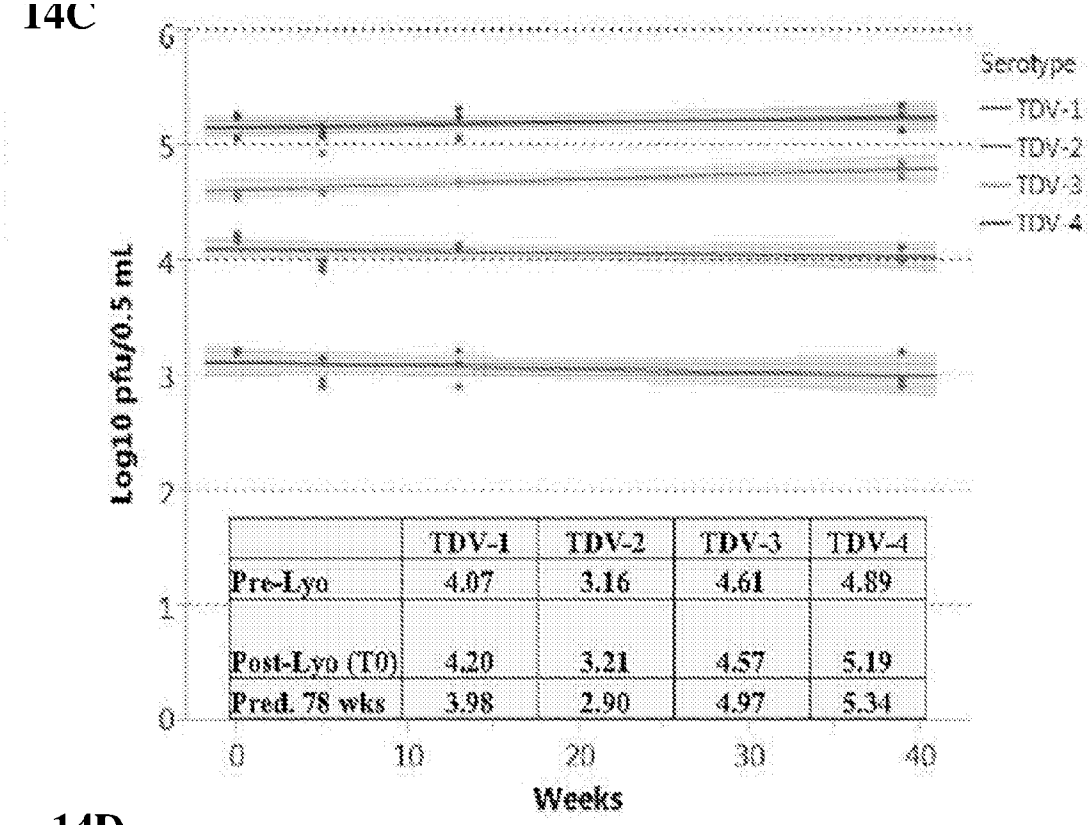
14B



	TDV-1	TDV-2	TDV-3	TDV-4
Pre-Lyo	4.03	3.09	4.62	5.15
Post-Lyo (T0)	3.65	2.69	4.14	4.78
Pred. 78 wks	3.36	2.78	3.89	4.57

