Application Note
Pharmaceutical industry

SCHMIDT HAENSCH

Determination of Amphetamine in Pharmaceutical Formulations

Reliable Enantiomeric Analysis Using the VariPol Polarimeter

Amphetamine, Alpha-methylphenethylamine, and its derivatives are widely used in pharmaceutical formulations for the treatment of neurological and behavioral disorders, particularly attention deficit hyperactivity disorder (ADHD), narcolepsy, and certain fatigue-related conditions.

As a chiral compound, amphetamine exists in two stereoisomeric forms that differ significantly in their pharmacological activity. The stereochemical composition of pharmaceutical amphetamine products therefore has a direct influence on therapeutic effectiveness, dosage requirements, and regulatory acceptance.

In pharmaceutical chemistry, chirality plays a fundamental role because many biologically active compounds interact stereoselectively with receptors, enzymes, and transport systems. Even small variations in enantiomeric composition may alter efficacy, metabolic behavior, or side-effect profiles. For this reason, modern pharmaceutical manufacturing requires reliable analytical methods capable of monitoring stereochemical purity with high precision.

Amphetamine belongs to the phenethylamine class and is structurally related to a wide range of psychoactive and therapeutic compounds. Depending on its stereochemical configuration, amphetamine can exhibit different physiological effects. Dextroamphetamine is considered the pharmacologically more active enantiomer, while levoamphetamine contributes differently to the overall pharmacodynamic profile.

Because of these differences, pharmaceutical manufacturers must ensure strict control over the stereochemical composition of both active pharmaceutical ingredients (APIs) and finished formulations.

In pharmaceutical production environments, several analytical challenges must be addressed:

- Verification of stereochemical composition
- Monitoring of batch-to-batch consistency
- Detection of deviations in optical activity
- Reliable documentation for regulatory compliance
- Efficient routine analysis in quality control laboratories

For routine quality control laboratories, rapid and reproducible analytical approaches are highly desirable. One established analytical principle for evaluating chiral pharmaceutical compounds is the measurement of optical activity with a polarimeter.

Chiral molecules interact with plane-polarized light and rotate its polarization plane
either clockwise or counterclockwise depending on their stereochemical configuration. This optical rotation provides valuable information regarding stereochemical composition and enantiomeric purity.

When acetylated amphetamine derivatives are dissolved in chloroform, they exhibit measurable optical rotation that can be correlated with stereochemical composition. This analytical principle enables highly reproducible determination of specific rotation values under controlled laboratory conditions.

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Solution from SCHMIDT + HAENSCH

Using the SCHMIDT + HAENSCH VariPol Polarimeter provides a highly precise method for determining the optical rotation. The system enables fast and reliable measurement of specific rotation, ensuring accurate control of enantiomeric purity of amphetamine formulations and compliance with pharmacopeial standards. The VariPol allows measurements under defined conditions of concentration, temperature, and wavelength. In combination with the Aquisys3 software, it offers secure data management, full traceability, and compliance with regulations such as 21 CFR Part 11, while supporting efficient workflows. This integrated solution ensures reliable quality control, and guarantees consistent pharmaceutical product quality.

VariPol
Polarimeter

Product type	Product
Polarimeter	VariPol B Modular Polarimeter for Pharma & more
Accessories	VariTouch Display
Accessories	VariTube Flow-through, 100 mm
Accessories	Quartz control plate

Advantages

- High-precision optical rotation measurement
- Excellent temperature stability
- User-friendly software and workflow integration
- Fast and reproducible analysis
- Ideal for enantiomeric purity determination
- Compliance with pharmacopeial standards
- Reliable quality control of chiral pharmaceuticals
- 21 CFR Part 11 compliant
- Non-destructive by design

Typical industries

- Pharmaceutical industry
- Analytical laboratories
- Quality control laboratories