Fig 1/16

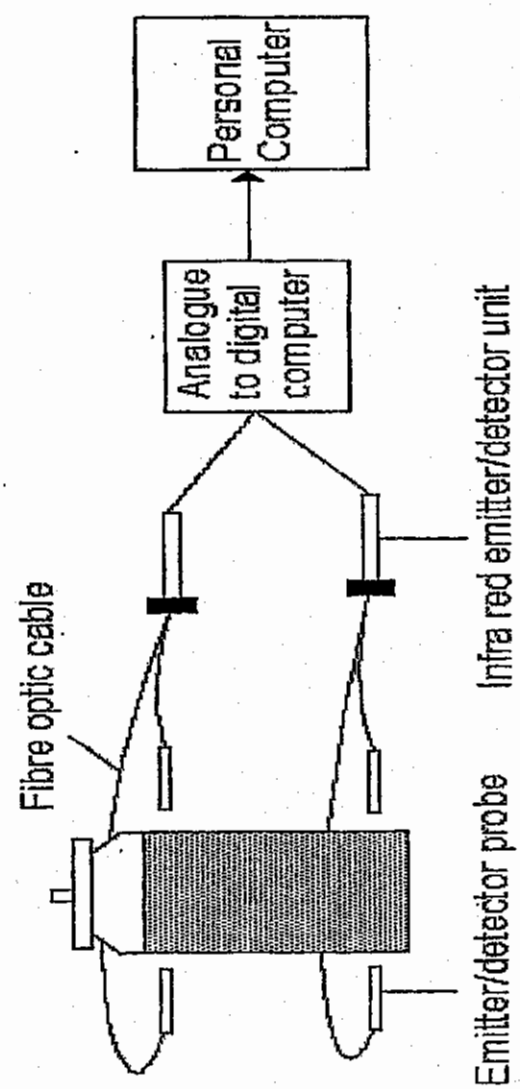


Figure 1: Schematic for OSCAR set-up

Fig 2/16

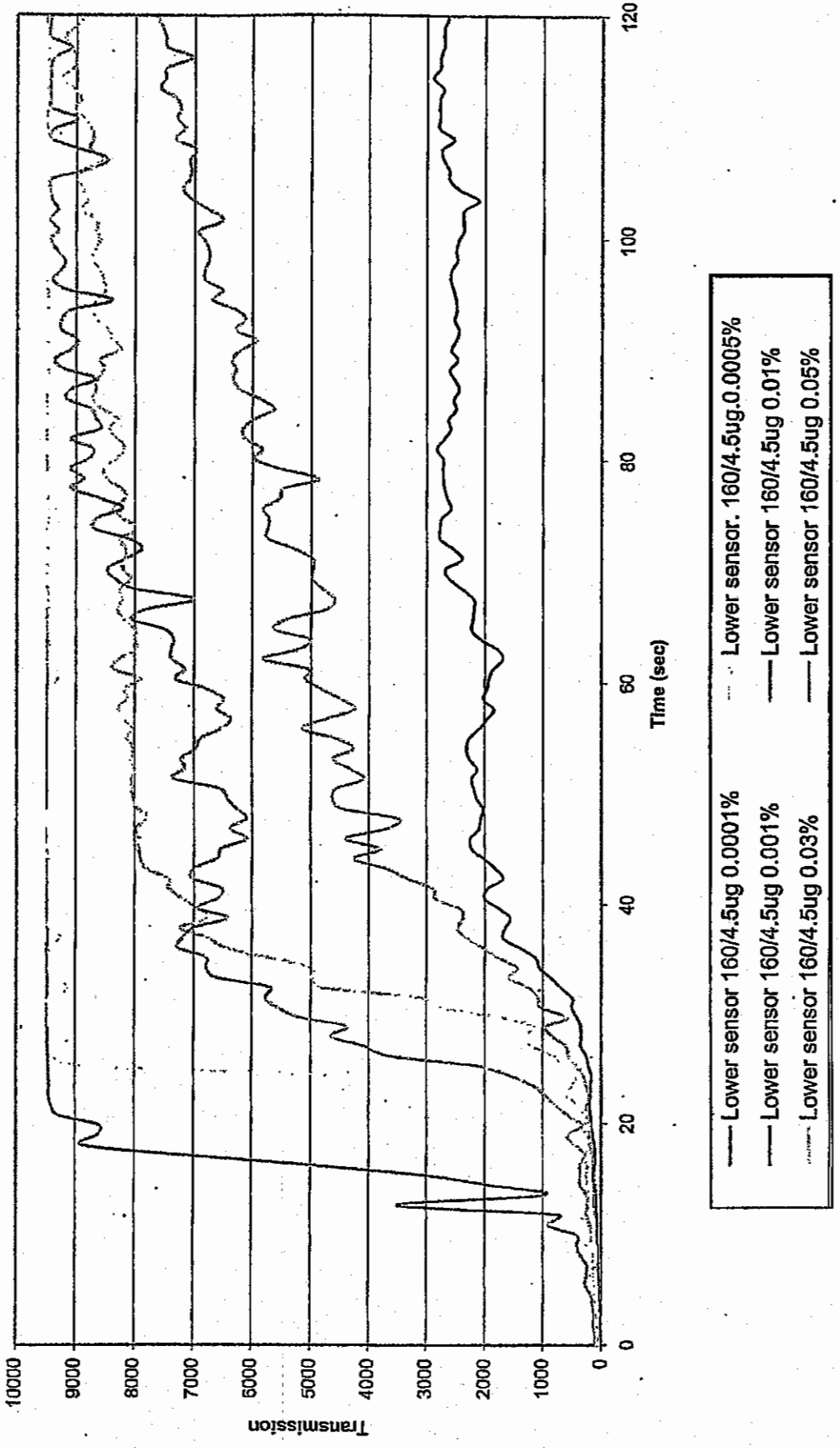


Figure 2: Averages of OSCAR data for formulation containing 160/4.5ug Budesonide/Formoterol. 0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25.

