

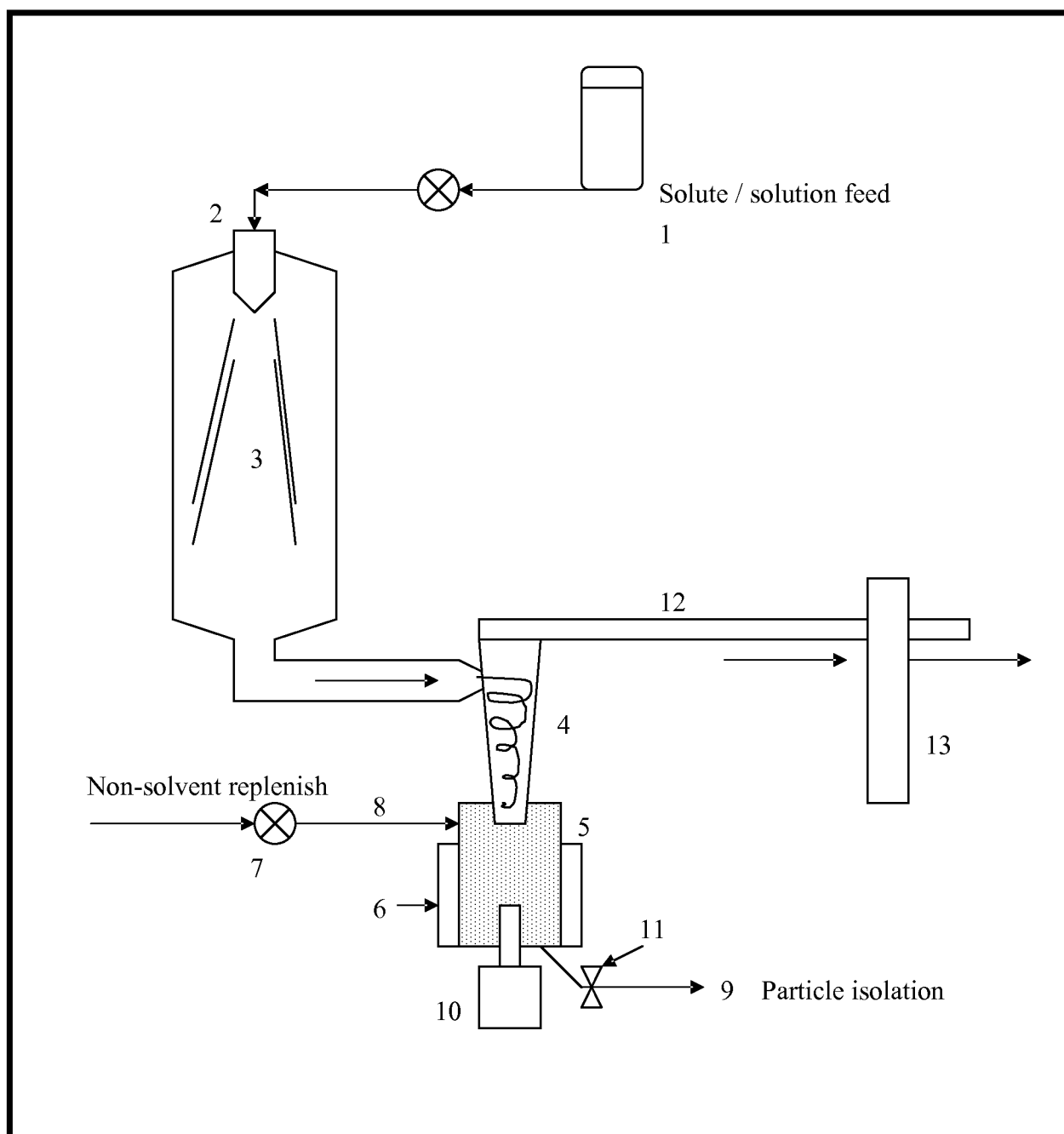


Fig. 1

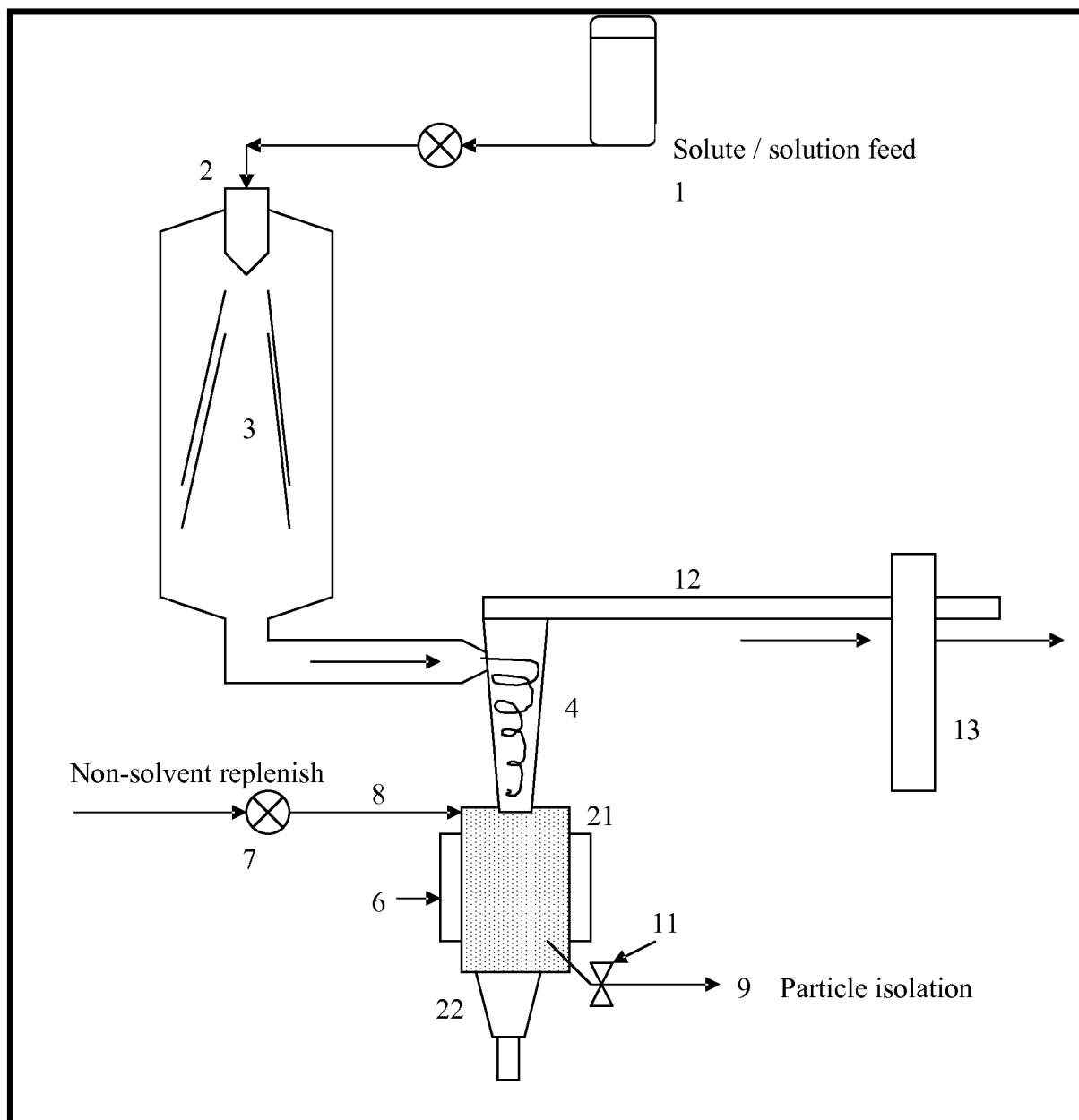


Fig. 2

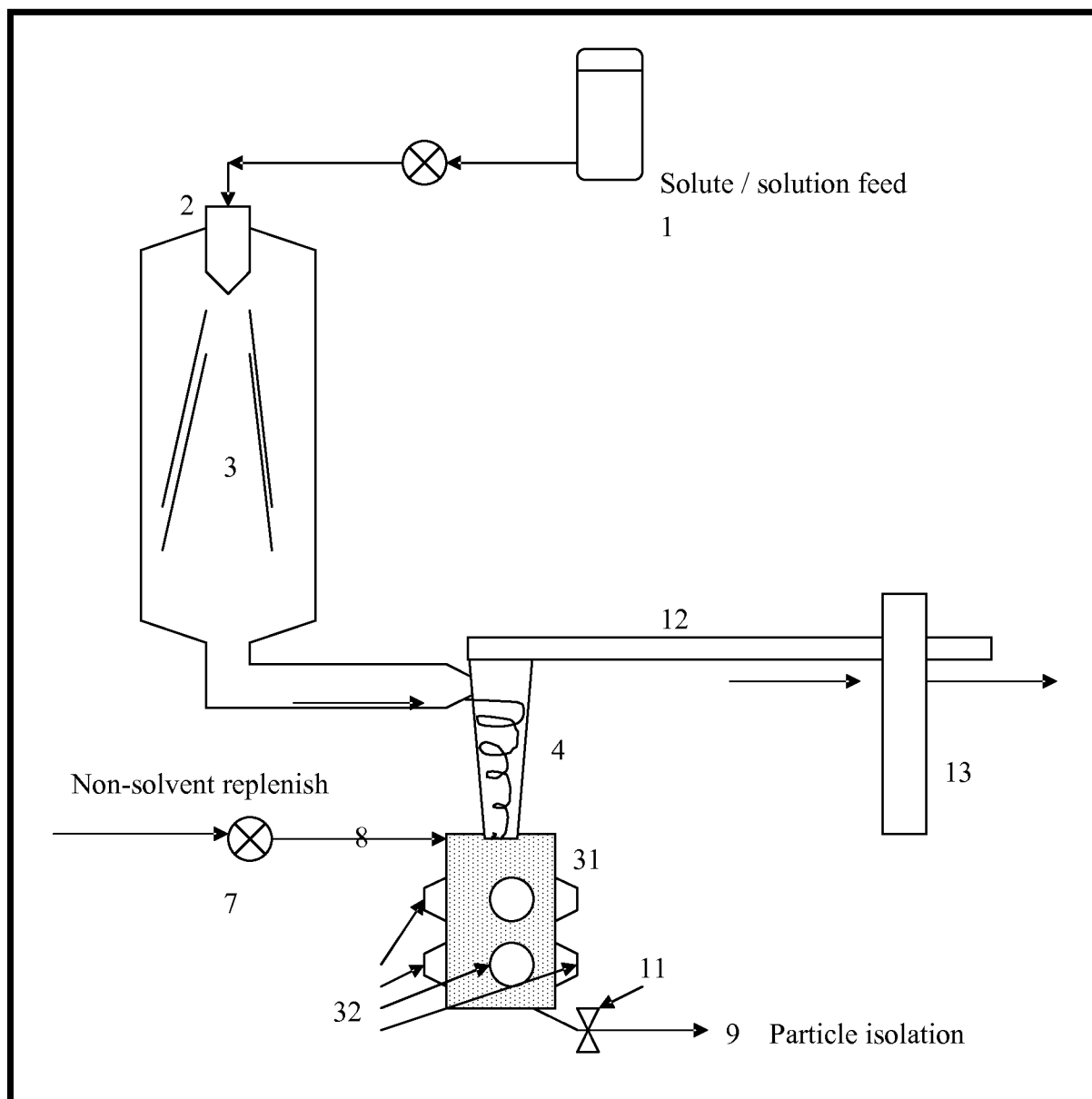


Fig. 3

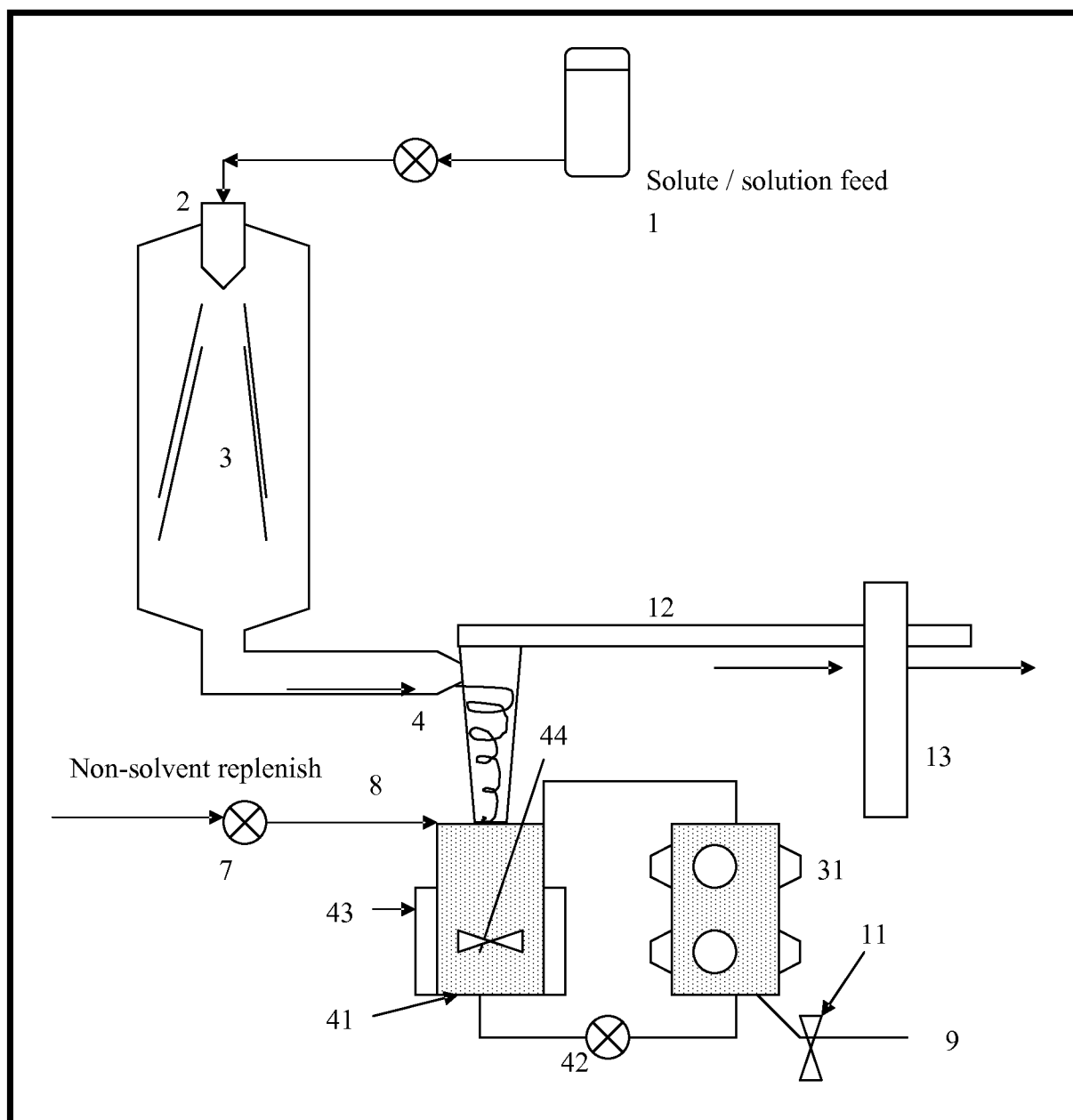


