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Preparative separation of nadolol racemates using reversed-phase liquid chromatography

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Nadolol is a nonselective beta-adrenergic receptor antagonist (β-blocker) pharmaceutical drug, widely used in the treatment of cardiovascular diseases, such as hypertension, ischemic heart disease (angina pectoris), congestive heart failure, and certain arrhythmias. Its chemical structure has three stereogenic centers which allows for eight possible stereoisomers. However, the two hydroxyl substituents on the cyclohexane ring are fixed in the cis-configuration, which precludes four stereoisomers; in fact, two pairs of enantiomers. Nadolol is presently marketed as an equal mixture of the four stereoisomers, designated as the diastereoisomers, “racemate A” and “racemate B” [1].

There are still few published works concerning the separation of nadolol stereoisomers. Most of these works refer the resolution at analytical scale and few refer the separation at preparative scale using the simulated moving bed (SMB) technology [2-4]. This technology is generally based on the use of chiral adsorbents which must have enough recognition for all the chiral species.

In this work it is proposed an alternative strategy, implementing a first achiral separation step, to be followed by two subsequent parallel chiral separation steps. In this first achiral step, C18 columns are used to perform the separation of the two pairs of nadolol enantiomers (“racemate A” from “racemate B”) under reversed-phase mode.

Extensive experimental and simulation results will be presented including solvent screening, measurement of equilibrium and kinetic data, and both fixed-bed and SMB preparative separations. These different separation strategies will be compared in terms of system productivity and solvent consumption.

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