Fig 3/16

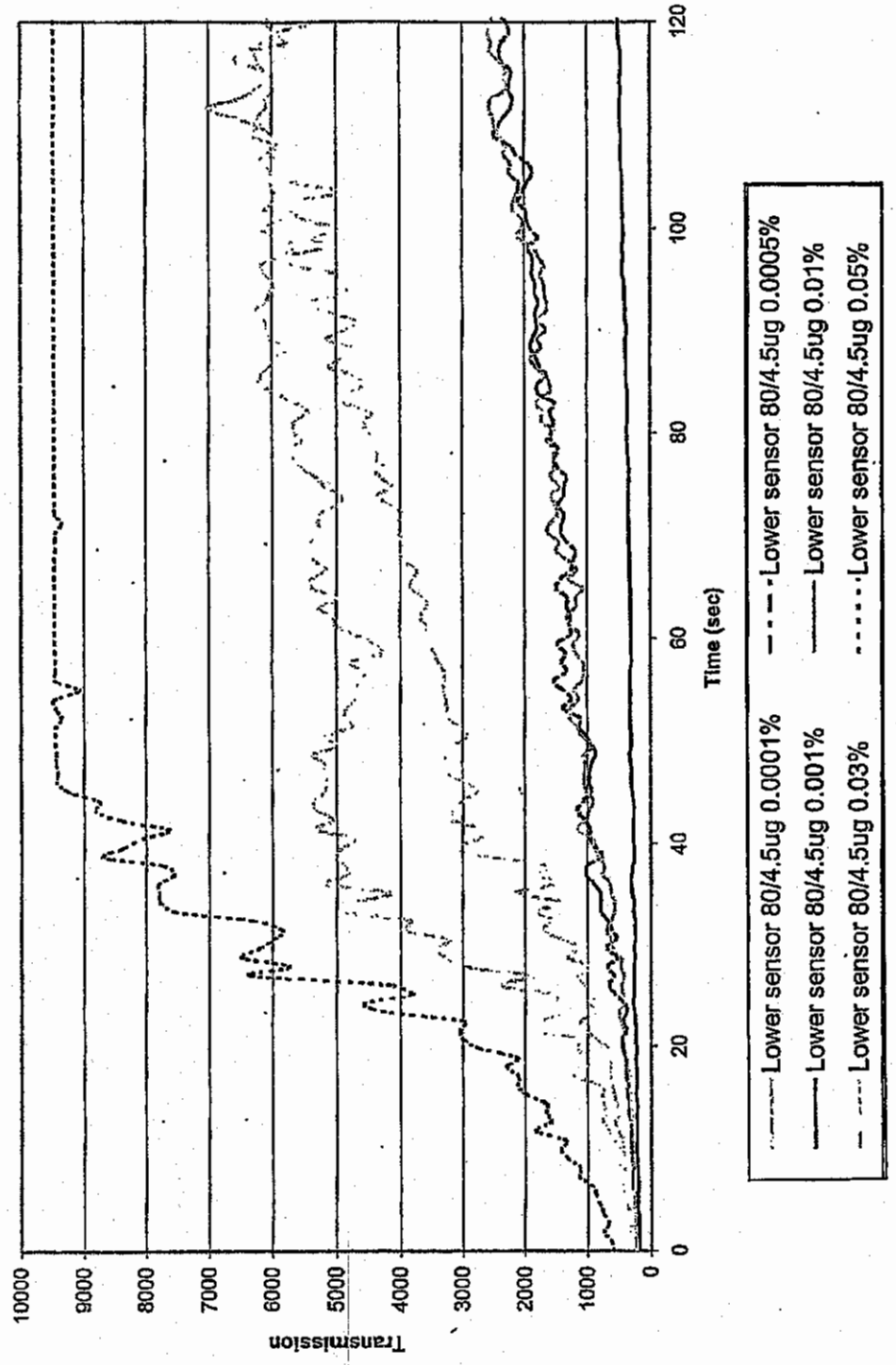


Figure 3: Averages of OSCAR data for formulation containing 80/4.5ug Budesonide/Formoterol. 0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25, in HFA 227.

Fig 4/16

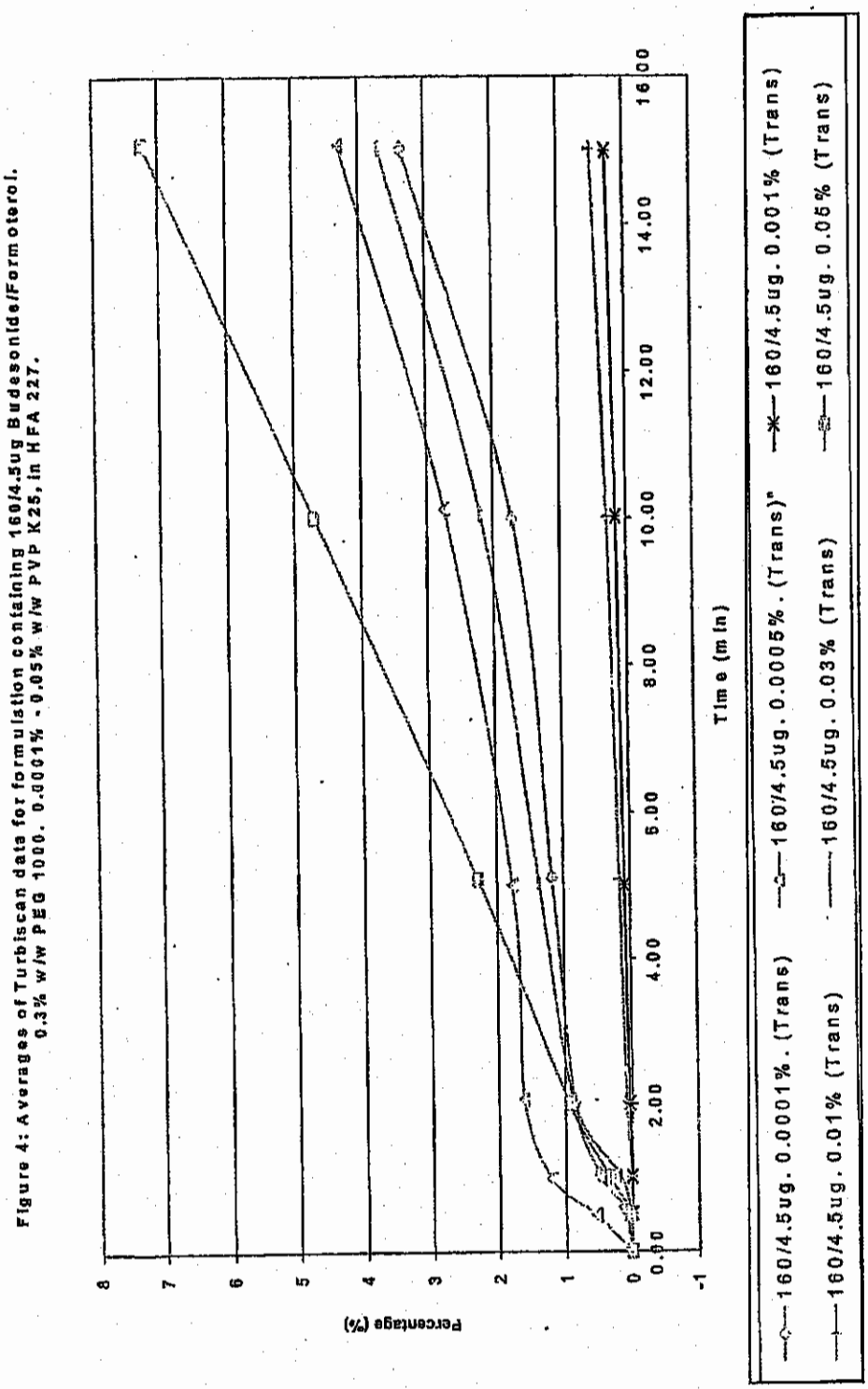

Figure 4: Averages of Turbiscan data for formulation containing 160/4.5ug Budesonide/Formoterol.
0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25, in HFA 227.
Percentage (%)
Time (min)
160/4.5ug. 0.0001%. (Trans)
160/4.5ug. 0.0005%. (Trans)"
160/4.5ug. 0.001% (Trans)
160/4.5ug. 0.01% (Trans)
160/4.5ug. 0.03% (Trans)
160/4.5ug. 0.05% (Trans)