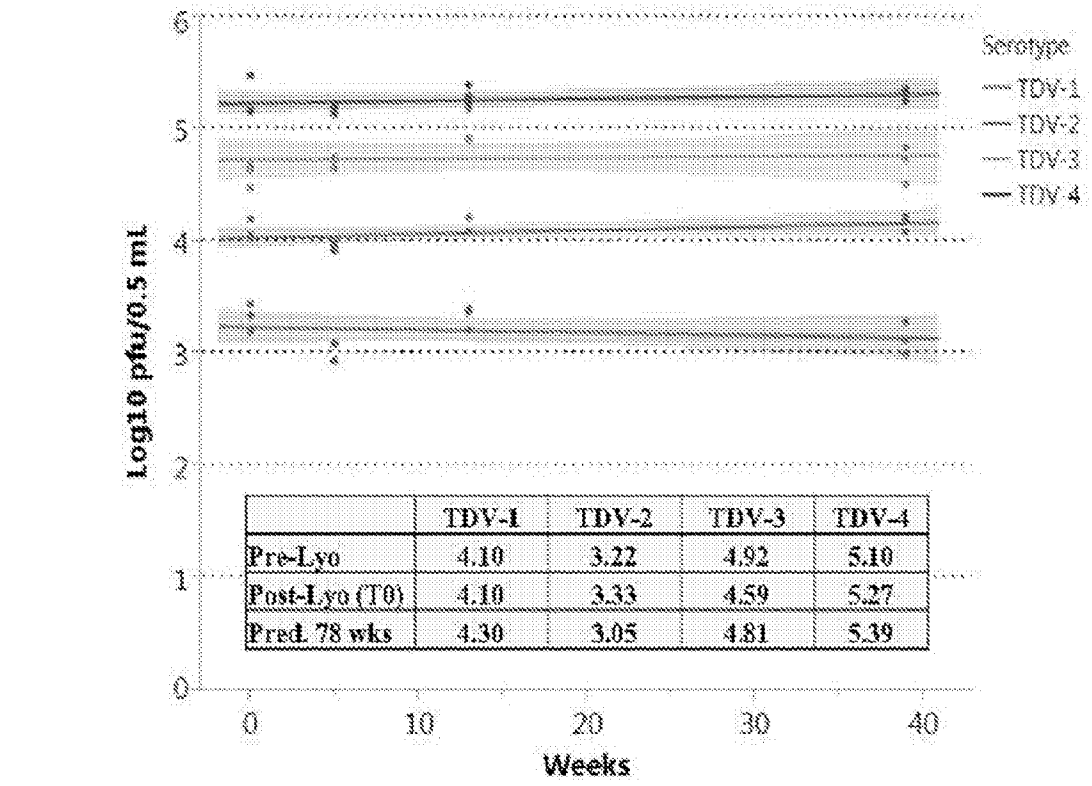
FIGS. 14A-14B

14C



	TDV-1	TDV-2	TDV-3	TDV-4
Pre-Lyo	4.07	3.16	4.61	4.89
Post-Lyo (T0)	4.20	3.21	4.57	5.19
Pred. 78 wks	3.98	2.90	4.97	5.34

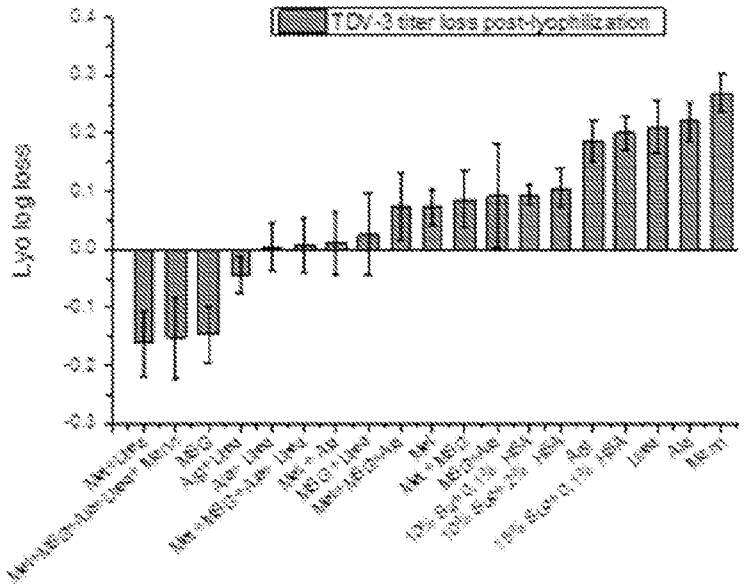
14D



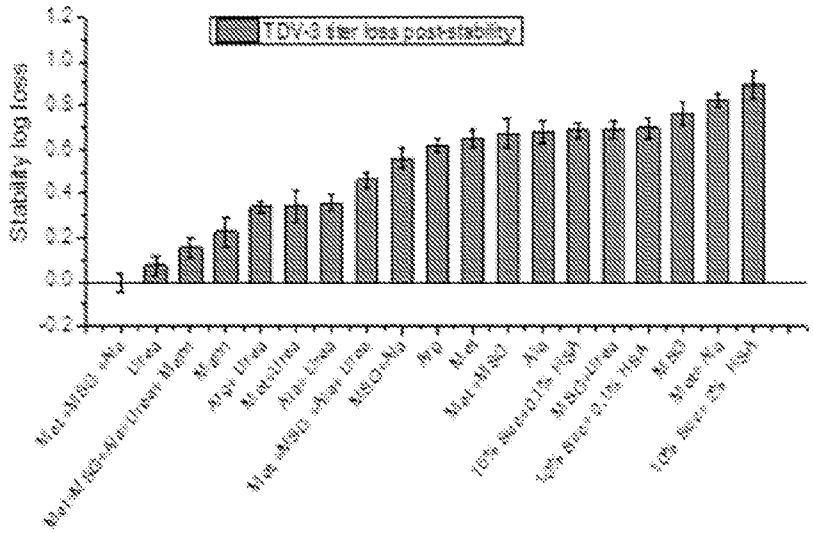
	TDV-1	TDV-2	TDV-3	TDV-4
Pre-Lyo	4.10	3.22	4.92	5.10
Post-Lyo (T0)	4.10	3.33	4.59	5.27
Pred. 78 wks	4.30	3.05	4.81	5.39

FIGS. 14C-14D

15A



15B



FIGS. 15A-15B