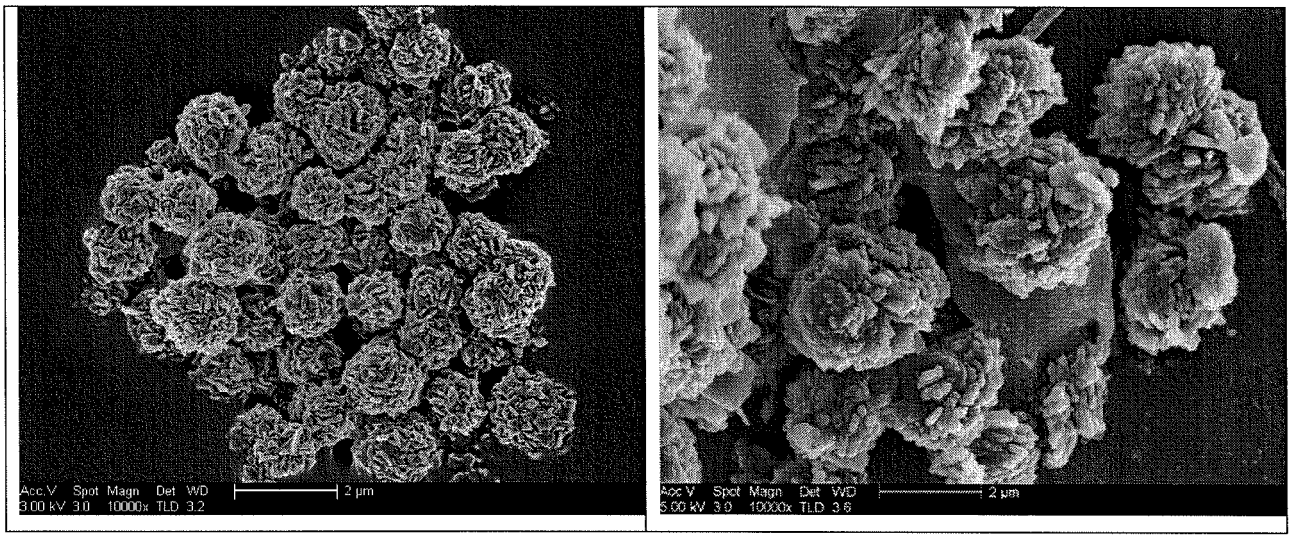


FIG. 1A FIG. 1B

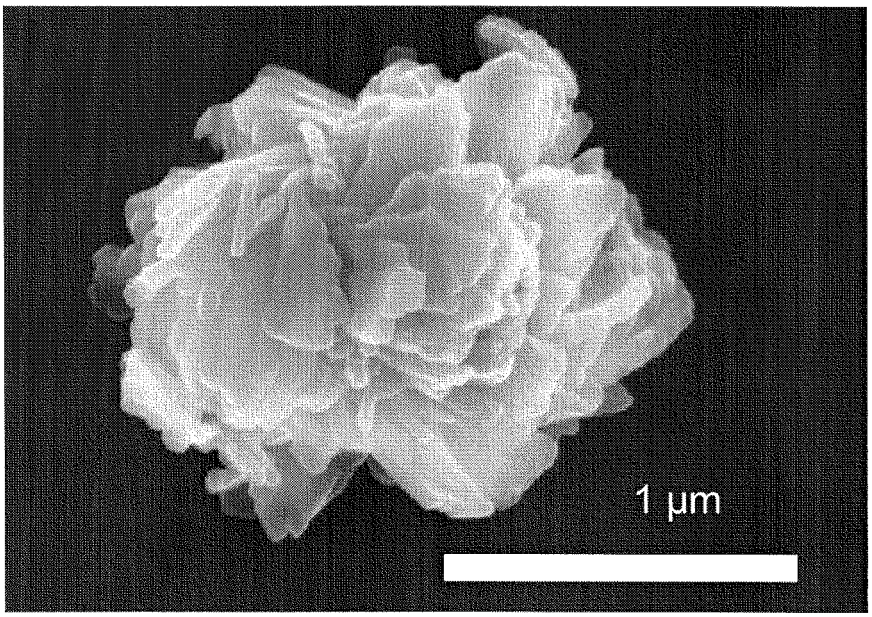