Fig 5/16

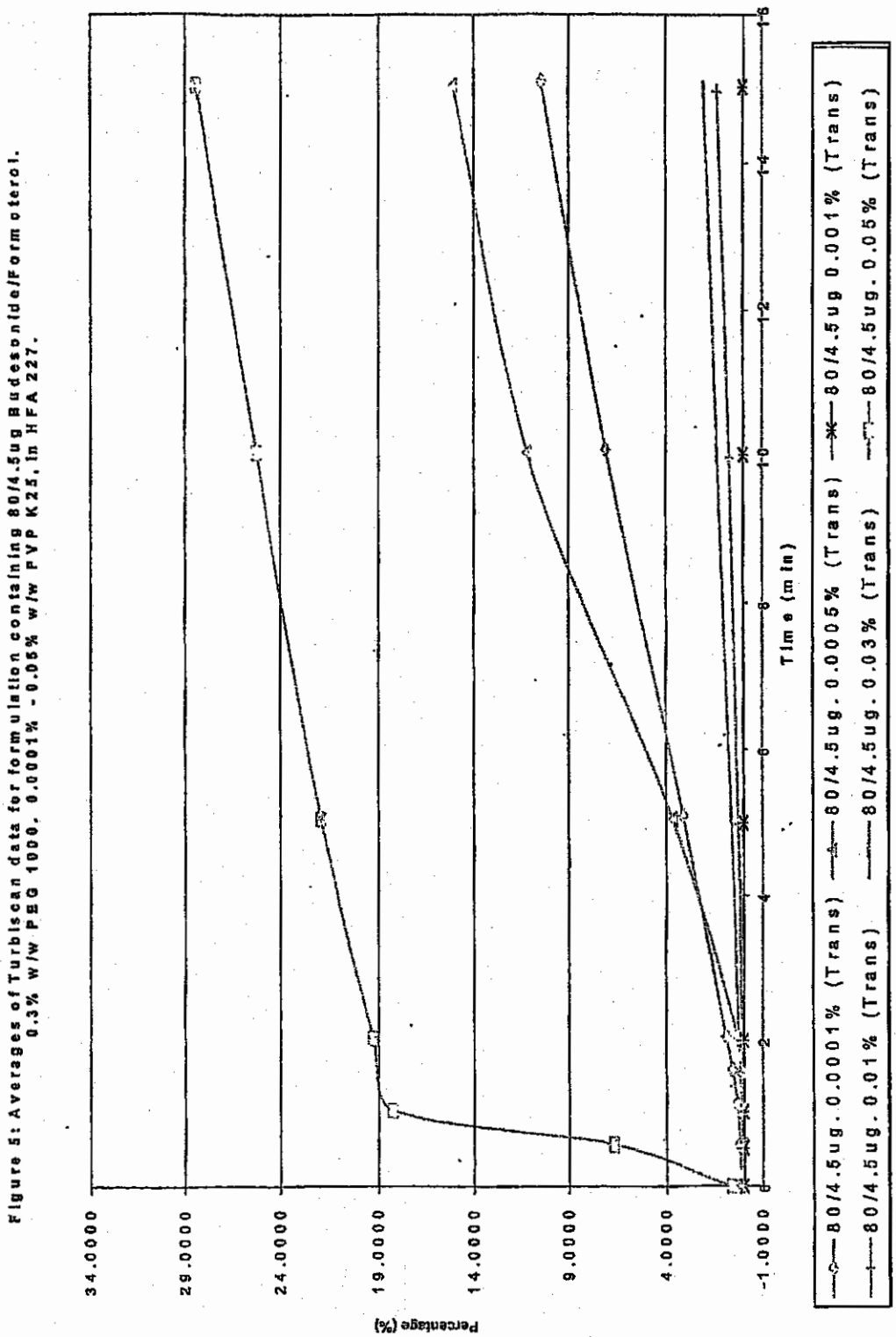

Figure 5: Averages of Turbiscan data for formulation containing 80/4.5ug Budesonide/Formoterol.
0.3% w/w PEG 1000, 0.0001% - 0.05% w/w PVP K25, in HFA 227.
Percentage (%)
34.0000
29.0000
24.0000
19.0000
14.0000
9.0000
4.0000
-1.0000
Time (min)
0
2
4
6
8
10
12
14
16
80/4.5ug. 0.0001% (Trans)
80/4.5ug. 0.0005% (Trans)
80/4.5ug 0.001% (Trans)
80/4.5ug. 0.01% (Trans)
80/4.5ug. 0.03% (Trans)
80/4.5ug. 0.05% (Trans)

Fig 6/16

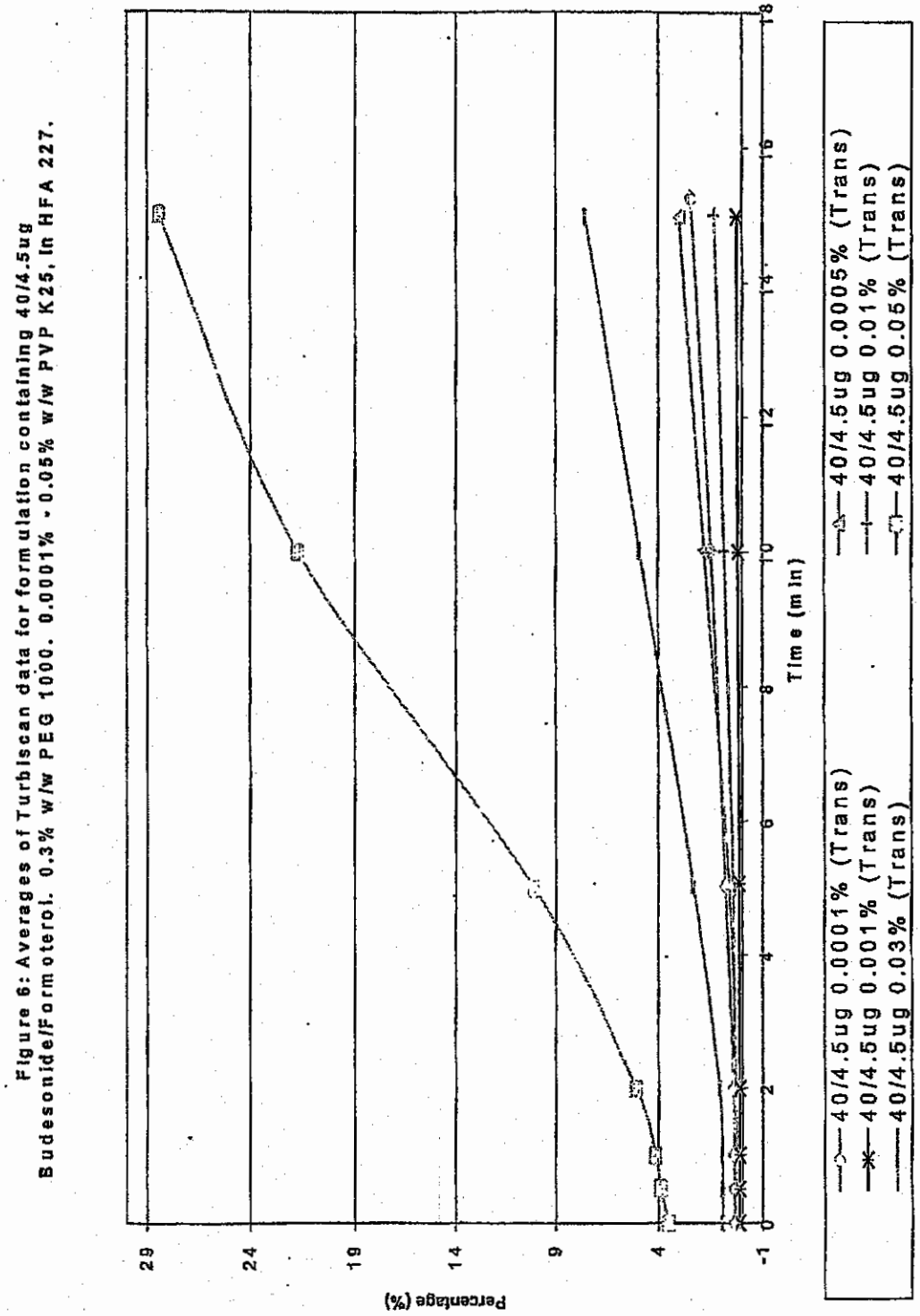

Figure 6: Averages of Turbiscan data for formulation containing 40/4.5ug Budesonide/Formoterol. 0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25, in HFA 227.
Percentage (%)
29
24
19
14
9
4
-1
Time (min)
0
2
4
6
8
10
12
14
16
18
40/4.5ug 0.0001% (Trans)
40/4.5ug 0.001% (Trans)
40/4.5ug 0.03% (Trans)
40/4.5ug 0.0005% (Trans)
40/4.5ug 0.01% (Trans)
40/4.5ug 0.05% (Trans)