Fig. 4

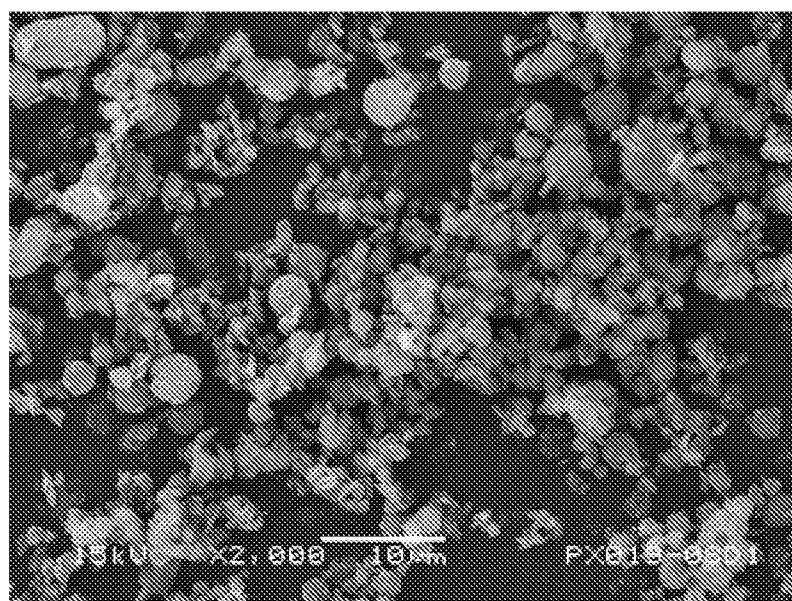


Fig. 5

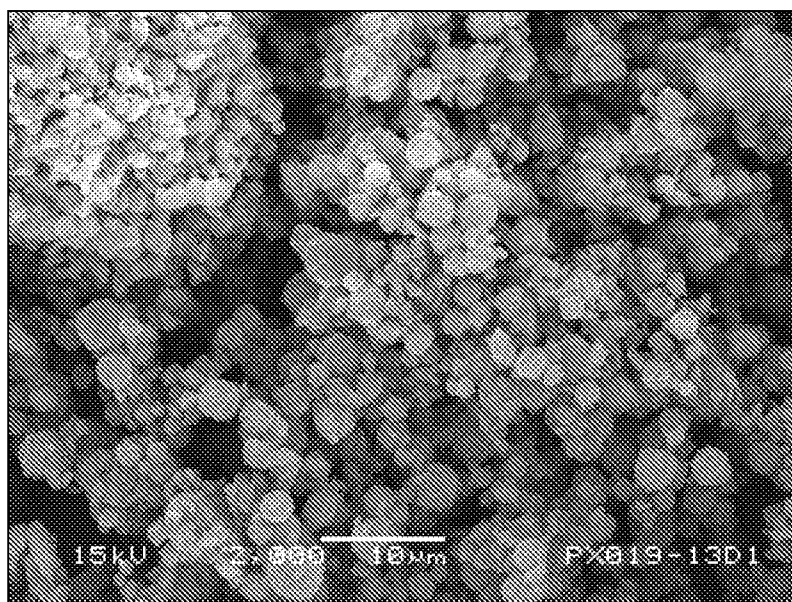


Fig. 6

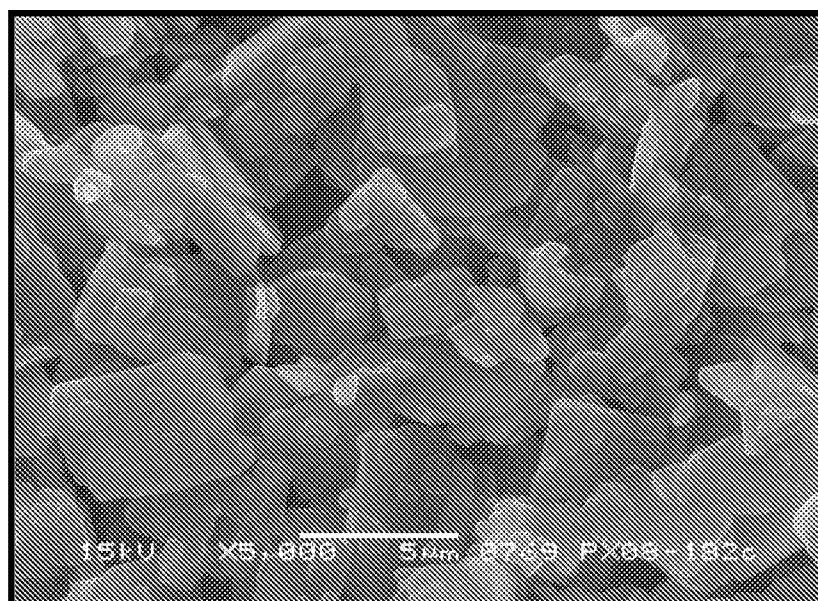


Fig. 7

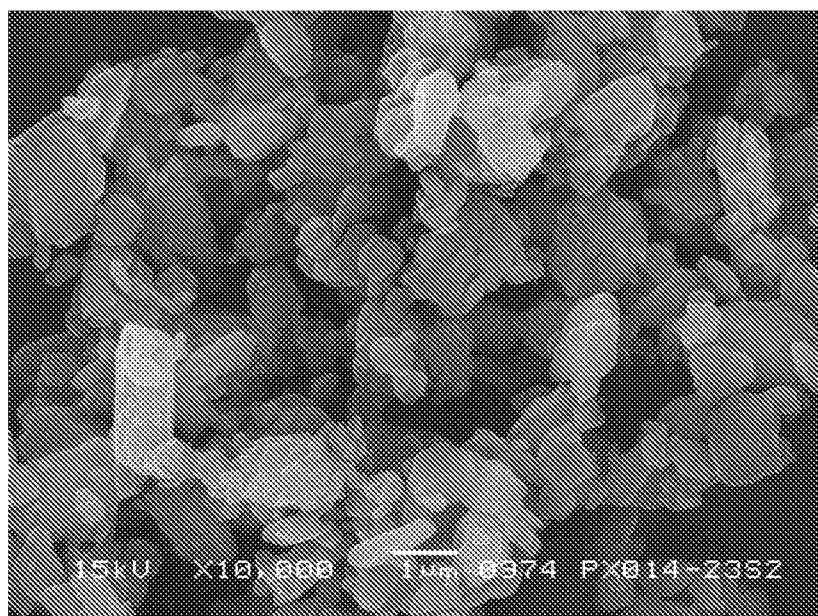


Fig. 8

Results: Aerosolization Efficiency				
	% Emitted Fraction ($\pm$ S.D.)	Fine Particle Dose ($\pm$ μ g)	FPF _{LD} ($\pm$ %)	MMAD ($\pm$ GSD)
Micronized	85.6 (4.2)	4.9 (0.9)	9.7 (0.7)	4.87 $\pm$ 1.97
Sample 2	93.7 (3.8)	7.5 (0.2)	14.9 (0.6)	4.48 $\pm$ 1.90
Sample 3	89.7 (3.7)	7.8 (0.4)	15.6 (0.5)	3.73 $\pm$ 2.17
Sample 4	90.7 (4.2)	2.5 (0.3)	5.1 (0.7)	4.85 $\pm$ 2.08