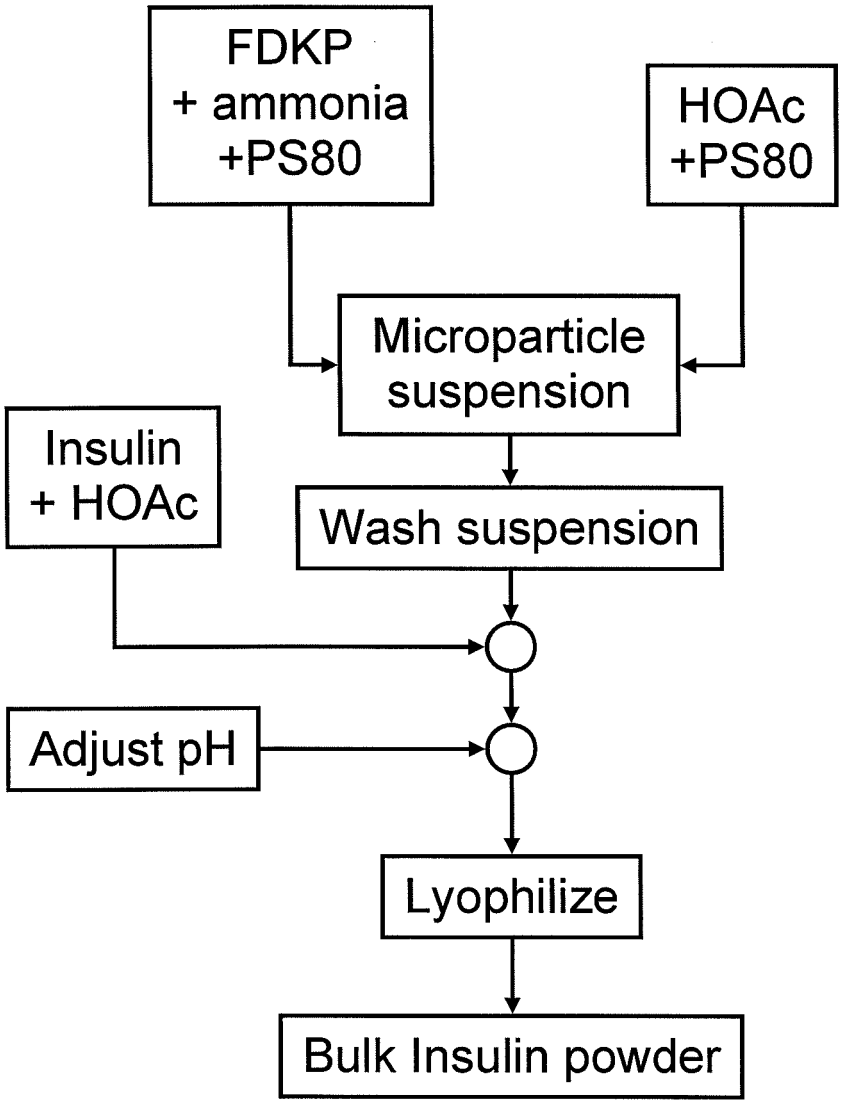
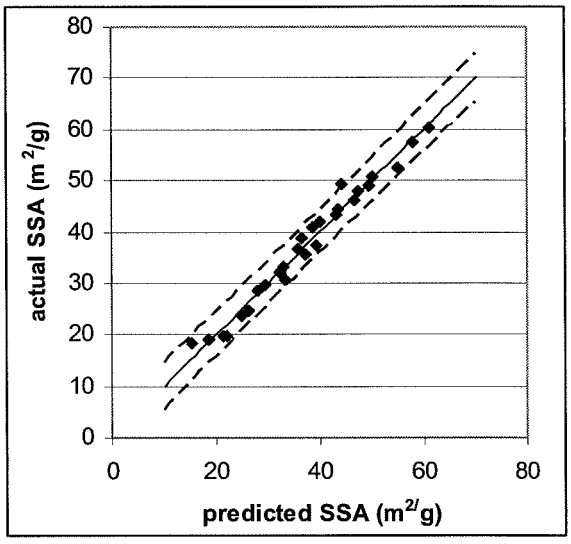