Fig 7/16

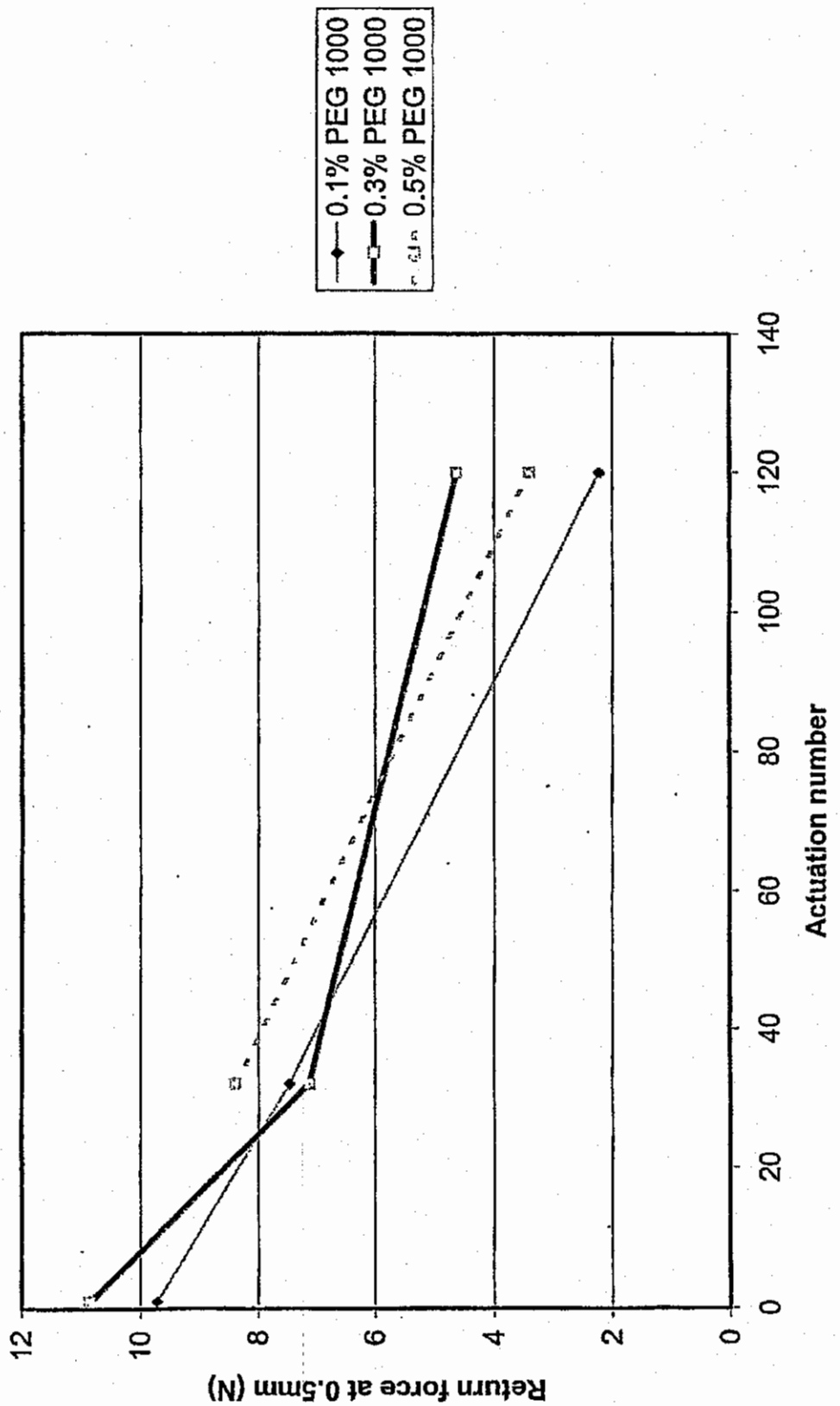

0.1% PEG 1000
0.3% PEG 1000
0.5% PEG 1000
Return force at 0.5mm (N)
Actuation number
0
2
4
6
8
10
12
0
20
40
60
80
100
120
140

