

Chapter in a Recently Published Book - Sulfobutylether-Cyclodextrins: Structure, Degree of Substitution and Functional Performance

A new book dealing with cyclodextrins entitled "Cyclodextrins: Synthesis, Chemical Applications and Role in Drug Delivery" has been recently released by Nova Science Publishers, Inc., New York (Editor: Francis G. Ramirez). Cyclolab colleagues (István Puskás, Erzsébet Varga, Kata Tuza, Julianna Szemán, Éva Fenyvesi, Tamás Sohajda and Lajos Szente) contributed to this hardcover edited collection with a chapter entitled "Sulfobutylether-cyclodextrins: Structure, Degree of Substitution and Functional Performance" and summarized in this editorial.

Sulfobutylether Cyclodextrins: Variability of DS and Performance

The major scope of the chapter is the demonstration of the applicability of different sulfobutylether cyclodextrins (SBECD) in the light of different cavity sizes and average DS. Some historical data are also presented. In the 1990's SBECD of different average DS were concurrently available and used in early phase drug formulation and toxicology studies. A number of publications dealt with the use of SBECD of low DS [1-4]. Qu et al. synthesized sulfobutyl ether- β -cyclodextrin of DS 2.5: ^1H NMR indicated that the primary hydroxyl group was mainly subject to the substitution. MS spectra showed that no more than one substitution occurred on a single glucose unit [5]. Comparative studies were demonstrated in the early patent of Stella et al. [6] wherein the association constants (K) of SBE7- β -CD, SBE4- β -CD and SBE1- β -CD (i.e. SBECD of DS=7; 4 and 1, respectively) with different substances were enumerated. In one case the DS versus K correlation had a minimum type of curve (for progesterone), while digoxin and phenytoin showed a descending correlation (SBECD of low DS binds the strongest) and testosterone showed an ascending correlation. Thompson [7] compared (amongst other CD derivatives) to what extent sulfobutylether cyclodextrin (SAECD) derivatives such as SBE7- β -CD, SBE4- β -CD and SBE1- β -CD show hemolytic behavior in concentrations typically used to solubilize pharmaceutical formulations. The hemolytic activity was found in the order of SBE7- β -CD < SBE4- β -CD << SBE1- β -CD << β -CD. From the data it may be derived that the use of SBE7- β -CD was considered the safest.

Mosher et al. demonstrated the applicability of SBEB CD of different average degrees of substitution (4, 7 and 11) for solubilizing amiodarone resulting in a liquid formulation which is dilutable without the risk of drug precipitation [8]. SBEB CD of average DS of 7 was found the preferred composition.

The effect of DS on the applicability of different CD derivatives in capillary electrophoresis for chiral separations in pharmaceutical analysis (SBEB CD included) was reviewed by de Boer et al. [9]. Herein it is emphasized that the use of commercially available CDs having a defined DS may lead to a better modeling, optimization, reproducibility, and to a more rugged separation system.

From the year 2000 the use of SBEB CD of DS 7 is overwhelming, since SBE7- β -CD was selected for the clinical studies and later this material was specified in the USP. It must be noted herein that the denotation of DS 7 is somewhat misleading, since the average DS of the USP compliant substance is between 6.2-6.9. The denotation reflects that the required distribution profile may be attained easier if the DS is closer to 7.

Zia et al. attempted to find correlation between the DS and binding of molecules to SBEB CDs with varying degrees of sulfobutyl ether substitution. Complexation constants of molecules to SBEB CDs were calculated as a function of temperature, enabling the estimation of thermodynamic parameters, including the enthalpy and entropy of binding. Binding constants of various molecules to SBEB CDs did not show a uniform trend to total degree of sulfobutylether substitution. However, a distinct pattern was observed with the enthalpy and entropy of complexation. The results showed the complexation of substrates to SBEB CDs to be more entropy-favored as the number of sulfobutyl ether groups increased. This favorable entropy was compensated by a less favorable enthalpy of interaction [10].