FIG. 2

FIG. 3


FDKP
+ ammonia
+PS80
HOAc
+PS80
Microparticle
suspension
Insulin
+ HOAc
Wash suspension
Adjust pH
Lyophilize
Bulk Insulin powder

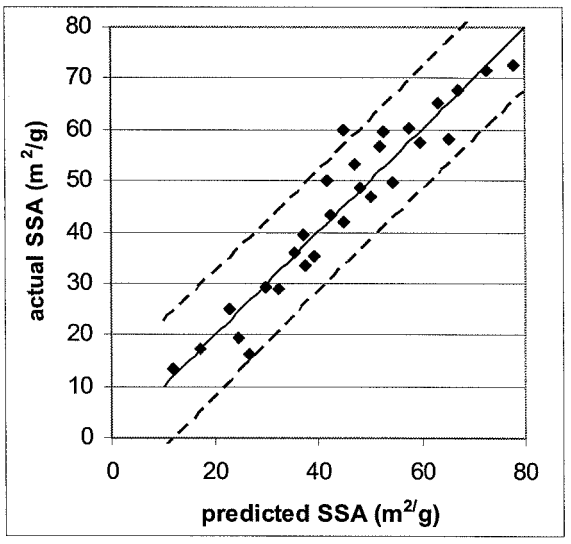


Regression equation (significant terms only):
$Y = 35.79 + 1.79A - 2.16B + 0.59C + 0.10A^2$

A: ΔFDKP (%)
B: ΔNH_4OH (%)
C: ΔHOAc (%)

Standard error of prediction: ±2.0 m^2/g

FIG. 4A



Regression equation (significant terms only):
$Y = 44.86 + 1.49A - 1.28B + 0.55C$

A: ΔFDKP (%)
B: ΔNH_4OH (%)
C: ΔHOAc (%)

Standard error of prediction: ±5.6 m^2/g

FIG. 4B

FIG. 5A

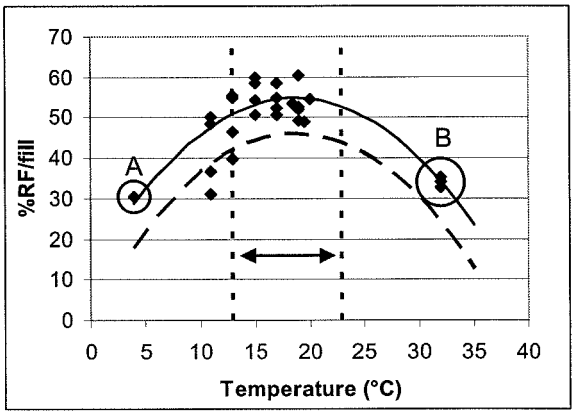


FIG. 5B

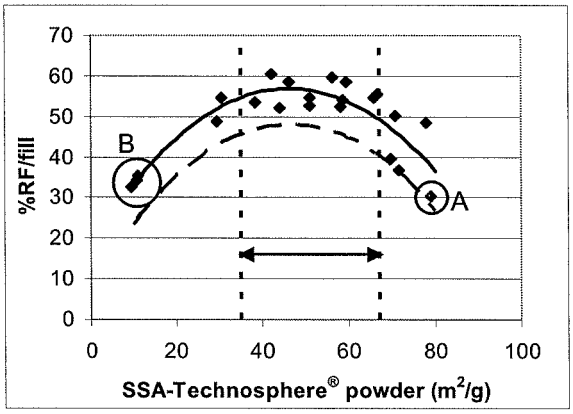
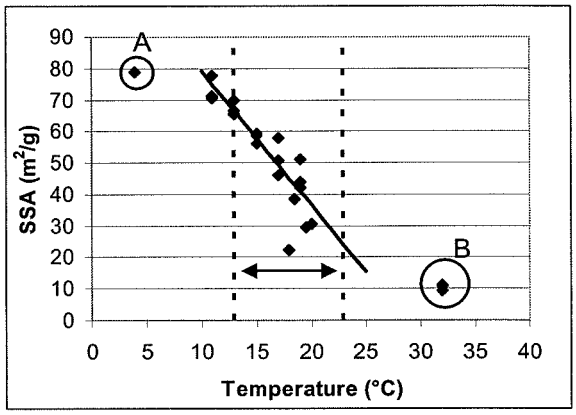


