Moravek, Inc.

GMP [^{14}C] API Manufacturing for Use in Clinical Trials

577 Mercury Lane, Brea CA 12,000ft^2 one of three facilities

GMP Solutions Offered by Moravek

- **GMP [^{14}C] API Manufacturing**
  For use in human clinical trials
- **Technical Batch Synthesis**
  Used to confirm synthetic pathway and establish radiolabeled compound stability
- **GMP HPLC Method Transfer, Development and Validation**
  Services include HPLC system suitability and are carried out utilizing six qualified HPLC and UPLCs
- **GMP Analytical Services and GMP Purification of [^{14}C] API**
  NMR of various nuclides, MS, GC/MS, LC/MS, HPLC, UPLC, Karl Fischer and other analytical services available
- **Quality Assurance Release of [^{14}C] API under GMP**
  Quality Assurance review and approval of all GMP production and analytical documentation prior to release of API
- **GMP Temperature Controlled Stability Studies**
  NIST traceable temperature recording at +4, -20 and -80°C utilizing qualified HPLC systems
- **Comprehensive Logistics Services**
  Storage, chain of custody, dispensing, shipping to clinics worldwide, temperature tracking

www.moravek.com info@moravek.com USA p 800-447-0100 International p + (1)714-990-2018

Quality Systems

Properly designed and implemented Quality Systems, including GMP Standard Operating Procedures, are essential to ensuring that your GMP [^{14}C] API will succeed in receiving approval from regulatory bodies for use in a clinical trial.

The GMP Quality Assurance team at Moravek has over thirty years of industry experience in GMP API Manufacturing.

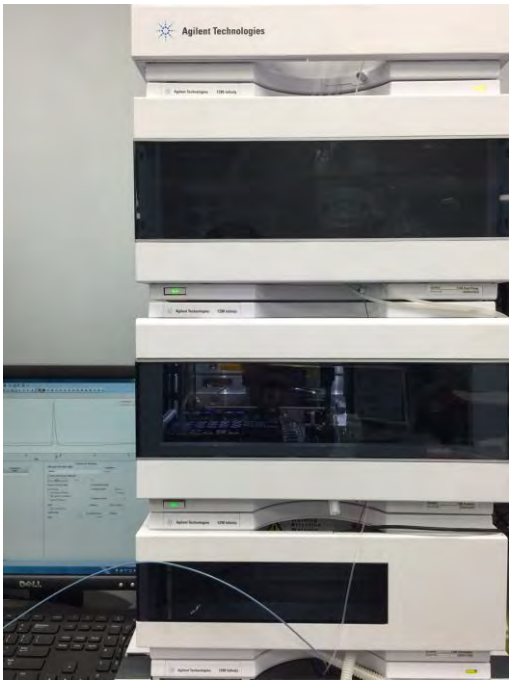
Moravek's Quality Assurance team has worked closely with regulatory bodies and dozens of clients to design and implement comprehensive GMP compliant quality systems and operating procedures that consistently satisfy all essential compliance activities including procurement, quarantine and release of reagents, manufacturing, isolation, quality control, chain of custody, temperature tracking, proper labeling, documentation and release of GMP [^{14}C] API while adhering to FDA GMP guidance ICH Q7A.

Since the addition of GMP ISO 7 Cleanrooms 2 and 3 in 2012, GMP Quality Systems and facilities at Moravek have successfully passed all client and regulatory body Quality Assurance inspections including a GMP inspection carried out by Merck and the California Department of Public Health. Moravek has passed all Quality Systems inspections and was approved to manufacture GMP [^{14}C] API for clinical trials.

Moravek has manufactured over thirty GMP [^{14}C] APIs since 2012, all of which have met both our client's Quality Assurance criteria as well as the acceptance criteria of the clinical trial regulatory bodies.

Moravek welcomes your Quality Assurance onsite inspection of our GMP facilities and systems. Please contact us to schedule an inspection.

