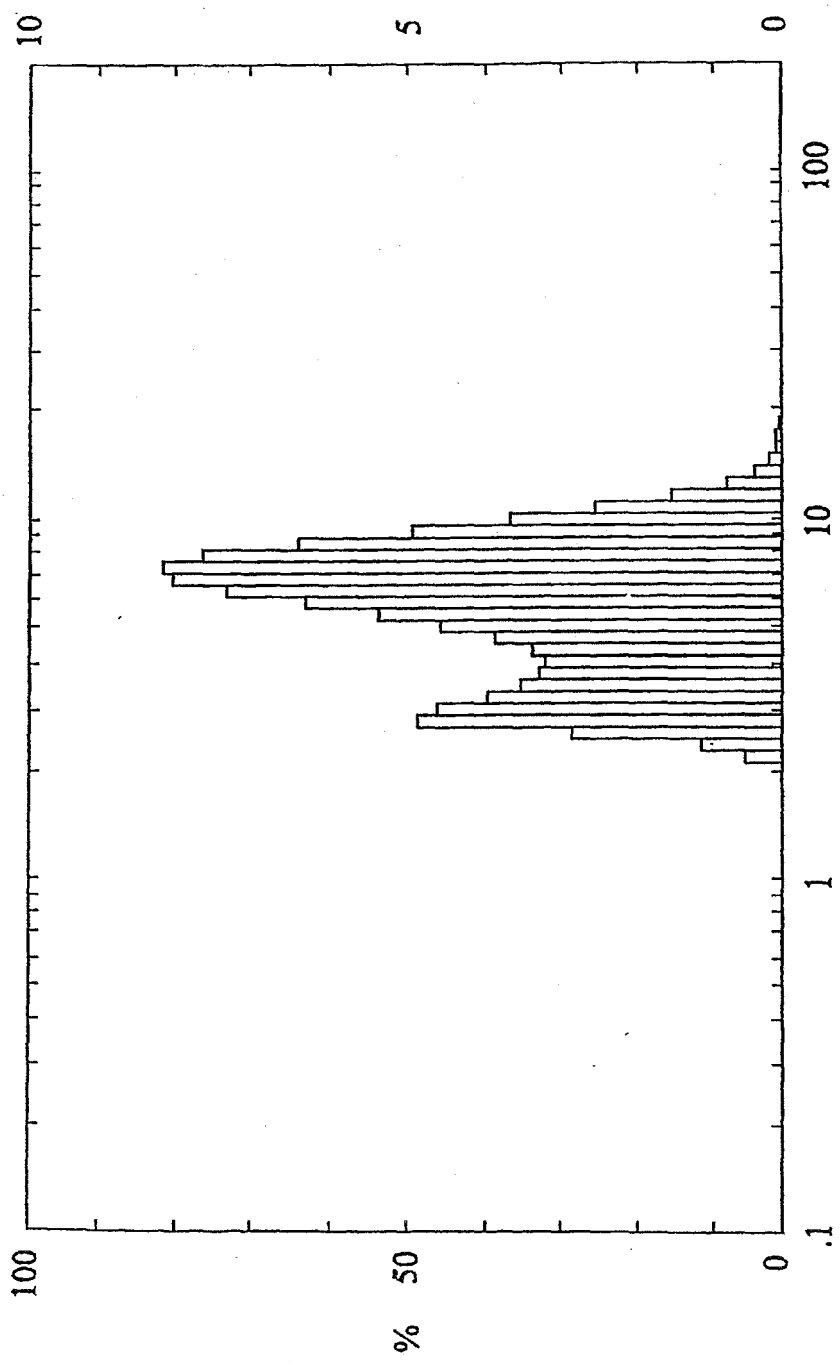


Particle sizing of micronised