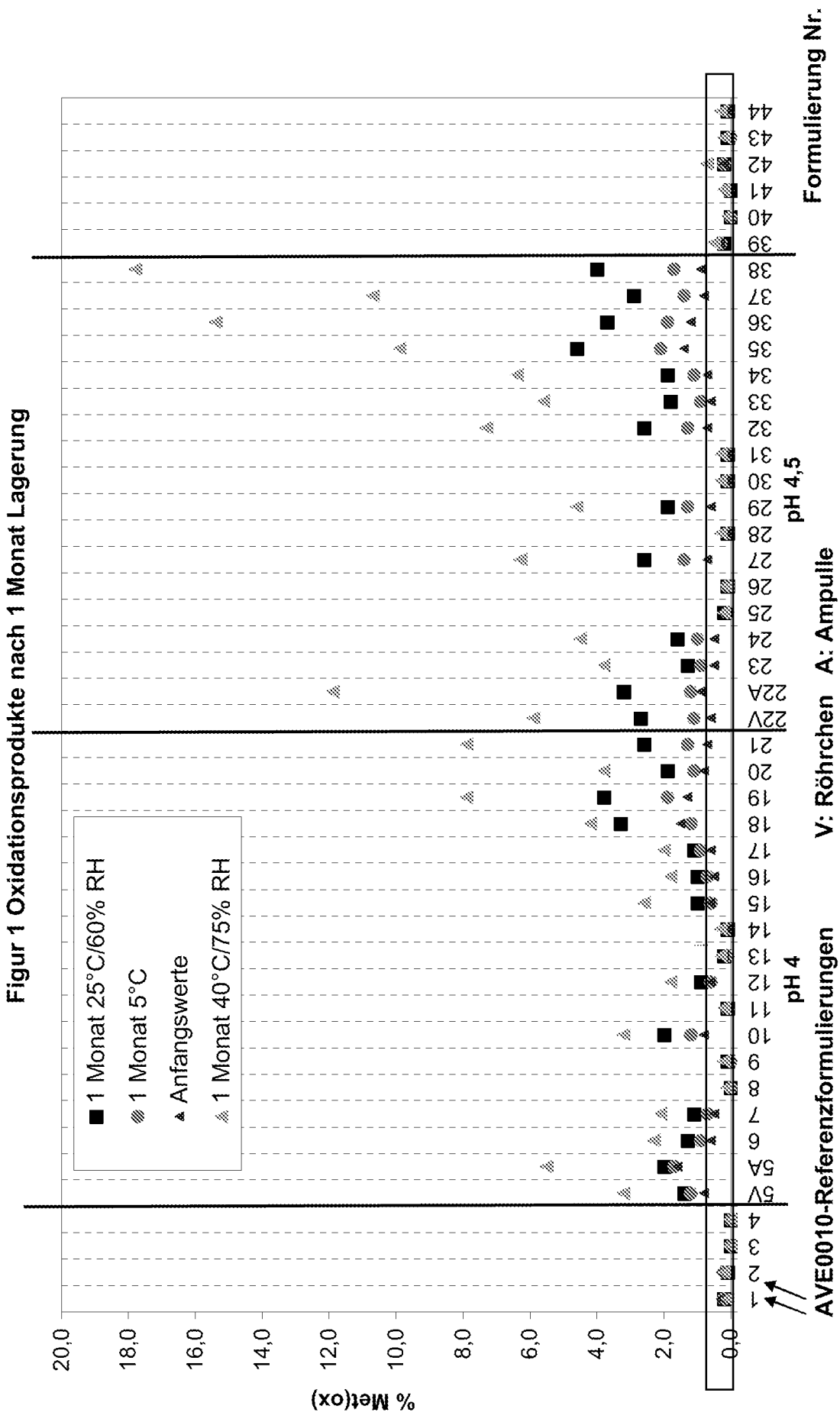
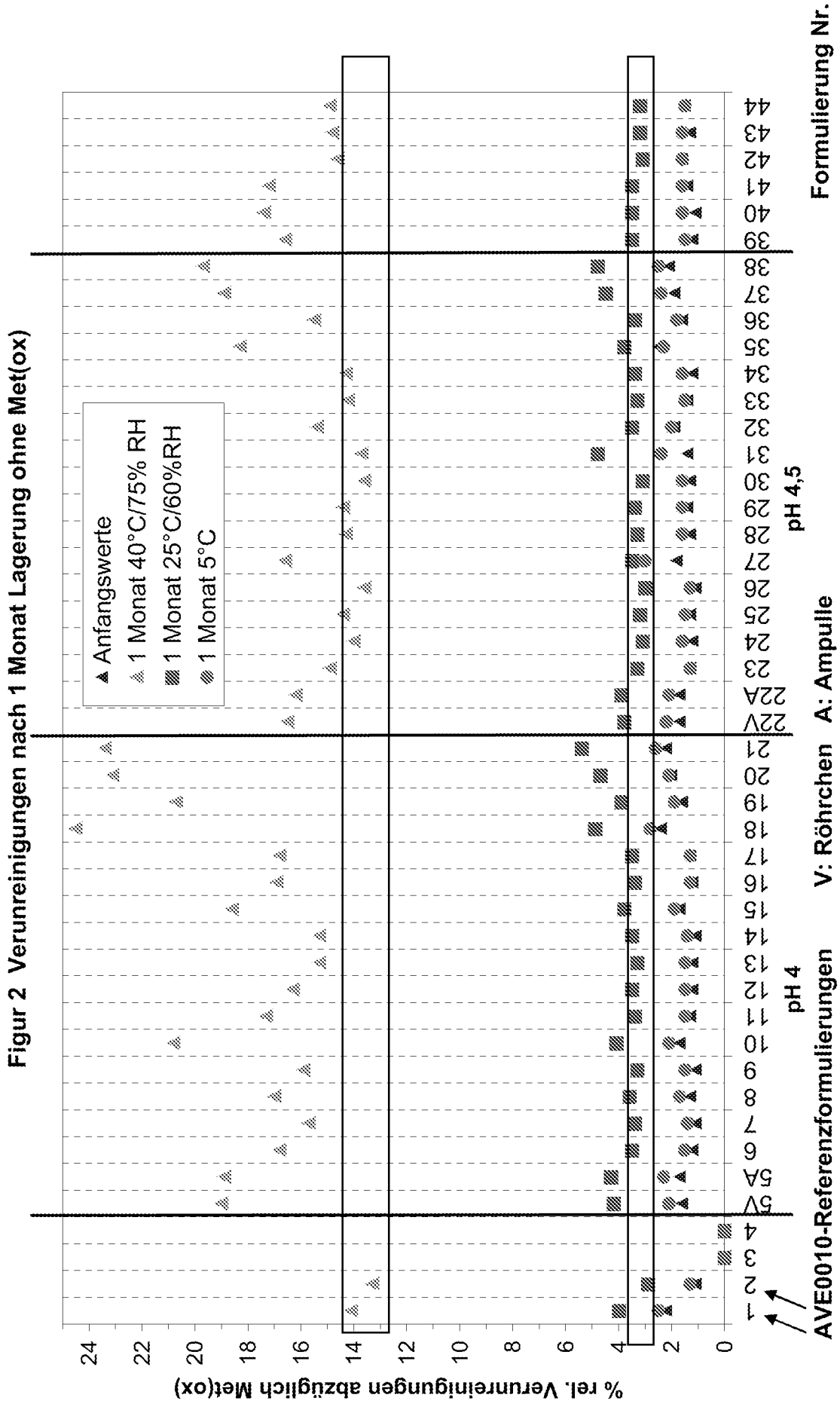
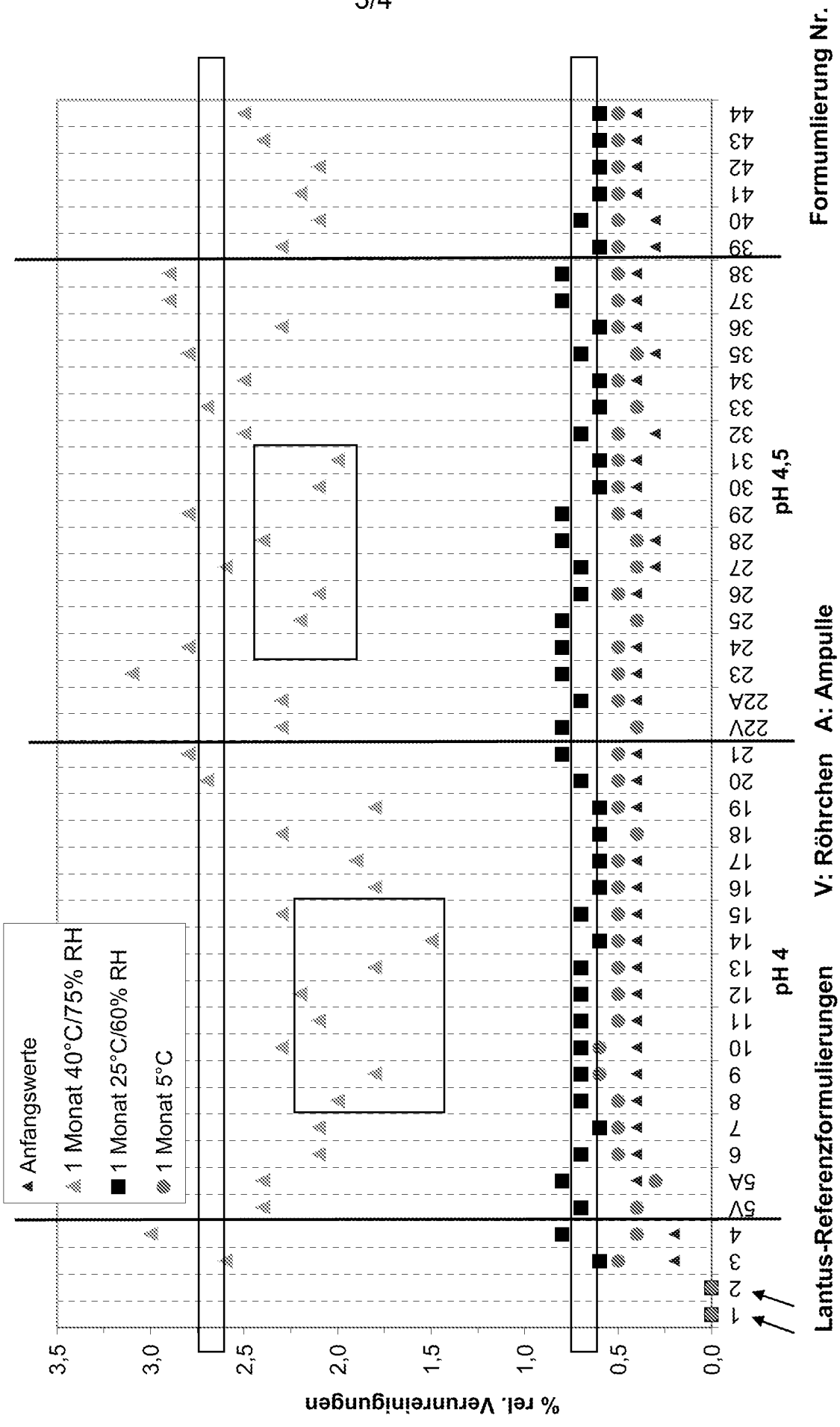
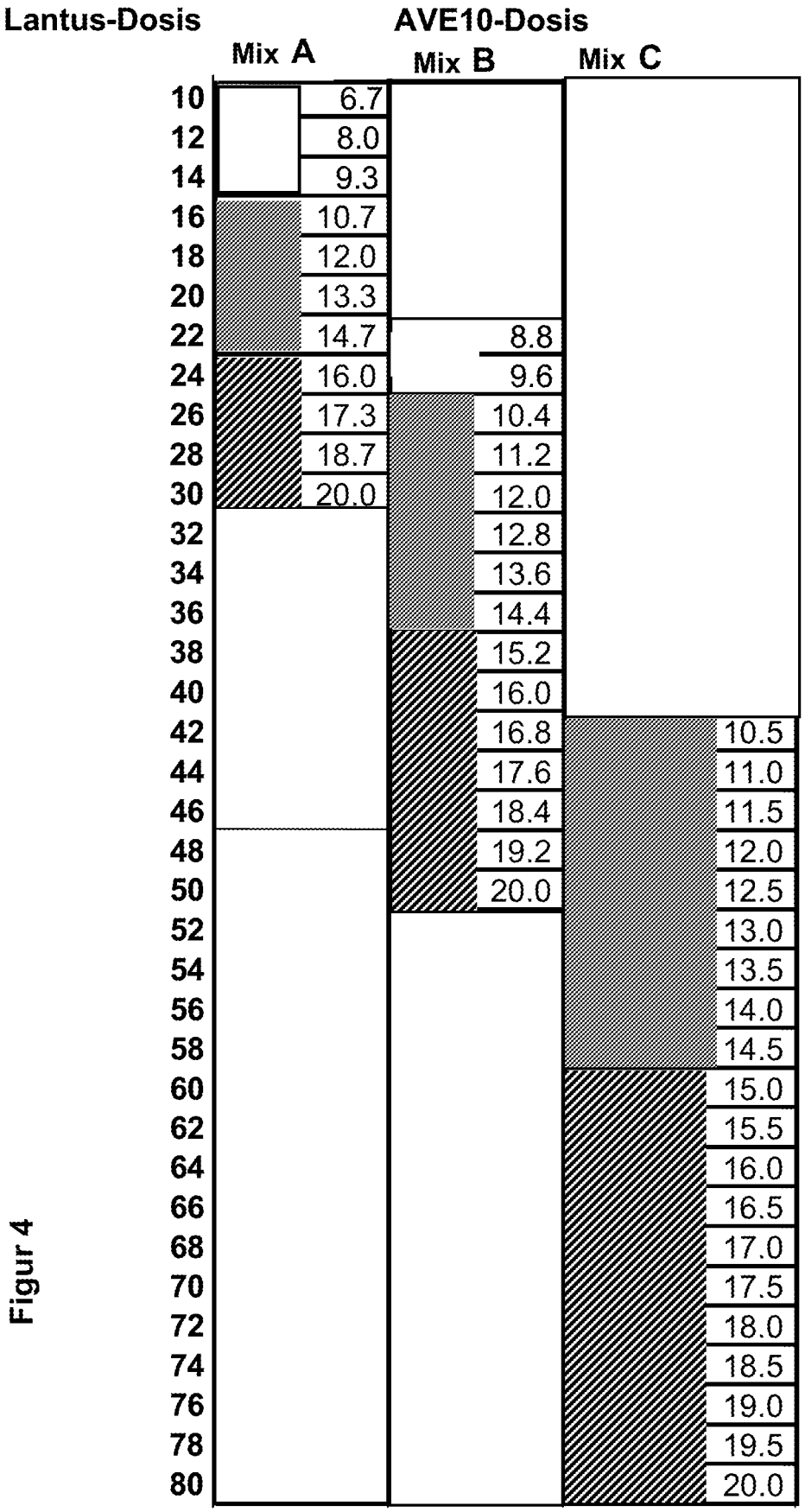

Figur 1 Oxidationsprodukte nach 1 Monat Lagerung
1 Monat 25°C/60% RH
1 Monat 5°C
Anfangswerte
1 Monat 40°C/75% RH
% Met(ox)
20,0
18,0
16,0
14,0
12,0