Fig. 8/16

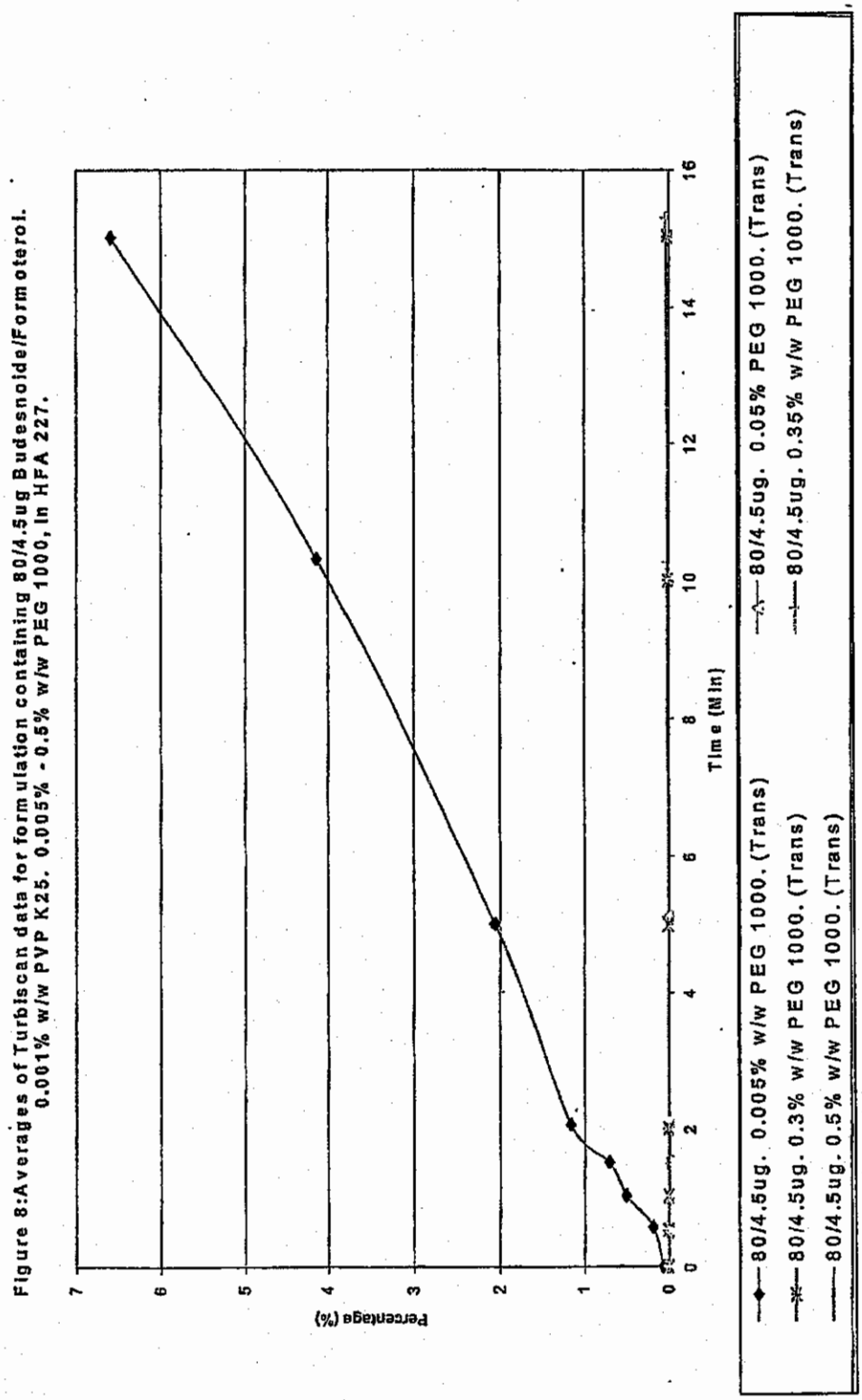

Figure 8:Averages of Turbiscan data for formulation containing 80/4.5ug Budesnoide/Formoterol.
0.001% w/w PVP K25. 0.005% - 0.5% w/w PEG 1000, In HFA 227.
Percentage (%)
Time (Min)
80/4.5ug. 0.005% w/w PEG 1000. (Trans)
80/4.5ug. 0.3% w/w PEG 1000. (Trans)
80/4.5ug. 0.5% w/w PEG 1000. (Trans)
80/4.5ug. 0.05% PEG 1000. (Trans)
80/4.5ug. 0.35% w/w PEG 1000. (Trans)