colistin sulphomethate sodium

FIG. 1

FIG. 2

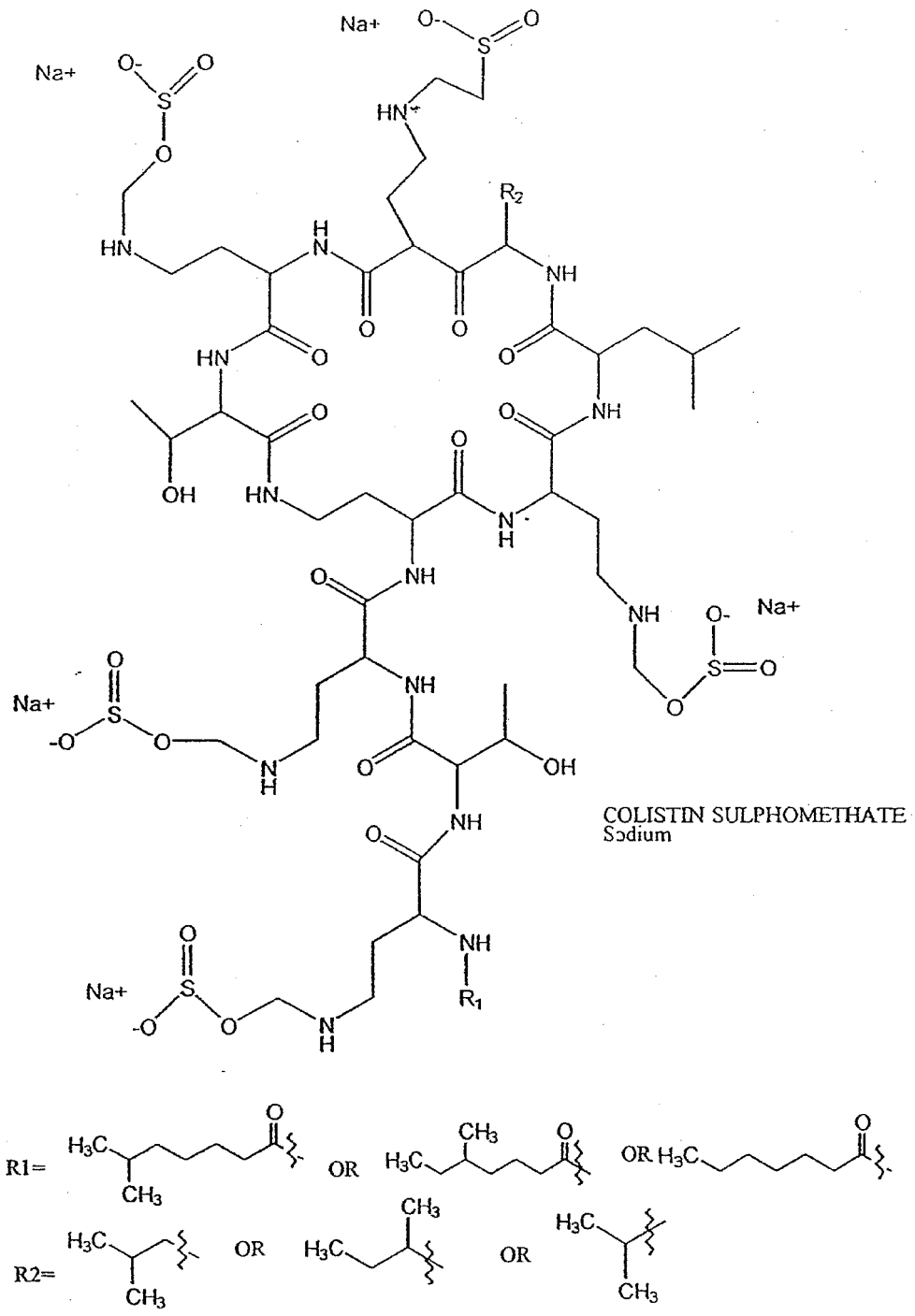
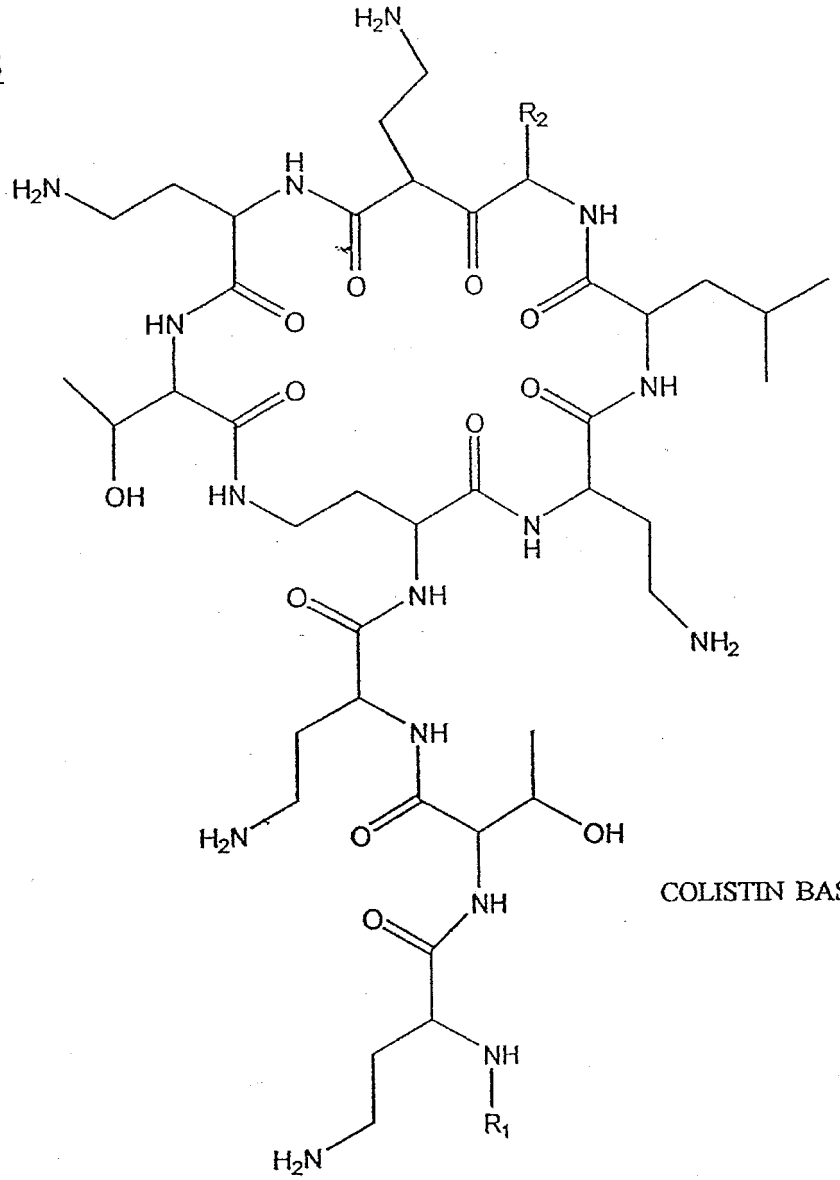