Fig. 9

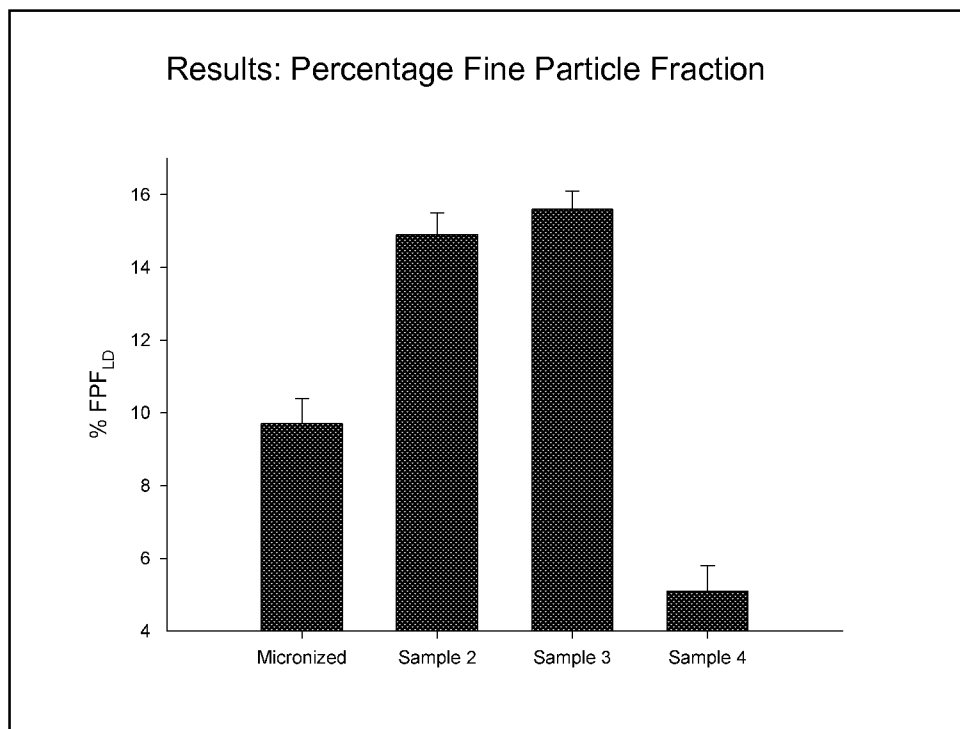


Fig. 10

Results: Aerosolization Efficiency Compared to Flixotide				
	% Emitted Fraction ($\pm$ S.D.)	Fine Particle Dose ($\pm$ μ g)	FPF _{LD} ($\pm$ %)	MMAD ($\pm$ GSD)
Flixotide	94.3 (3.4)	6.1 (0.2)	12.1 (0.2)	3.43 $\pm$ 2.13
Sample 2	93.7 (3.8)	7.5 (0.2)	14.9 (0.6)	4.48 $\pm$ 1.90
Sample 3	89.7 (3.7)	7.8 (0.4)	15.6 (0.5)	3.73 $\pm$ 2.17
Sample 4	90.7 (4.2)	2.5 (0.3)	5.1 (0.7)	4.85 $\pm$ 2.08