FIG. 5C



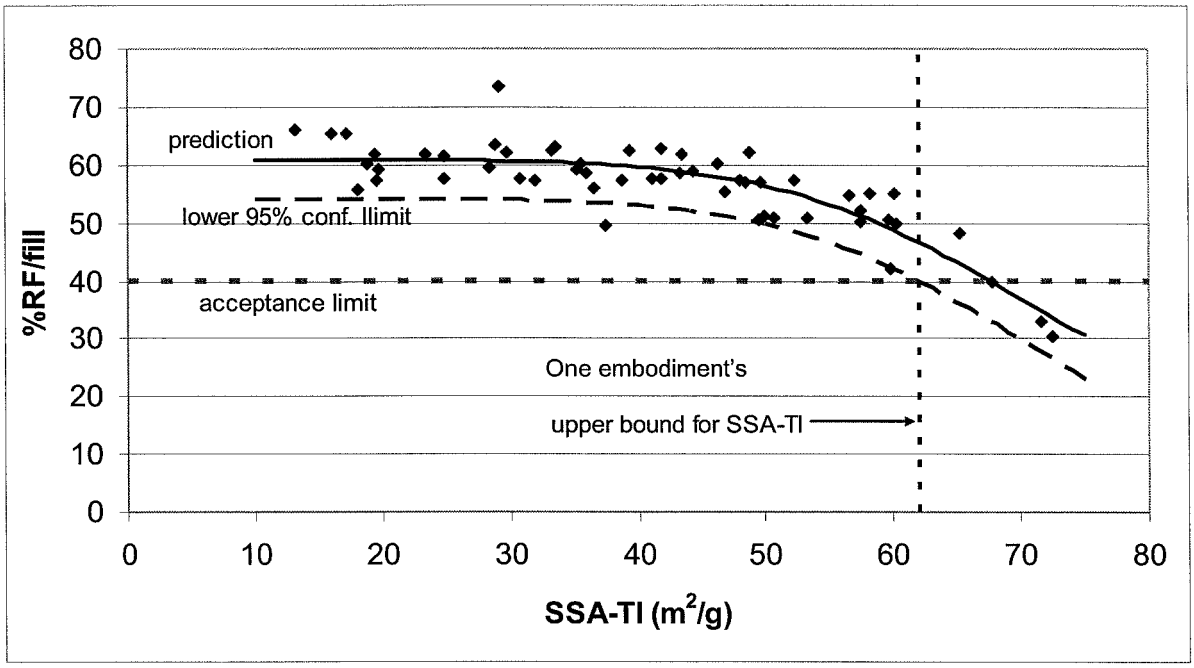

80
70
60
50
40
30
20
10
0
%RF/fill
prediction
lower 95% conf. llimit
acceptance limit
One embodiment's
upper bound for SSA-TI
0
10
20
30
40
50
60
70
80
SSA-TI (m²/g)

