THE CONNECTING LINK
TRANSO-PHARM

Transo-Pharm's successful co-operation with the USP - during the update of the Epinephrine USP 42.2 monograph

With the USP 42.2 - effective 1st of December 2019 – several changes have been implemented in the Epinephrine USP monograph.
The current USP 43.1, which is in place since 1st of August 2020 does not contain any changes to Epinephrine.

1. The Epinephrine USP monograph prior to the December 2019 revision was completely outdated and did not meet the global requirements of the ICH (International Conference of Harmonization) e.g. regarding impurities. In contrast to the USP, the corresponding Ph. Eur. Monograph (under the name of Adrenaline) has long been able to meet these international requirements.

2. Transo-Pharm supported the USP with regards to the revision of the Epinephrine monograph. We were in correspondence and discussion with the responsible USP Scientific Officer in the course of the update process. Here we were able to establish the HPLC purity test method. The USP opted for a 3.0% enantiomeric purity limit. Mainly because Transo-Pharm would otherwise probably be the only supplier of pharmacopoeia quality being able to meet this parameter.
Syn-Tech (Transo-Pharm's CMO) has already regularly tested the ***enantiomeric purity*** [1] at the start of production in 2016 and has always generated results between 0.8 – 1.1%. The manufacturing method transferred from Boehringer Ingelheim is a highly innovative and enantioselective process, which is based on a homogeneous catalyst that generates this unique purity in the first process step. Thus, this is one of our unique selling points compared to the synthesis route of the competitors who rely on the classic, old Racemate split.

3. In addition, we have already developed, validated and used an ***HPLC test method*** [1] for the epinephrine assay determination when we started producing. The USP finally took over this superior methodology after 3 years with its revision.

Conclusion: Our first Epinephrine batch from 2016 was already in line with today's USP 43.1.

Did you know ?
USP changed the **numbering** system for all **USP** Reference Standard catalog numbers into a year based name and version. It starts with the official date on 05/01/2021 with publication title 2021-1 (previously *USP* 44–*NF* 39), followed by 2021-2 (previously *First Supplement* to *USP* 44–*NF* 39) on 08/01/2021 and 2021-3 (previously *Second Supplement* to *USP* 44–*NF* 39) on 12/01/2021.

[1] https://www.transopharm.com/blog/enantiomeric-purity-and-the-associated-advantages-of-transo-pharms-epinephrine-synonym-adrenaline