Fig. 11

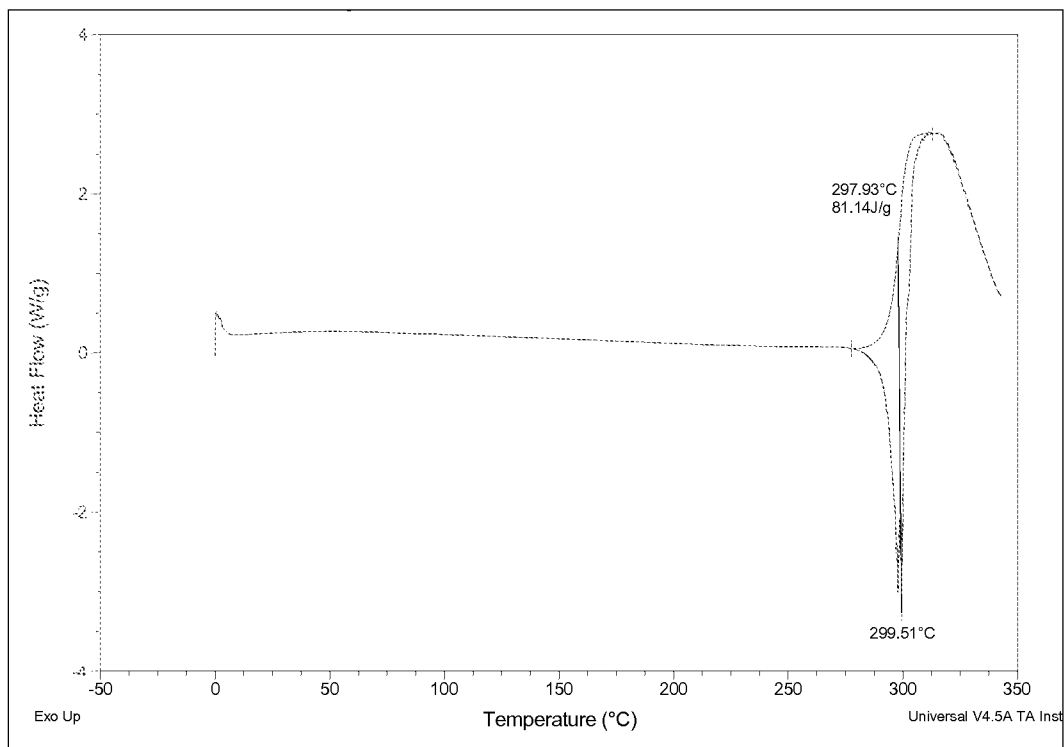


Fig. 12

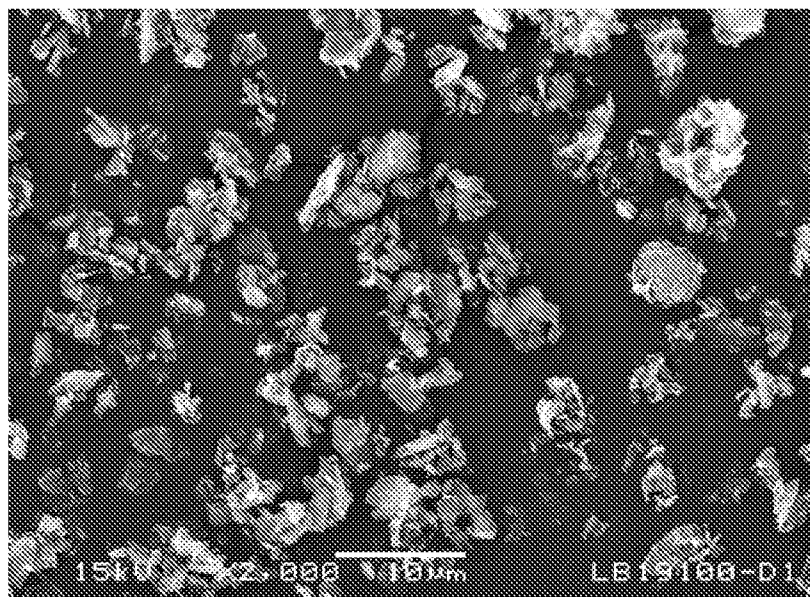


Fig. 13

Results: Aerosolization Efficiency – 3 Months

	FPD ($\pm$ μ g) t = 0	FPF _{LD} ($\pm$ %) t = 0	FPD ($\pm$ μ g) t = 1 m	FPF _{LD} ($\pm$ %) t = 1m	FPD ($\pm$ μ g) t = 3 m	FPF _{LD} ($\pm$ %) t = 3m
Micronized	4.9 (0.9)	9.7 (0.7)	2.5 (0.1)	5.0 (0.2)	1.6 (0.2)	3.2 (0.7)
Sample 2	7.5 (0.2)	14.9 (0.6)	6.9 (1.3)	13.8 (1.8)	5.4 (1.2)	10.7 (1.2)
Sample 3	7.8 (0.4)	15.6 (0.5)	7.3 (0.4)	14.6 (0.6)	7.6 (0.3)	15.2 (1.6)
Sample 4	2.5 (0.3)	5.1 (0.7)	1.8 (0.2)	3.6 (0.3)	1.9 (0.5)	3.9 (0.7)

Fig. 14

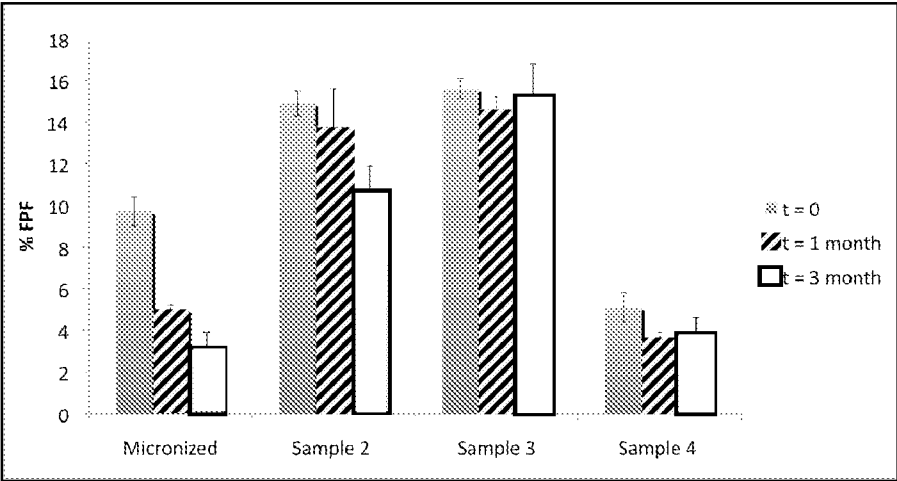


Fig. 15

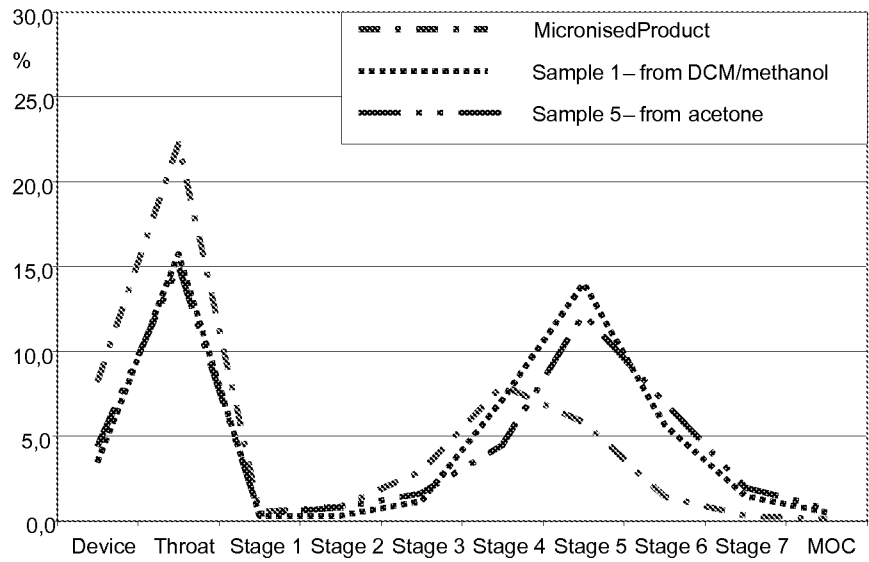


Fig. 16

Results: % Fine Particle Fraction of FP after 1 m storage

			T = 0		T = 1 month	
			FPF [%/LD]	SD	FPF [%/LD]	SD
FP	Cyclohaler	Micronized	13.9	1.2	15.4	0.2
		Sample_2	16.7	1.1	17.5	0.4
		Sample_3	18.9	0.8	17.2	0.8
		Sample_4	17.6	3.1	17.7	1.1
	Rotahaler	Micronized	14.4	2.0	14.4	0.9
		Sample_2	15.5	1.7	17.5	0.6
		Sample_3	18.5	1.1	19.0	0.9
		Sample_4	5.3	0.7	8.2	1.3