Fig. 9/16

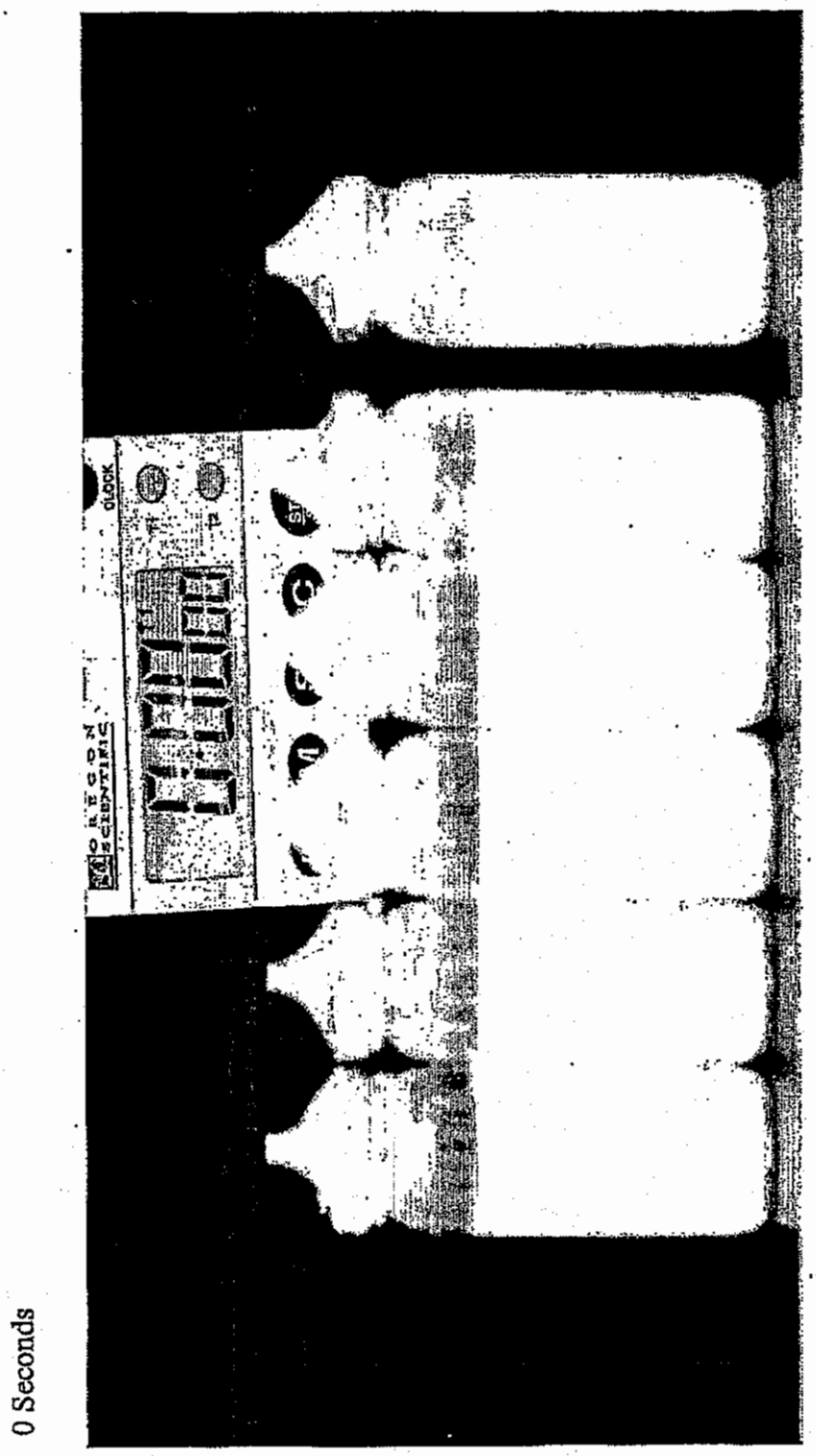


Fig. 10/16

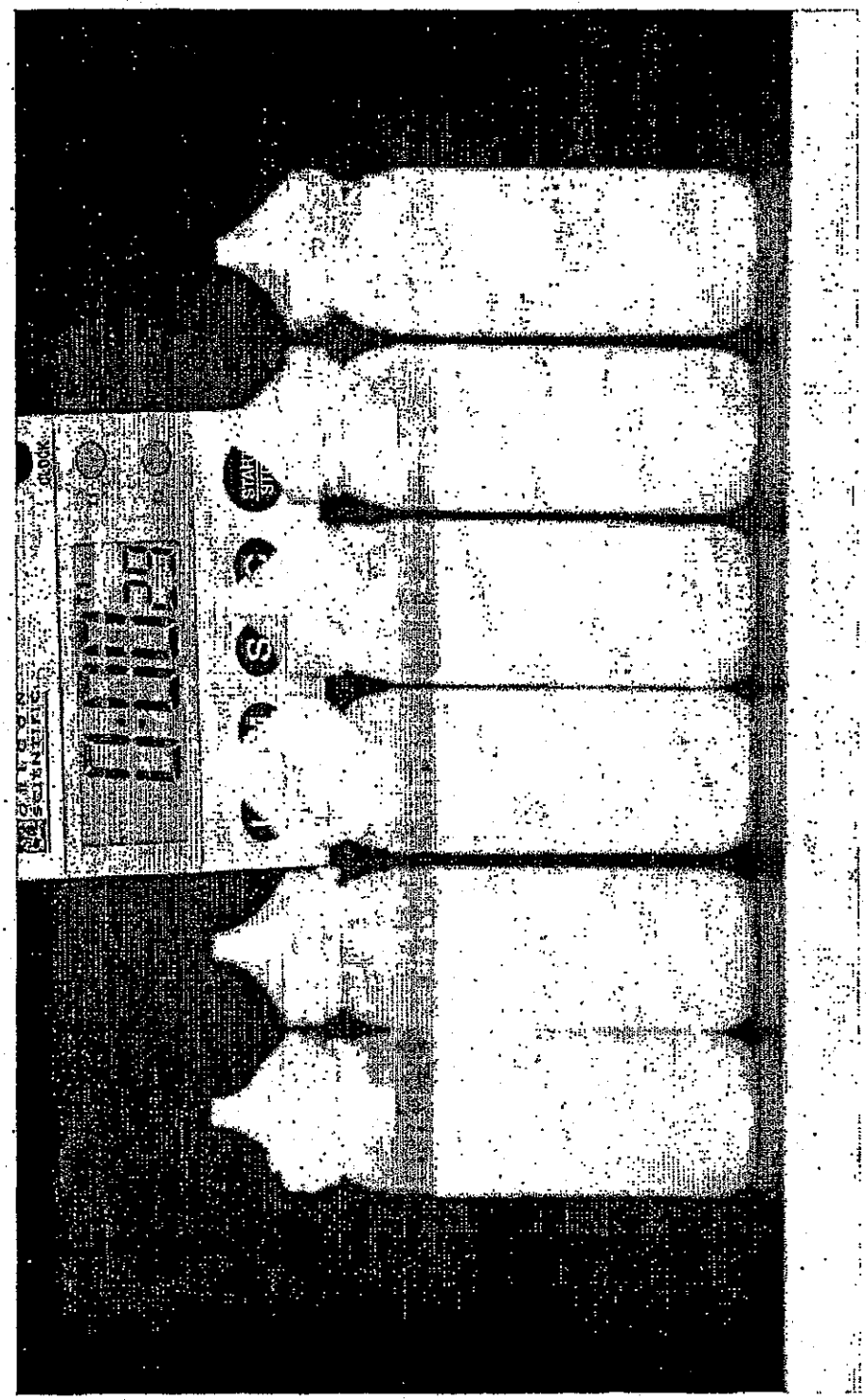


Fig. 11/16

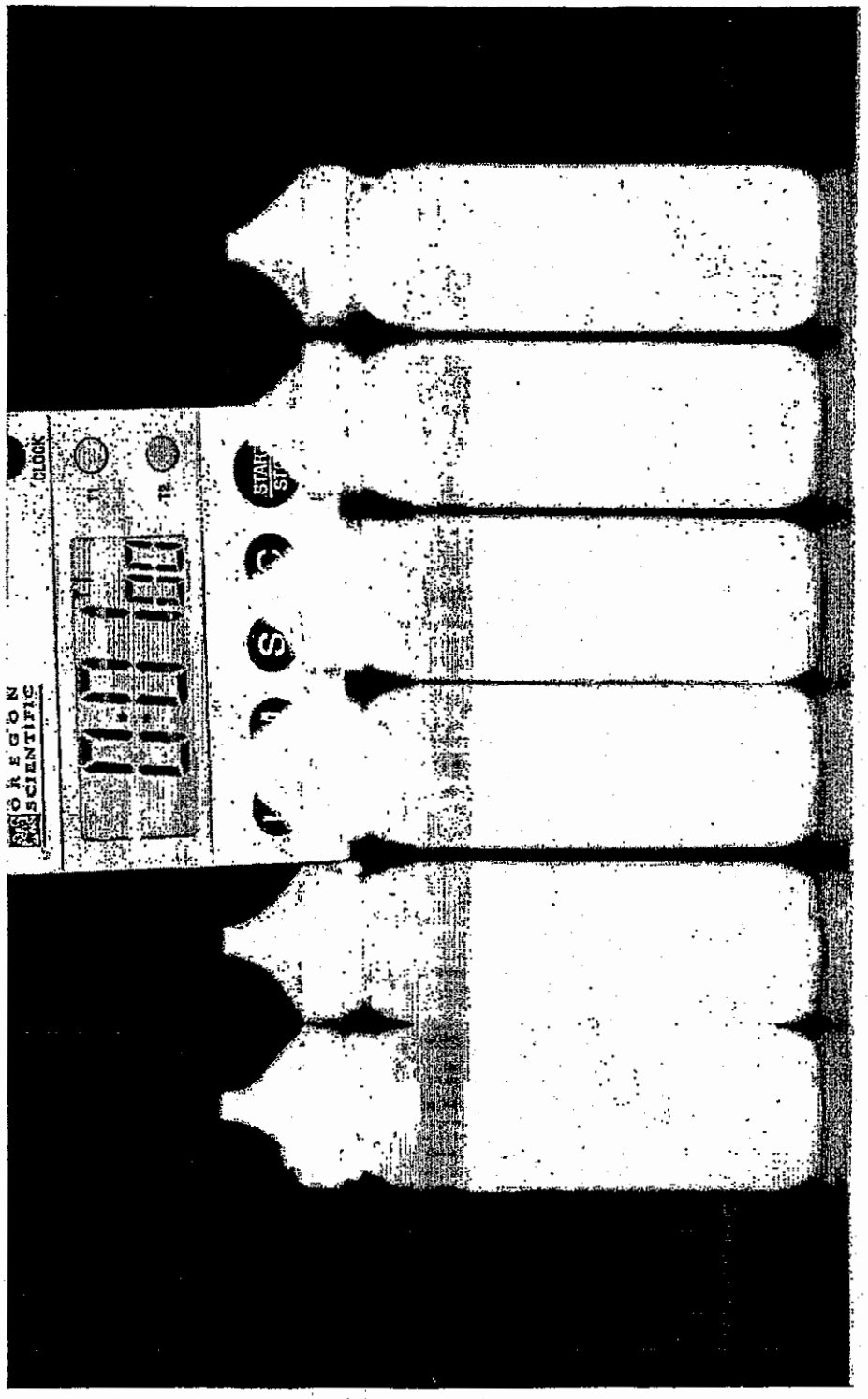