One of two NMRs



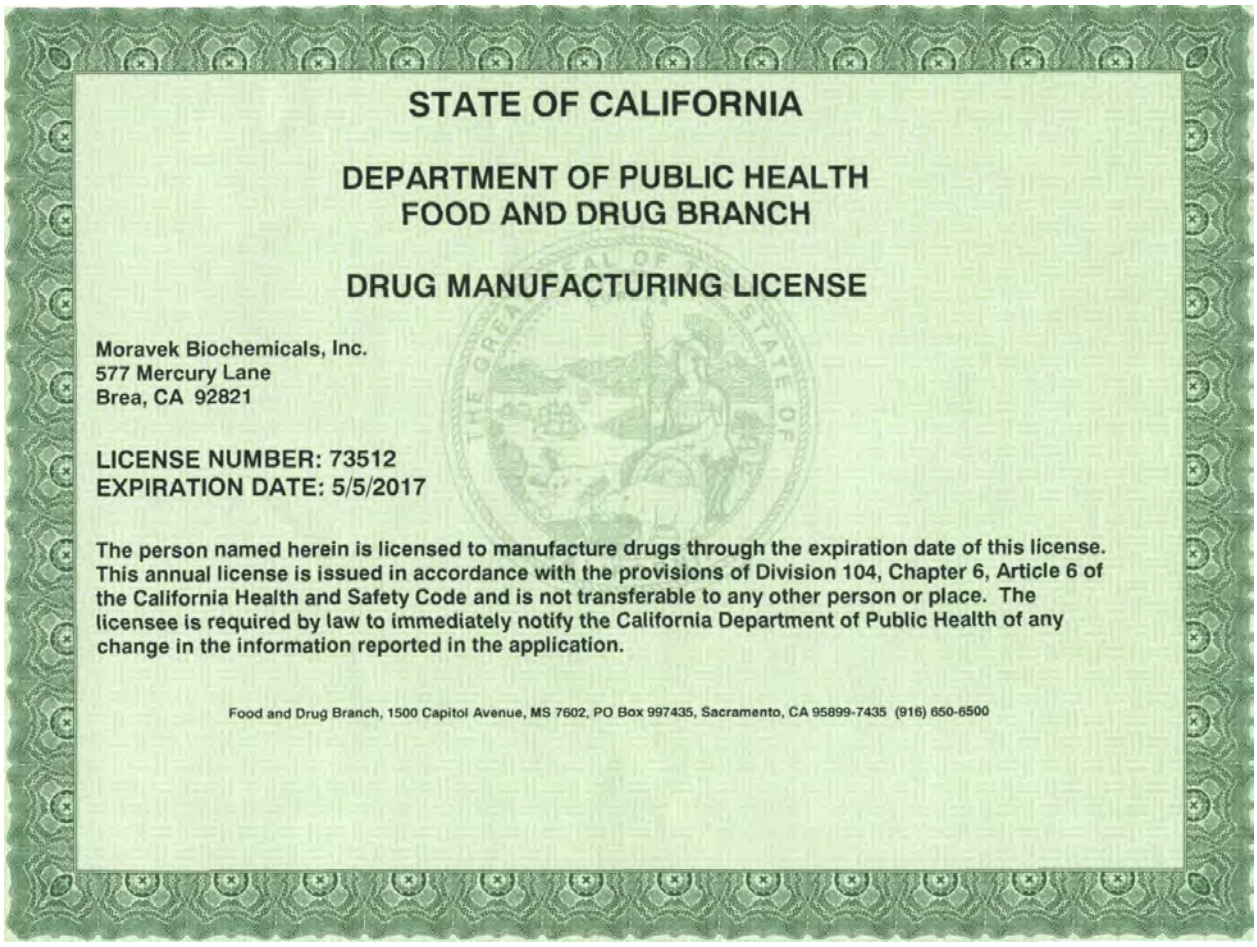
One of six qualified UPLC and HPLCs

The GMP [^{14}C] API manufacturing process begins with a conversation between you and Moravek GMP and radiochemistry specialists. Project scope of work, clinical requirements and scheduling are all discussed. All elements essential to your clinical trial's success will be discussed in order to arrive at an appropriate scope of work and to insure the success of your GMP [^{14}C] API campaign.

Contact Moravek by phone at 714-990-2018 or email at info@moravek.com to schedule a teleconference or to arrange an inspection of the Quality Assurance program and Moravek GMP facilities.

GMP [^{14}C] API Manufacturing and Controlled Substance

GMP [^{14}C] Active Pharmaceutical Ingredients (APIs) are manufactured under license from the California Department of Public Health while adhering to FDA GMP guidance ICH Q7A.



STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DRUG MANUFACTURING LICENSE

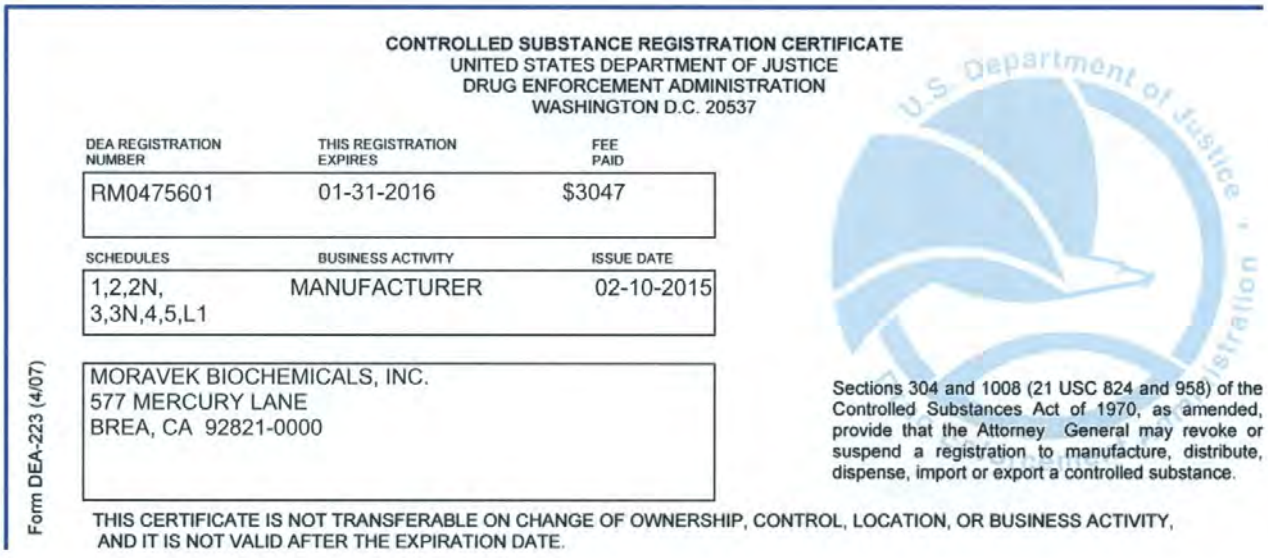
Moravek Biochemicals, Inc.
577 Mercury Lane
Brea, CA 92821

LICENSE NUMBER: 73512
EXPIRATION DATE: 5/5/2017

The person named herein is licensed to manufacture drugs through the expiration date of this license. This annual license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Moravek can manufacture a nearly unlimited variety of GMP [^{14}C] APIs including all DEA schedule 1 through 5 substances under a current Manufacturing License from the Federal DEA.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0475601	01-31-2016	$3047

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L1	MANUFACTURER	02-10-2015

MORAVEK BIOCHEMICALS, INC.
577 MERCURY LANE
BREA, CA 92821-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (4/07)

GMP [^{14}C] API Manufacturing Facilities and Equipment

Three Purpose Built ISO Class 7 Certified GMP [^{14}C] API Manufacturing Suites

Qualified Instrumentation

- Five Agilent HPLCs and one Agilent 1290 UPLC are all maintained under current IQ/OQ
- Four Mettler UMX2 ultra-microbalances are all maintained under current IQ/OQ
- Four Mettler XP205 semi-microbalances are all maintained under current IQ/OQ
- Two Thermo Finnigan triple quad mass spectrometers are both maintained under current IQ/OQ
- Mettler Toledo V20 compact volumetric Karl Fischer titrator with current IQ/OQ
- Bruker UltraShield 400 Plus NMR with broadband probe
- GE Analytical Instruments Model 900 Laboratory TOC analyzer utilized for verification of laboratory cleanliness prior to release of any of our three clean rooms for a new GMP campaign
- HEPA filtration of incoming air is used to reduce particulates in each of the three GMP laboratories
- UV light treatment of incoming air is used to reduce bacteria in each of the three GMP laboratories
- Clean room compatible two part epoxy painted walls and ceiling minimize dust in each of the three GMP laboratories
- Positive pressurized isolated changing area in each of the three GMP laboratories
- Cleanroom engineered Armstrong Medintec welded seam flooring in each of the three GMP suites and changing areas
- Interconnected cleanroom entry doors utilize a lock system that prevents any gowning area door and cleanroom door from being open at the same time
- Sub-Zero stainless steel +4^{o}C and -20^{o}C storage with computer temperature logging in each of the GMP laboratories
- Computer logging of GMP laboratory pressure, humidity, HEPA filtration performance and UV light operation in each of the three GMP laboratories
- Laminar flow make up air system with less than 100 linear feet per minute for GMP laboratories 2 and 3
- Automatic electrical backup natural gas powered generator for uninterruptable power to enable continuation of computer logging, refrigerator and freezer operation in case of electrical power failure

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