Fig. 17

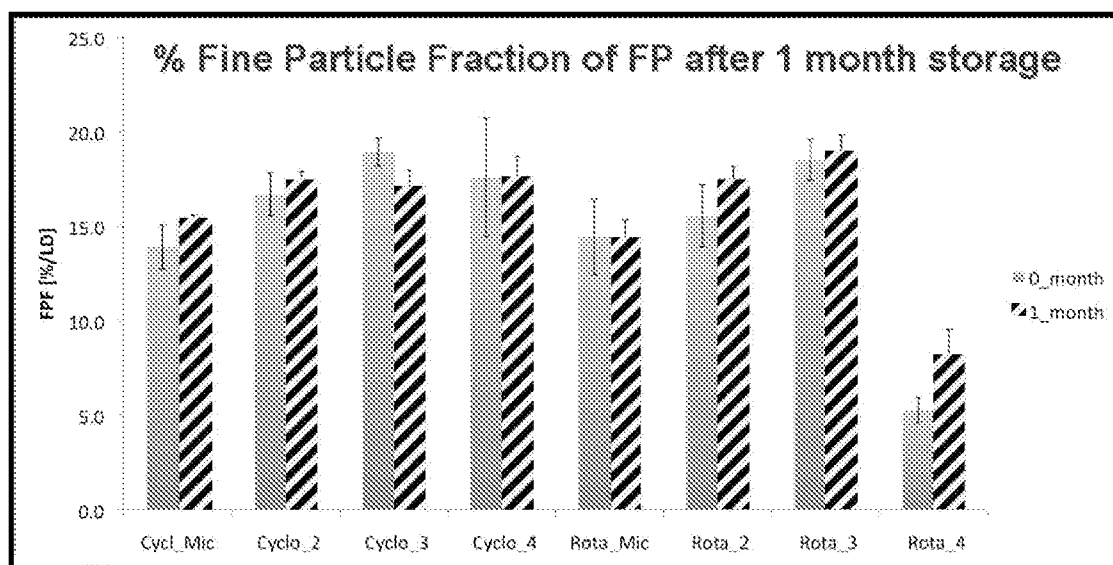


Fig. 18

12/14

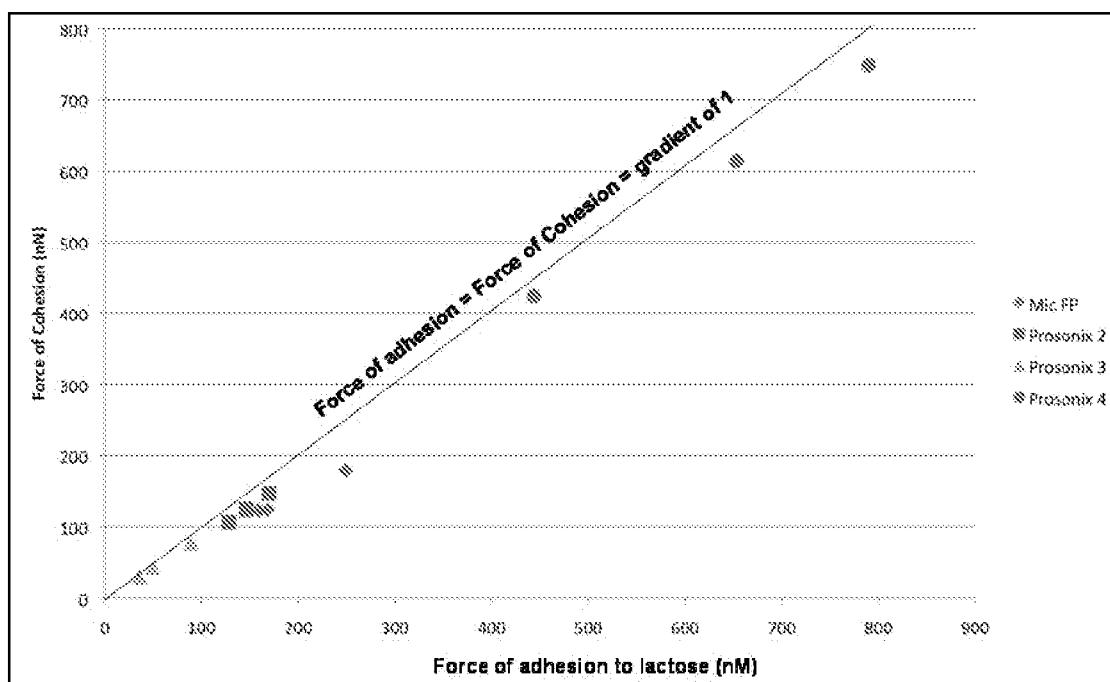


Fig. 19

Example 5: Content Uniformity for 500(FP)/25(SX)

The poor content uniformity of the micronized formulation resulted in the formulation not be fired.	% Relative Standard Deviation	
	Micronized	Prosonix 3
FP	8.76	3.43
	% Relative Standard Deviation	
	Micronized	Prosonix 3
SX	15.95	4.55

Example 5: % Fine Particle Fraction of FP and SX for 500(FP)/25(SX)

	Fine Particle Dose ($\mu\text{g} \pm \text{S.D.}$)	Fine Particle Fraction of loaded dose (% $\pm$ S.D.)
FP	79.1 (2.6)	15.8 (0.8)
	Fine Particle Dose ($\mu\text{g} \pm \text{S.D.}$)	Fine Particle Fraction of loaded dose (% $\pm$ S.D.)
SX	11.0 (1.0)	44.0 (2.6)