Skanchy et al. elaborated a separation technique for the enantiomers of the basic drug bidisomide from five closely related known process impurities using novel sulfobutylether derivative mixtures and separated fractions having a specific DS (i.e isolated SBEB CD types having degrees of substitution from one to seven). Fractions having a lower DS provided adequate chiral and achiral selectivity allowing both chiral and achiral purity to be determined in a single run [11].

It may be therefore concluded from all these prior studies that the number of the sulfobutyl ether moieties (presumably owing to a combined effect of steric and electrostatic factors) may play a significant role in the binding process. Strict standardization of the DS profile evidently yields greater trust in the reproducible performance in the pharmaceutical and analytical fields of use. However, the versatile features of the potential variable SBEB CD compositions may not be fully exploited this way.

The chapter also presents the own work of Cyclolab conducted on the investigation of possible impact of the degree of substitution and number of anhydroglucose units. The applicability of sulfobutylated cyclodextrins was also studied in several aspects.

The utility of three different analytical techniques (HPLC, capillary electrophoresis and NMR) for investigating these cyclodextrin compositions were evaluated and compared. The strength of NMR is that the determined DS value is not distorted since the result is based on the signal areas corresponding to the anomeric glucose and sulfobutyl side-chain protons. On the other hand NMR only provides the average DS value, while by capillary electrophoresis (CE) the distribution profile may be obtained, too. The drawback of using CE is poor intermediate precision, moderate pH and background electrolyte composition sensitivity, questionable accuracy and limitation in the characterization of high-DS SBE-CDs. An alternative HPLC method was elaborated to overcome such disadvantages. By this technique the separation of SBEB CD components is based on anion exchange and inclusion complexation providing efficient separation of not only the SBEB CD components, but also residual beta-cyclodextrin and the synthesis related impurities. The HPLC method, however, can not be used for calculation of degree of substitution because of the non-linear characteristics of the evaporative light scattering detection method.

CE and solubility tests were utilized for the characterization of the host-guest type interactions between drug molecules and various sulfobutyl ether cyclodextrin compositions. Comparative data were collected how SBE-CD compositions differing from the favored, highly specified grade complying US Pharmacopoeia 37 may be used for pharmaceutical purposes. The aim of the study was to establish grounds for future extension of the applicability of sulfobutylated cyclodextrins in the field of e.g. pharmaceuticals, analytical method development and environmental technologies. Based on the collected data it has been demonstrated that multiple factors may play significant role in the binding process ensuring some sort of selectivity amongst the members of the cyclodextrin library used. Besides the dimensions of the cavities, the steric effect of the relatively bulky sulfobutyl ether moieties as well as the charge born on the terminal of the substituent chains influence the strength of interaction.

The research conducted by Cyclolab also focused on the effect of degree of substitution on complex stability constants. Within the study 12 test molecules were investigated. Many of these molecules prefer the cavity of β -CD. Complex stability constants were determined with CE by calculation using the x-reciprocal method. The stability constants vs. DS were plotted. The compounds were classified into four groups according to the type of trend.

- I. Minimum curve
- II. Maximum curve
- III. Ascending curve
- IV. Descending curve

12 drugs were selected based on the potential utility and due to the fact that these pharmaceuticals are commonly used. Their structures represent a wide versatility, therefore firm correlation on the found trends and the chemical characteristics should not be made. Nevertheless it is assumed that two major factors influence the affinity of SBEB CDs ranked in increasing DS.

- The bulky sulfobutylether substituents block the cavity of the β -CD exposing a steric hindrance for the binding process (geometric factor).
- By increasing the DS, the charge of the host increases making the SBEB CD molecule more attractive to guest of opposite charge (electrostatic factor).

In conclusion it may be postulated that in certain cases the association may be primarily driven by geometric factors or primarily by electrostatic factors. For the minimum and maximum curve type drugs, probably the resultant of both factors influence the interaction.

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Antifungal activity, Biodegradable active films, Bio-active hydrocolloids, Controlled release, β -Cyclodextrin, Propionic acid

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