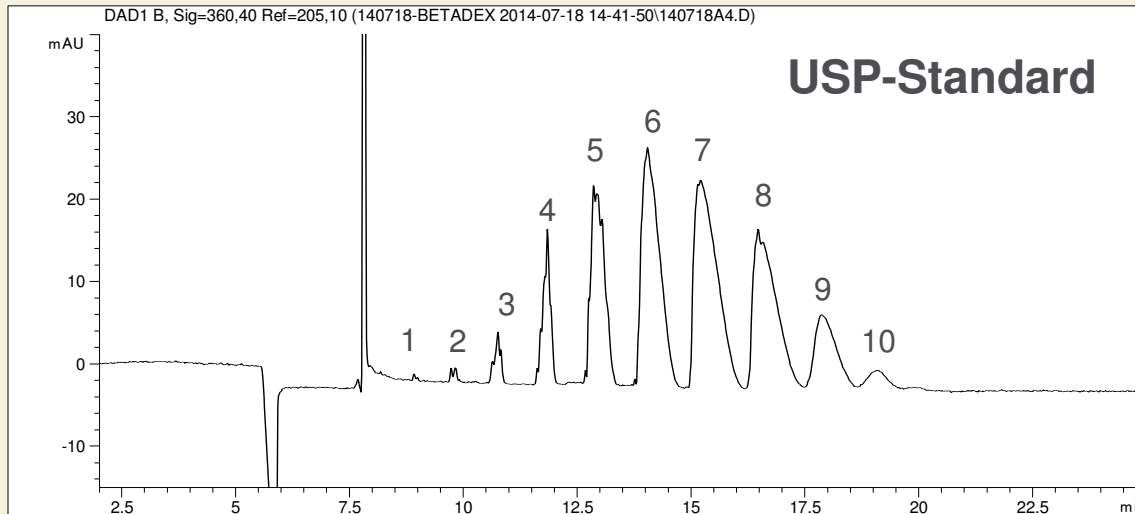


# Betadex Sulfobutylether

Synonyme: *CAPTISOL*, *SBE- $\beta$ -CD*.  
 Betadex wird u.a. als Lösungsvermittler  
 und zur Verbesserung der Haltbarkeit in  
 Arzneimitteln verwendet.

USP NF31, December 1, 2013, page 1909-1910  
 Betadex Sulfobutyl Ether Sodium Peaks I - X



Gerät: Kapillarelektrophorese  
 Elektrolyt: 30 mM Benzoesäure, Tris  
 Kapillare: fused silica, 50  $\mu$ m ID, 50 cm  
 Injektion: 10 s / 34 mbar  
 Temperatur: 25°C  
 Trennung: U= - 30 kV mit einer  
 anfänglichen Spannungsrampe von 10 min  
 Detektion: indirekte UV 205 nm (BW10)

| level of substitution | normalized peak area | limit range (% peak area) | acceptance criterion for limit range (% peak area) |
|-----------------------|----------------------|---------------------------|--|
| 1                     | 0,17                 | 0-0,3                     | fulfilled  |
| 2                     | 0,65                 | 0-0,9                     | fulfilled  |
| 3                     | 2,29                 | 0,5-5,0                   | fulfilled  |
| 4                     | 7,31                 | 2,0-10,0                  | fulfilled  |
| 5                     | 16,74                | 10,0-20,0                 | fulfilled  |
| 6                     | 23,43                | 15,0-25,0                 | fulfilled  |
| 7                     | 23,93                | 20,0-30,0                 | fulfilled  |
| 8                     | 16,79                | 10,0-25,0                 | fulfilled  |
| 9                     | 6,99                 | 2,0-12,0                  | fulfilled  |
| 10                    | 1,68                 | 0-4,0                     | fulfilled  |

Ergebnis:

average degree of substitution: **6,43**  
 acceptance criterion for  
 average degree of substitution: 6,2-6,9 **fulfilled**