Fig. 20

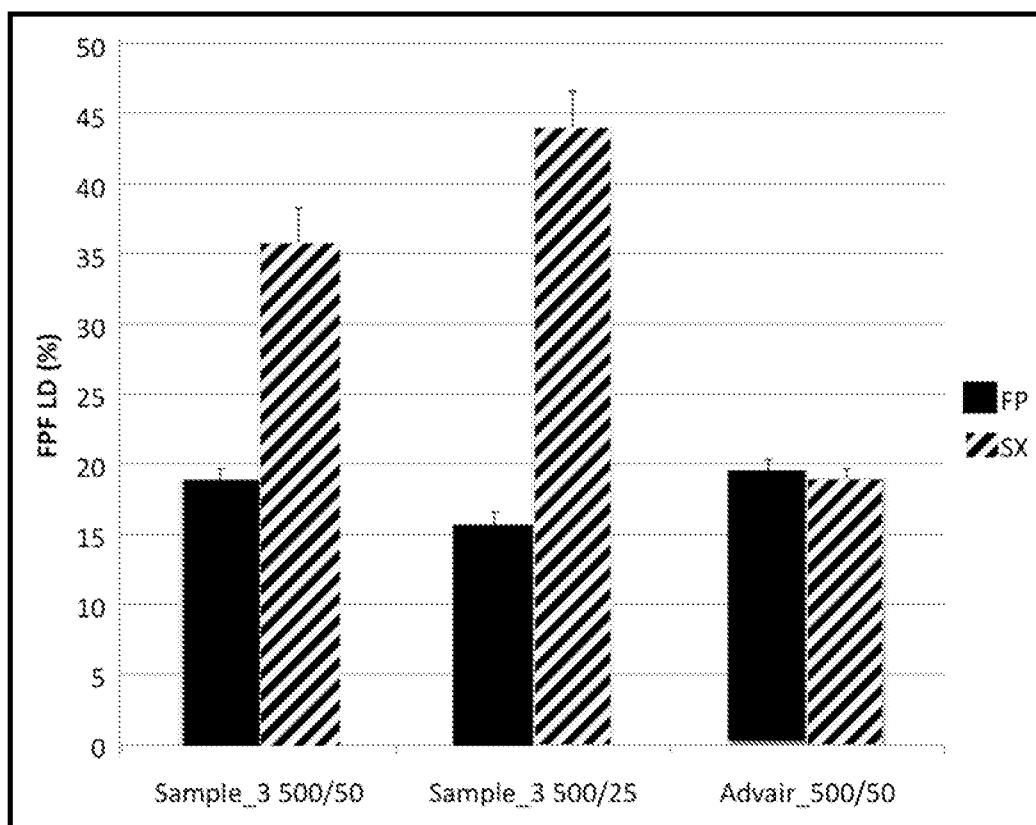


Fig. 21

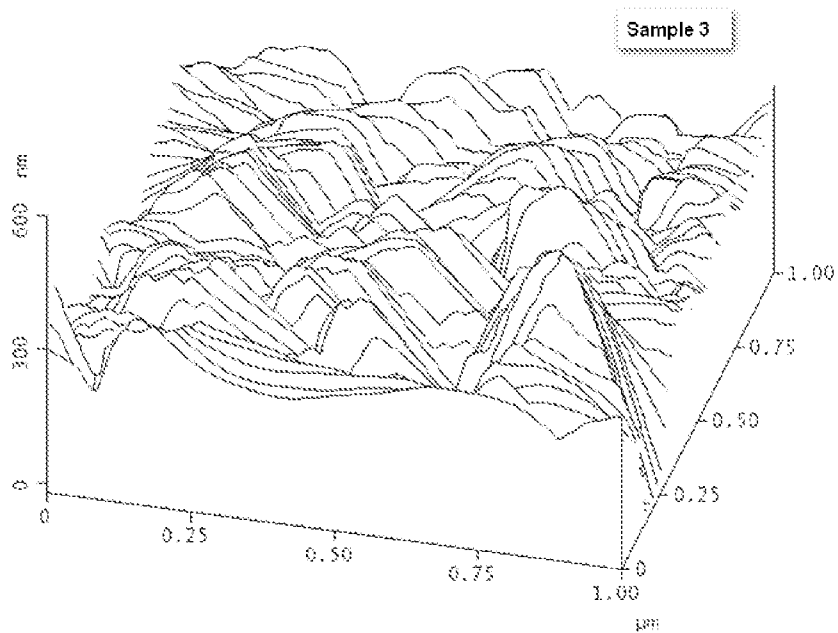
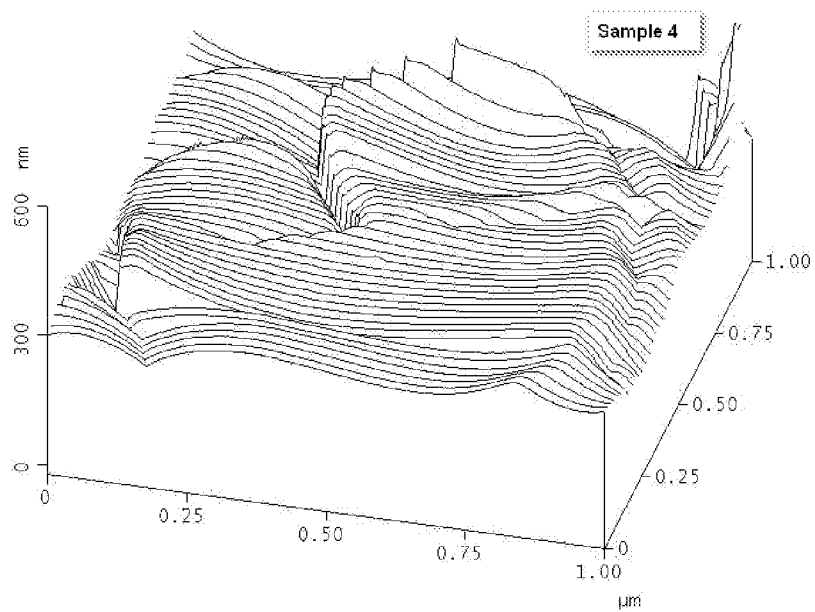


Fig. 22

**Fig. 23**