FIG. 6A

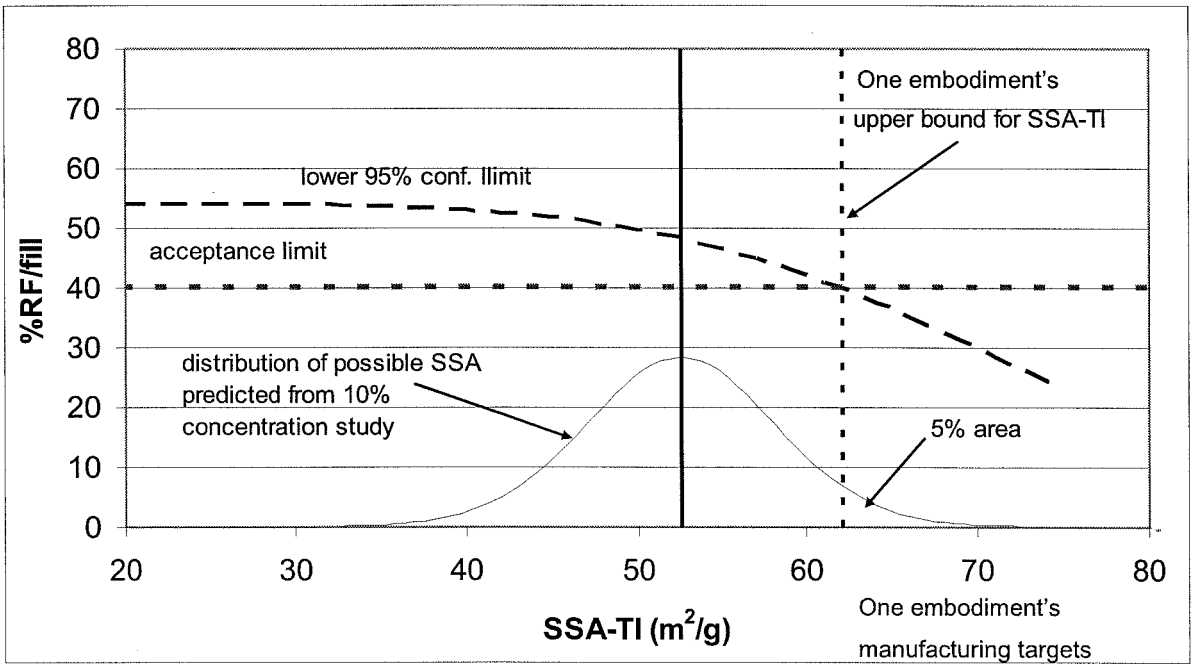

80
70
60
50
40
30
20
10
0
%RF/fill
One embodiment's
upper bound for SSA-TI
lower 95% conf. llimit
acceptance limit
distribution of possible SSA
predicted from 10%
concentration study
5% area
20
30
40
50
60
70
80
SSA-TI (m²/g)
One embodiment's
manufacturing targets