Fig. 12/16

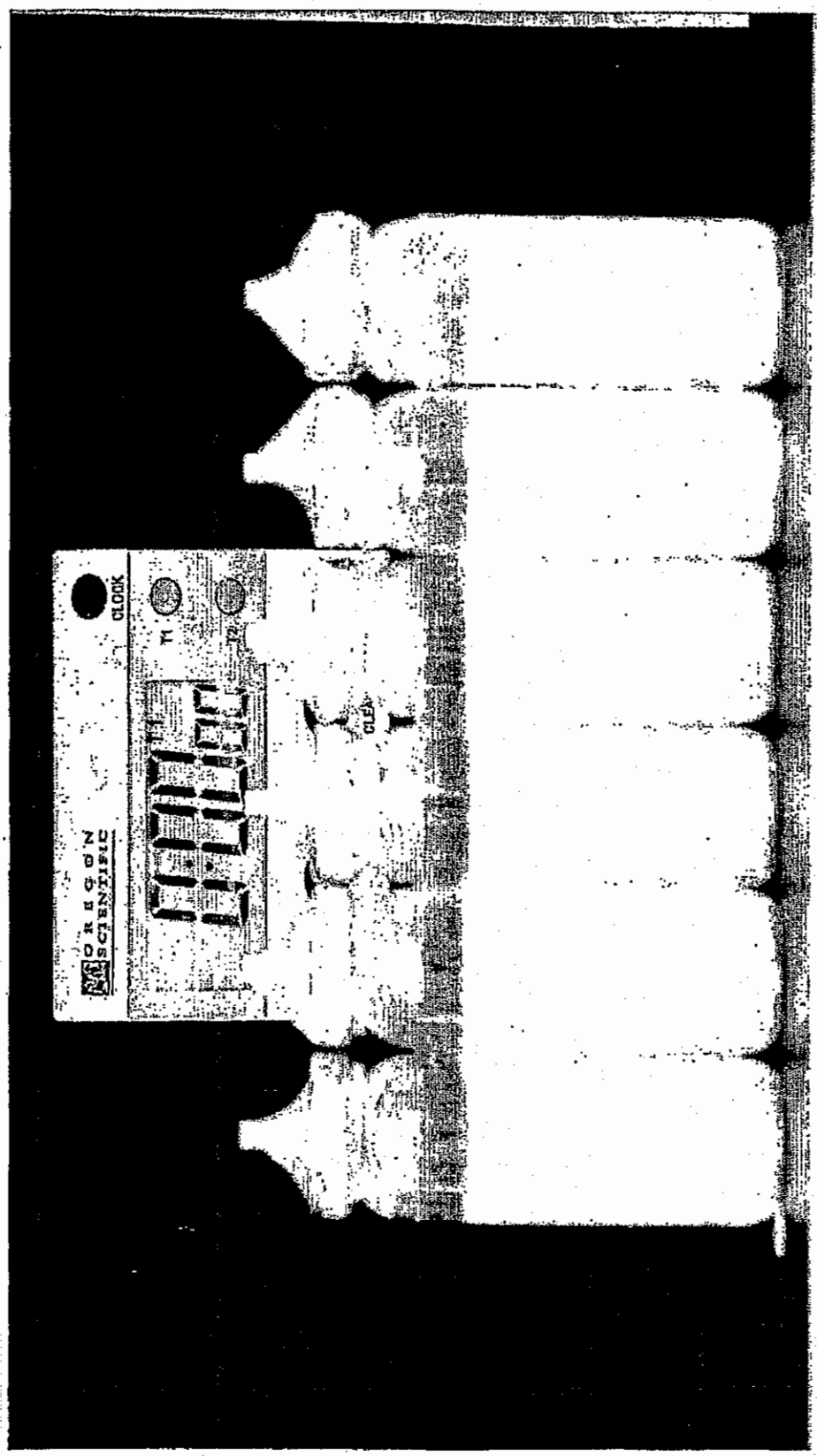


Fig. 13/16

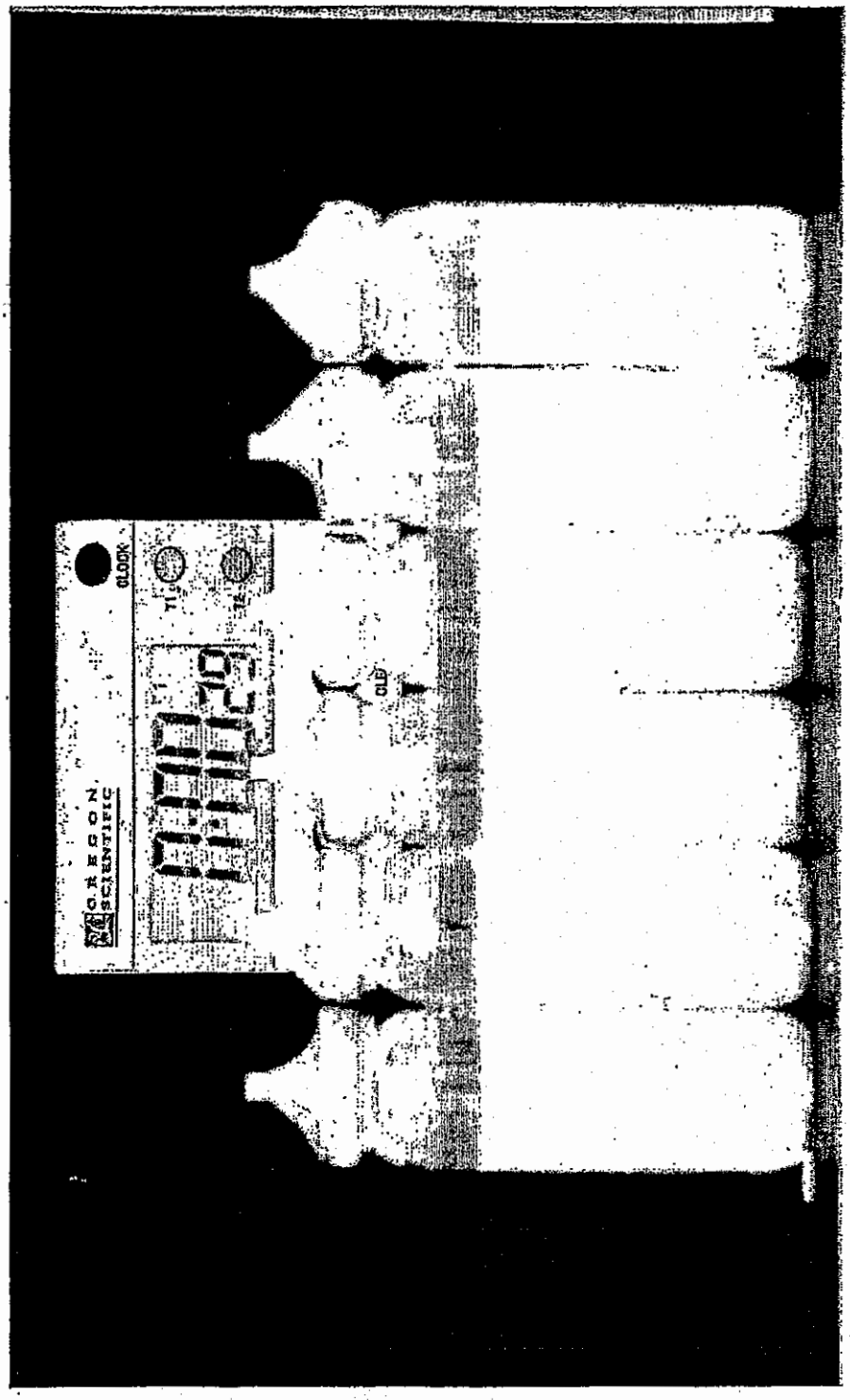


Fig 14/16