10,0
8,0
6,0
4,0
2,0
0,0
AVE0010-Referenzformulierungen
pH 4
pH 4,5
V: Röhrchen A: Ampulle
Formulierung Nr.
1 2 3 4 5V 5A 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22V 22A 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44


Figur 2 Verunreinigungen nach 1 Monat Lagerung ohne Met(ox)
% rel. Verunreinigungen abzüglich Met(ox)
Anfangswerte
1 Monat 40°C/75% RH
1 Monat 25°C/60%RH
1 Monat 5°C
AVE0010-Referenzformulierungen
V: Röhrchen
A: Ampulle
pH 4
pH 4,5
Formulierung Nr.



Figur 3 Verunreinigungen von Insulin Glargin nach 1 Monat Lagerung


Lantus-Dosis
AVE10-Dosis
Mix A
Mix B
Mix C
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
54
56
58
60
62
64
66
68
70
72
74
76
78
80
6.7
8.0
9.3
10.7
12.0
13.3
14.7
16.0
17.3
18.7
20.0
8.8
9.6
10.4
11.2
12.0
12.8
13.6
14.4
15.2
16.0
16.8
17.6
18.4
19.2
20.0
10.5
11.0
11.5
12.0
12.5
13.0
13.5
14.0
14.5
15.0
15.5
16.0
16.5
17.0
17.5
18.0
18.5
19.0
19.5
20.0

Figur 4