

Enantiomeric Purity of Epinephrine Base and Bitartrate

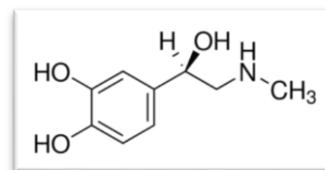
Chirality is one of those fundamental properties of molecular systems which are ubiquitous in nature. Notably, a number of important biological compounds including proteins, amino acids, nucleosides, sugar, and a number of hormones, which are the basic building blocks of life, are chiral and thus the chemistry of many fundamental biological (metabolic and regulatory) processes are directly controlled by such molecular systems [1].

Chiral molecules are stereoselective with regard to specific biological functions. Enantiomers differ considerably in their physiological reactions with the human body [1].

Adrenaline/Epinephrine as part of **TRANSO-PHARM**'s product portfolio is such a typical example. Natural occurring Adrenaline emerges in R-configuration and turns the oscillation plane of light to the left ($[\alpha]_{20/D}$: -50.0 to -54.0°).

L-Adrenaline (R-(-) Adrenaline)

R-Epinephrine is approx. 15 to 40 times more pharmacologically active than its S- enantiomer (D-Adrenaline). Therefore, high purity of the "right" enantiomer has to be ensured by the production process and efficiently analytically controlled. Patient safety has to be safeguarded!

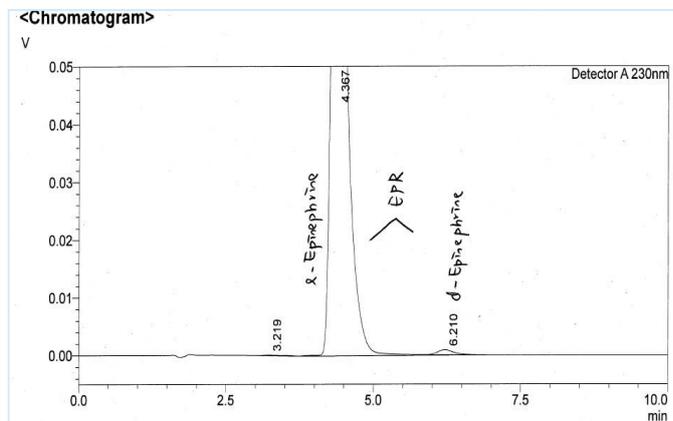


Asymmetric synthesis is a mature approach to the production of single enantiomers [1] compared to the old-school racemate segregation by means of diastereomer precipitation. Since **TRANSO-PHARM** well established a stereo-selective process we have been in the position to supply our customers with commercial L-Adrenaline showing an Enantiomeric Excess (ee) of 99% for some years now.

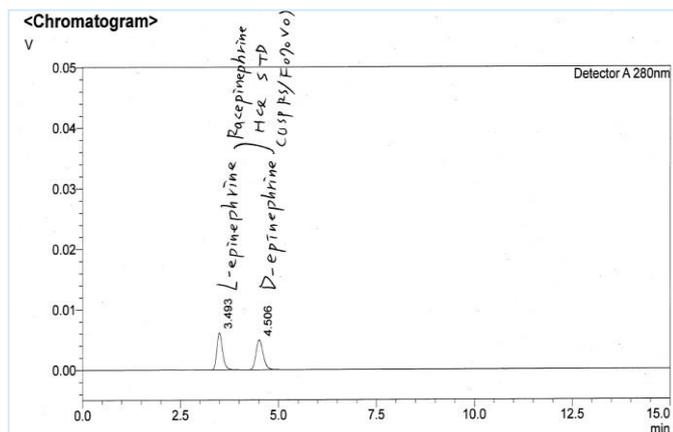
The applied homogenous catalyst is not commercially available in the market. Therefore, it is manufactured in-house in Germany using our own IP, which ensures a reliable & robust supply chain.



Illustrative ee – inhouse HPLC chromatogram



Illustrative ee – USP HPLC chromatogram (SST)



Conclusion

Transo-Pharm's homogenous enantioselective Epinephrine synthesis stands out due to:

- 99% enantiomeric excess in commercial batch size
- straightforward process flow without repetition of purification/enrichment steps
- low consumption of organic solvents
- chromatographic purity of 99.8% and better
- 5 years re-test

[1] Enantiomeric Recognition and Separation by Chiral Nanoparticles; A. Gogoi, N. Mazumder, S. Konwer, H. Ranawat, N. Chen, G. Zhuo; *Molecules* 2019, 24, 1007