FIG. 6B

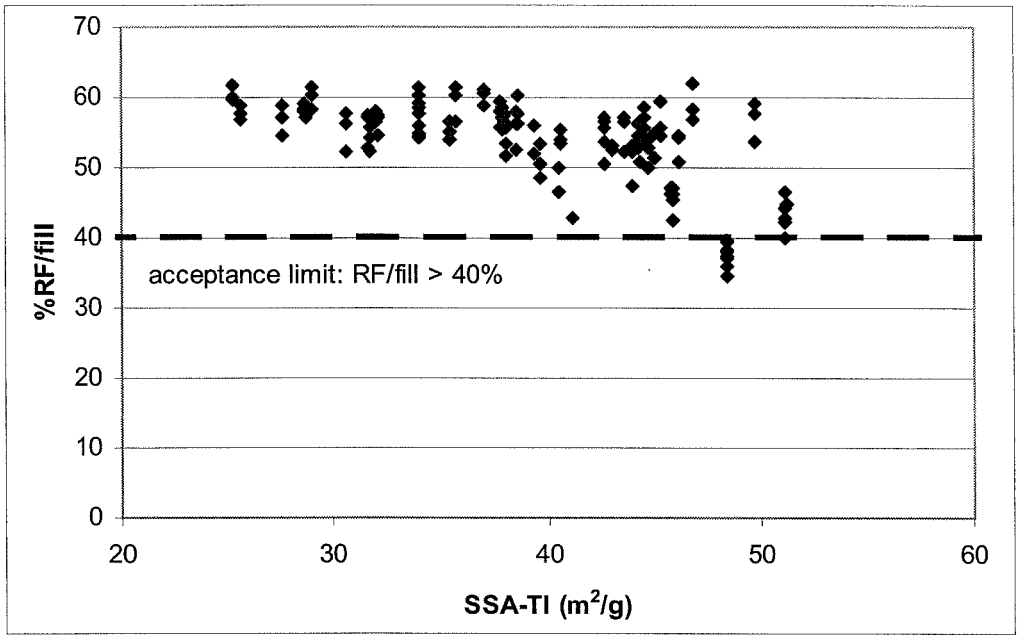


FIG. 7

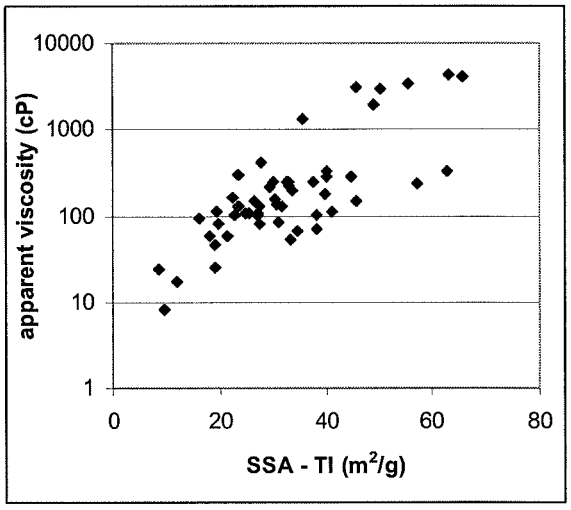


FIG. 8A

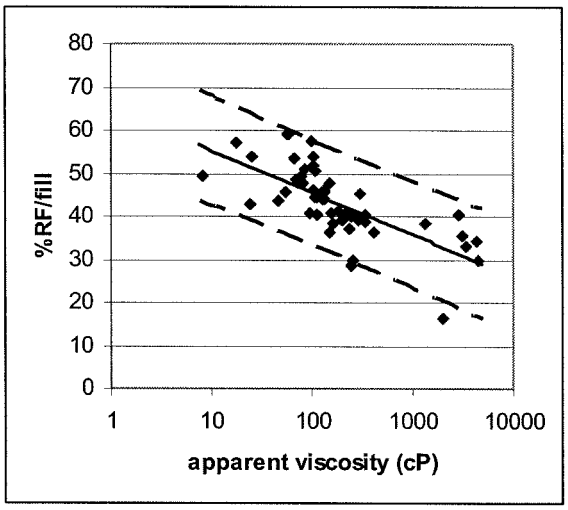


FIG. 8B

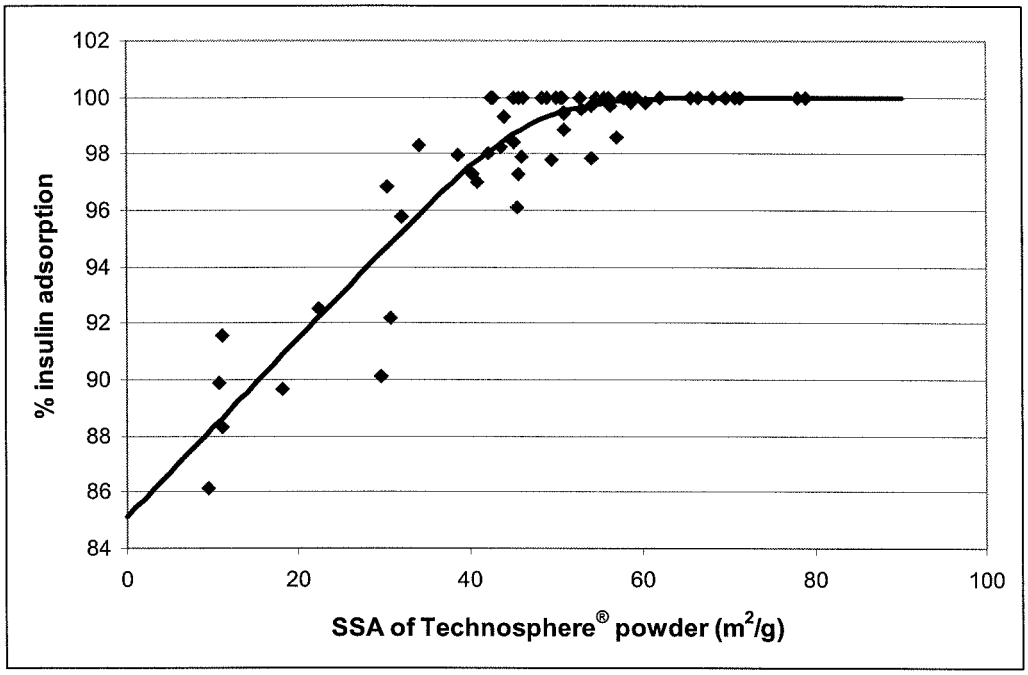

% insulin adsorption
102
100
98
96
94
92
90
88
86
84
0
20
40
60
80
100
SSA of Technosphere® powder (m²/g)

FIG. 9