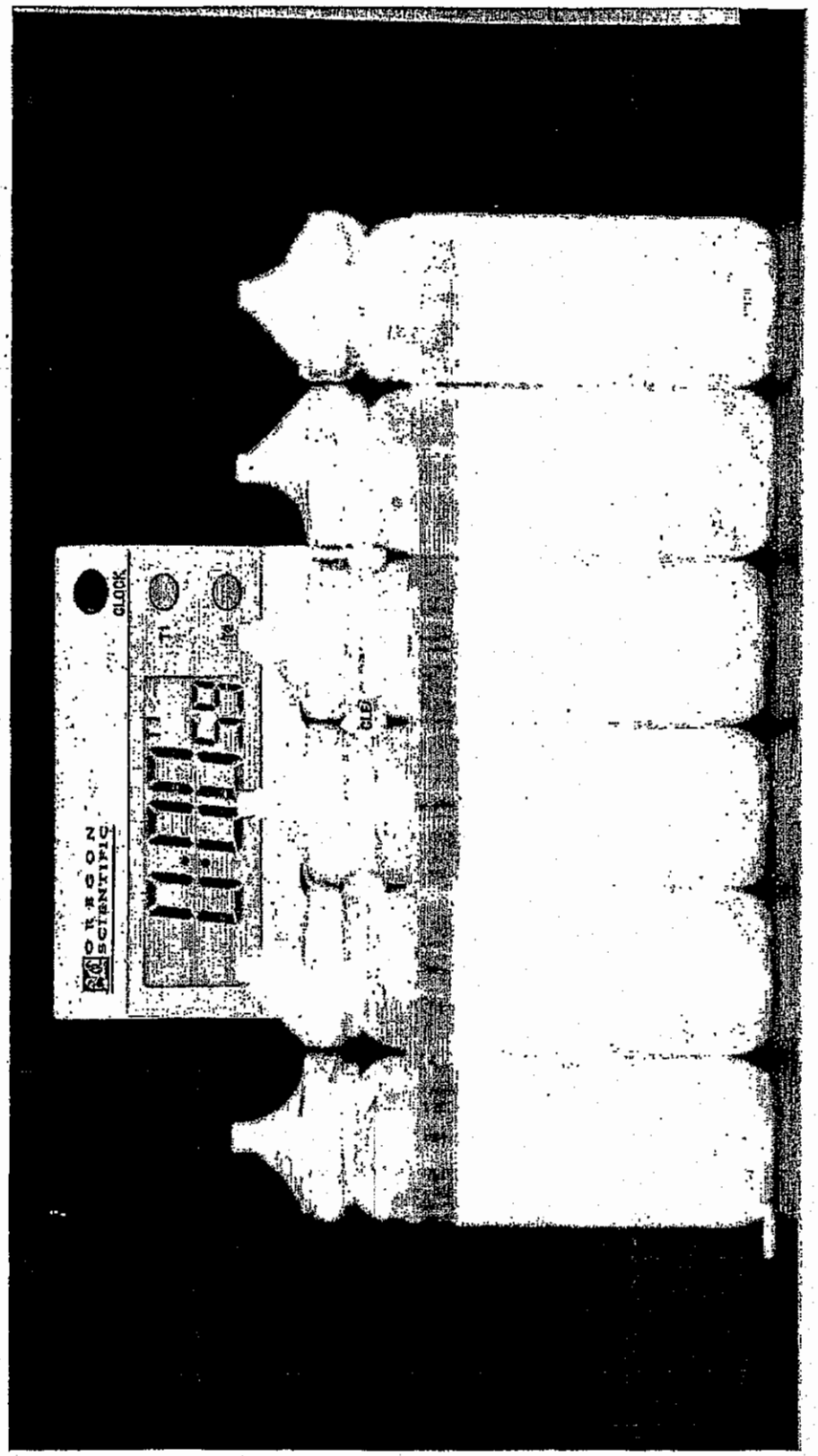
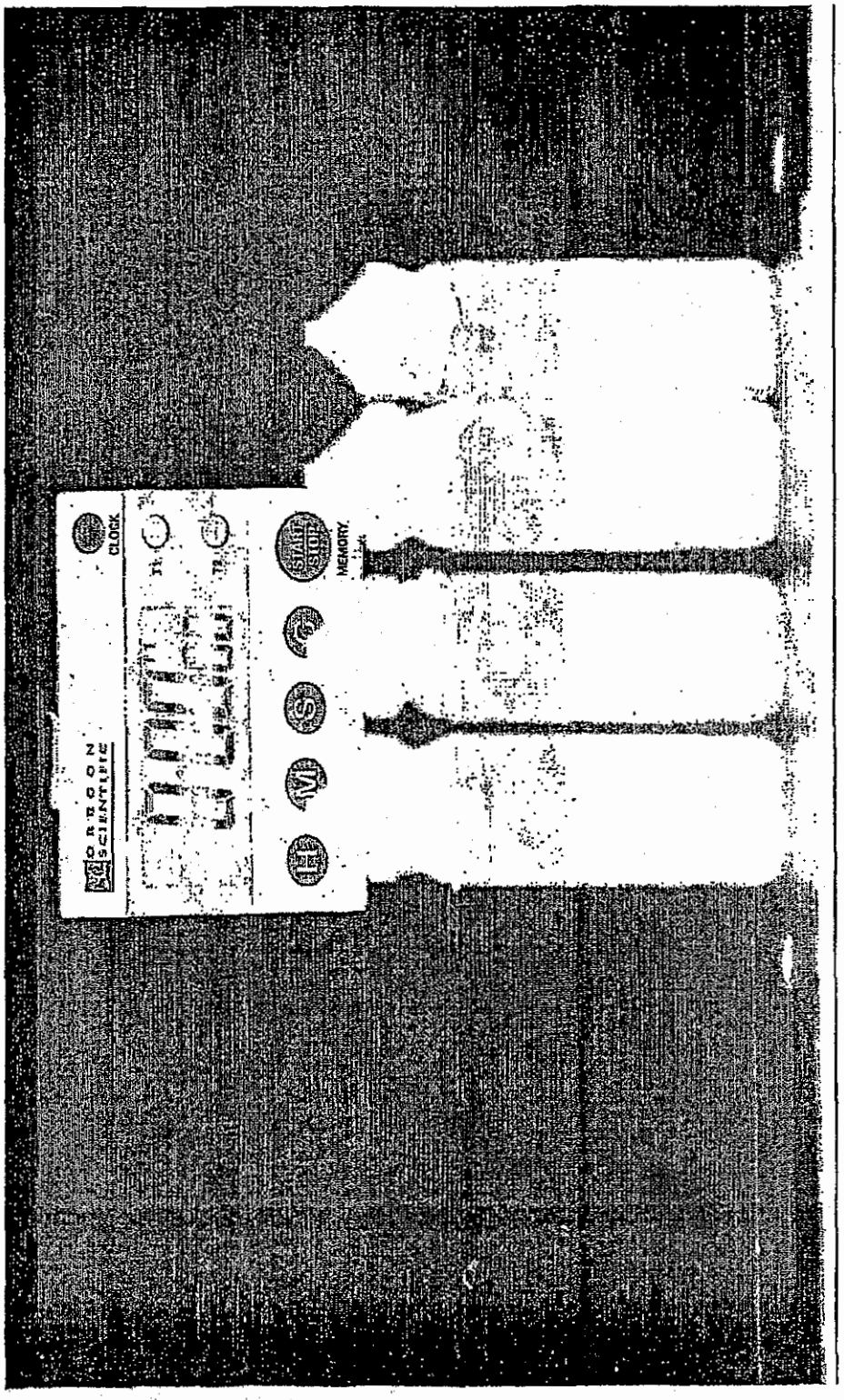


Fig. 15/16



PEG concn = left – right 0.005, 0.05, 0.35 and 0.5 % w/w

Fig. 16/16