Na+
O-
S
O
HN+
HN
H
N
R2
NH
HN
O
OH
NH
N
H
NH
Na+
COLISTIN SULPHOMETHATE
Sodium
R1=
OR
CH3
R2=

FIG. 3



COLISTIN BASE

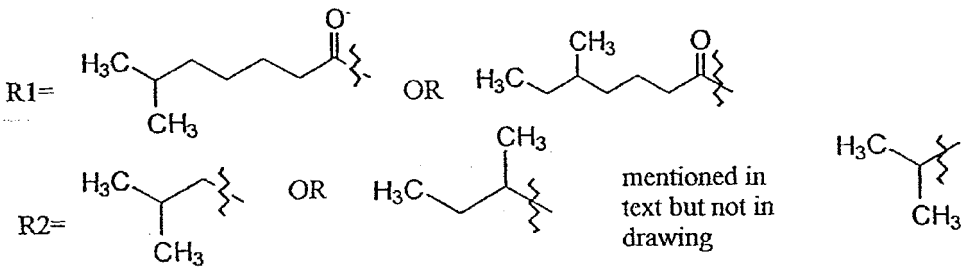


FIG. 4

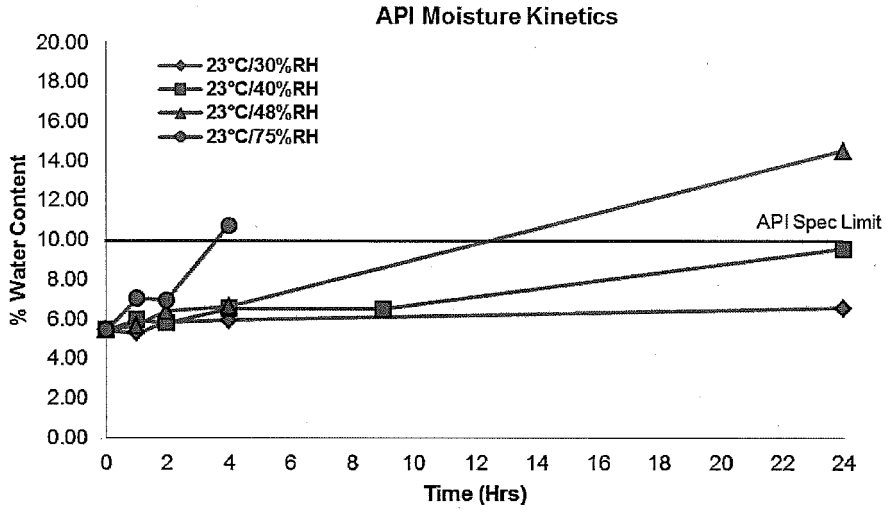

API Moisture Kinetics
% Water Content
Time (Hrs)
23°C/30%RH
23°C/40%RH
23°C/48%RH
23°C/75%RH
API Spec Limit
20.00
18.00
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
0
2
4
6
8
10
12
14
16
18
20
22
24

FIG. 5

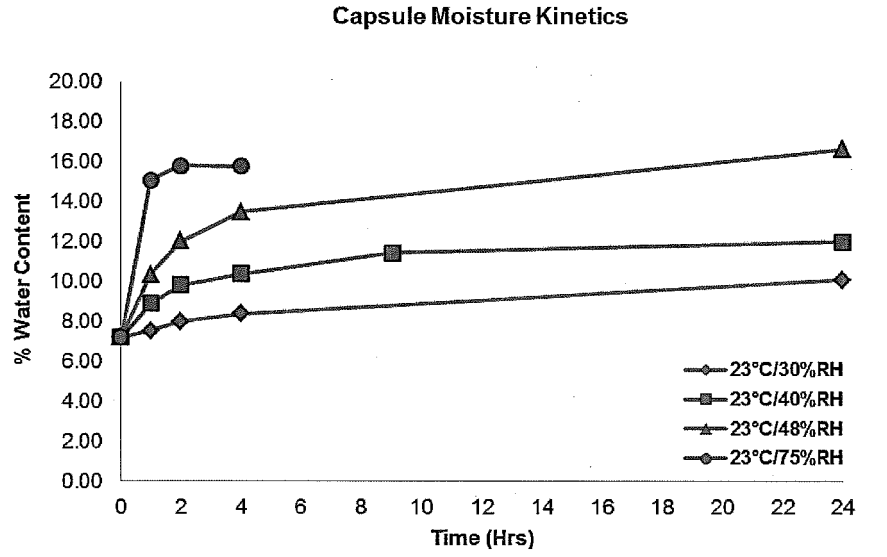

Capsule Moisture Kinetics
% Water Content
Time (Hrs)
23°C/30%RH
23°C/40%RH
23°C/48%RH
23°C/75%RH
20.00
18.00
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
0
2
4
6
8
10
12
14
16
18
20
22
24

