

CONTROLLED SUBSTANCES

At Recipharm we have been supporting customers with their controlled substance projects for more than 25 years. Our state-of-the-art manufacturing facilities have the infrastructure to safely and securely handle potent materials and we are approved to import, store, manufacture and export Class 1-5 controlled substances.

Our experience can seamlessly guide you to the most appropriate formulation and manufacturing process for your product requirements, even for complex products, such as modified release or abuse deterrent formulations. We also have the experience to formulate cohesive, adhesive and electrostatic drug substances.



WHAT IS A CONTROLLED SUBSTANCE AND HOW ARE THEY REGULATED?

A controlled substance is a drug or chemical whose manufacture, possession, or use is regulated by authorities. This class includes many compounds that cause significant problems due to abuse, however many compounds are also valuable as a pharmaceutical.

Therefore the manufacture of controlled drugs (CD) is a vital part of today's pharmaceutical industry that looks set to grow substantially over the coming years. Understandably, control of goods in this market requires an appropriate set of stringent rules and regulations, which manufacturers and distributors alike must adhere to.



SCHEDULES FOR CONTROLLED SUBSTANCES

SCHEDULE	DESCRIPTION	EXAMPLES
I	These drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.	Heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4- methylenedioxy-methamphetamine (ecstasy), methaqualone, and peyote.
II	These drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.	Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.
III	These drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.	Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.
IV	These drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.	Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.
V	These drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for anti-diarrheal, antitussive, and analgesic purposes.	Cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

Source: Drug Scheduling (dea.gov)

Our integrated offering means we can be your single source for controlled drug substance and product development through to commercial manufacture and packaging.

At Recipharm we offer:

- ▶ Development, testing and commercial manufacture of CD
- ▶ An established supply chain for import and export of drug substance and drug product within Europe and the USA
- ▶ Storage of CD products
- ▶ Capabilities within both non-GMP and GMP
- ▶ Various stages of clinical formulation development from Phase I to Phase III clinical studies
- ▶ Supporting analytical chemistry development and stability studies



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 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 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.