Recipharm
good for business

PHARMACEUTICAL DEVELOPMENT SERVICES

IMPURITY IDENTIFICATION

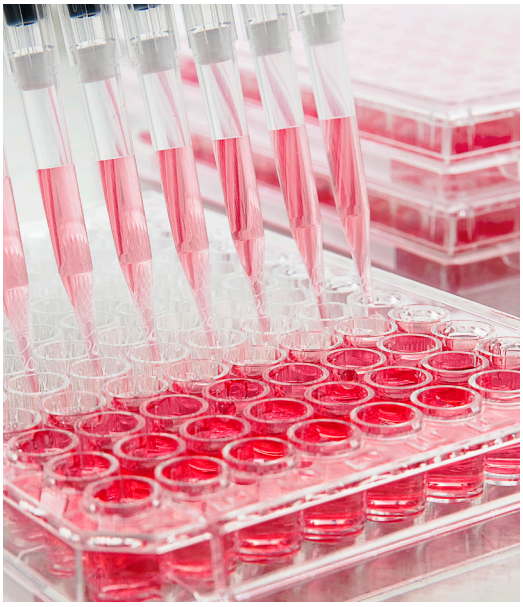
Recipharm has extensive experience and a wide range of analytical and synthetic equipment to conduct successful impurity identification in pharmaceutical products.

According to the ICH Q3A(R2) and Q3B(R2) guidelines, impurities in any dosage form, or API, must be identified during the product development. Additionally, any degradation product, observed in stability studies at recommended storage conditions, at a level greater than the identification threshold should also be identified.

At Recipharm we offer:

- Development of a mass spectrometry (MS)-suitable ultra performance liquid chromatography (UPLC) method for the separation of the examined impurity
- High resolution mass spectrometry (HRMS) analysis for the determination of molecular weight and formula of the impurity using a QTof mass spectrometer
- Fragmentation mass spectrometry (MS/MS) analysis of the impurity and related compounds for the structure elucidation of the impurity
- Verification of the structure-MS/MS spectrum consistency based on ion thermochemistry using the NIST MS Interpreter 2.0 software
- Isolation of the impurity, from the drug product, using preparative high performance liquid chromatography (HPLC)
- Nuclear magnetic resonance (NMR) analysis for the structure elucidation of the impurity
- Proposition of the molecular structure of the examined impurity on the basis of the MS/MS and NMR analyses results
- Chemical synthesis of the reference material with the proposed structure
- Confirmation of the proposed structure by comparative UPLC-MS/MS analysis employing the synthesized reference material
- Suggestion of the impurity origin and its formation pathway

Recipharm
good for business



About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 6,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 20 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

For more information contact: info@recipharm.com

recipharm.com