FIG. 6

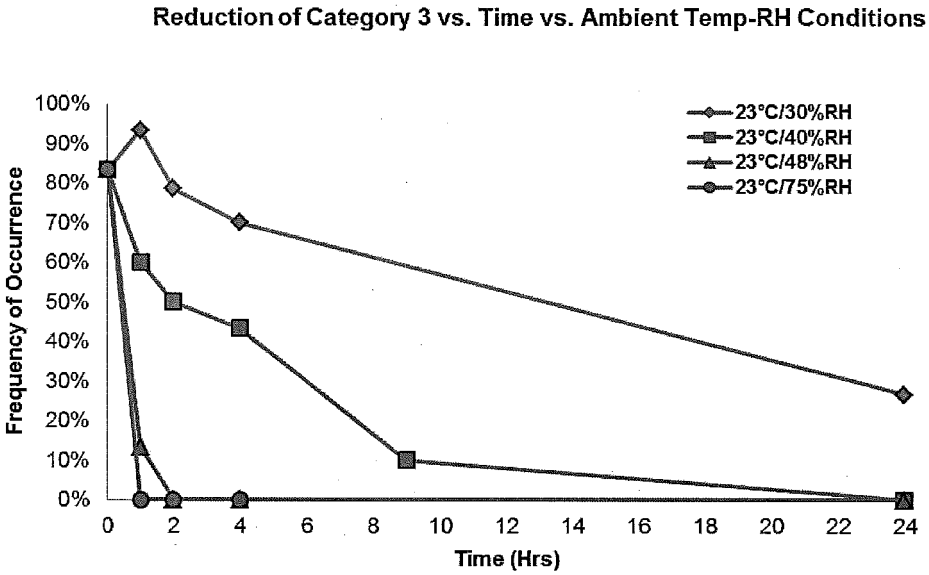
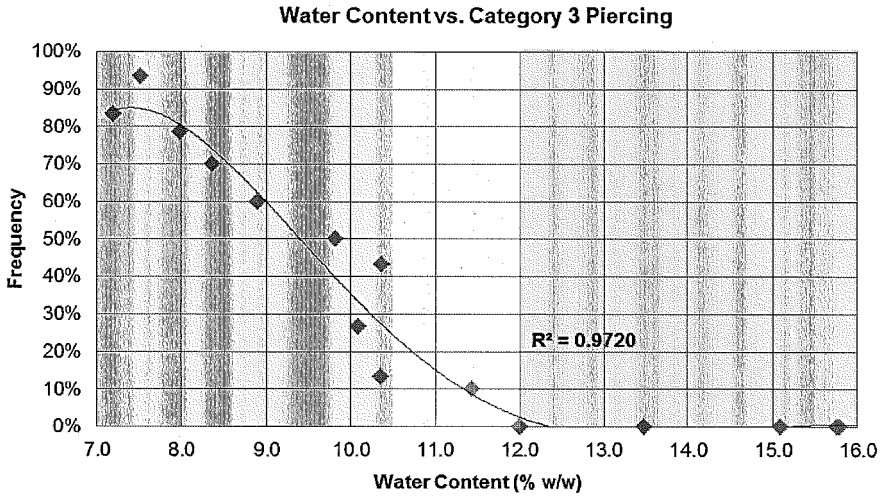

Reduction of Category 3 vs. Time vs. Ambient Temp-RH Conditions
Frequency of Occurrence
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
2
4
6
8
10
12
14
16
18
20
22
24
Time (Hrs)
23°C/30%RH
23°C/40%RH
23°C/48%RH
23°C/75%RH

FIG. 7


Water Content vs. Category 3 Piercing
Frequency
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
7.0
8.0
9.0
10.0
11.0
12.0
13.0
14.0
15.0
16.0
Water Content (% w/w)
R² = 0.9720