

## Capability, Dependability, and Trust

Teva's API Division, a leading supplier of Active Pharmaceutical Ingredients with more than 70 years of experience and over \$1 billion in annual sales, is now offering custom synthesis and contract manufacturing of steroids, cytotoxics, high potency compounds, vitamin D derivatives, fermentation products, peptides, and nanoparticle technology.

Teva's API Division is poised to deploy our highly experienced team of scientists and state-of-the-art R&D and manufacturing facilities to provide you with a full range of development services from basic research to full scale commercial GMP manufacturing.

### EXPERIENCE COUNTS

Teva's API Division includes over 3,250 employees and 18 FDA, EMEA, & JP inspected and approved manufacturing sites worldwide. The facilities incorporate cutting-edge technologies and state-of-the-art computerized manufacturing systems to promote high and consistent product quality, improved productivity, and reliability. Teva's API Division is prepared to build the required production capabilities as part of a long-term commitment to support our customers.

Teva's API Division offers more than 250 APIs, most of which are registered in various regulated markets that include the US, Canada, Europe, and Japan. Teva's API Division has supported a variety of dosage form applications including ANDAs, NDAs, and 505(b)(2) applications. Because we are a global enterprise, we are not only well-versed in the CMC sections of US FDA applications, but we are also experienced with the registration of products worldwide including Canada, Europe, and Japan.

The R&D group employs approximately 500 top scientists worldwide who are specialized in the fields of chemical synthesis, fermentation, high potency compounds (both synthetic and fermentation), analytical chemistry, physical properties, and nanotechnology.

### PROJECT MANAGEMENT

Your entire project – from development of synthetic strategies employing a diverse range of chemical reactions, development of analytical methods for purification and analysis, validation of processes and scale up, stability, identification of impurities for registration and commercial scale production, GMP production and post-approval regulatory support – will be managed by our experienced teams.

We can develop a novel process or use your already developed process. We will work closely with your team and arrange meetings, laboratory and manufacturing site visits, and audits. All work will be carried out under strict confidentiality and, if required, we will enter into a formal written confidentiality agreement.

Teva's API Division has over 2,500 patents issued and pending worldwide. As part of our development procedures, we aim to ensure protection of all intellectual property and industry property rights. We will collaborate with our customers in managing these rights.



## **Our Custom Synthesis and Contract Manufacturing Expertise**

### **STEROIDS, CYTOTOXICS, AND HIGH POTENCY COMPOUNDS**

- Over 20 years of experience in development and manufacturing
  - Synthetic, semi-synthetic, and fermentation
- State-of-the-art facilities to handle high potency compounds
- DSP development
- Capacity to produce grams, kilograms, and metric tons of API
  - Four production sites supporting R&D, lab scale, pilot scale, and commercial scale requirements

### **VITAMIN D DERIVATIVES**

- Over 30 years of experience in development and manufacturing
- Multi-step synthesis capabilities
  - Extensive experience with handling sensitive compounds
- Capacity to produce grams, several hundred grams, and kilograms of API
  - Two production sites supporting R&D, lab scale, pilot scale, and commercial scale requirements

### **FERMENTATION**

- Over 50 years of experience in development and manufacturing
- Biotechnology and strain improvement
- DSP development
- Production of API with superior quality and yields
  - One of the largest manufacturers of "statins" worldwide
  - Large variety of fermentation and semi-synthetic products
- Capacity to produce grams to metric tons of API
  - Two production sites supporting R&D, lab scale, pilot scale, and commercial scale requirements

### **PEPTIDES**

- Over 15 years of experience in development and manufacturing
- Solid phase, solution phase, and hybrid approaches
  - Synthetic capabilities include unnatural amino acids, peptide conjugates, fatty acid derivatives, and glycopeptides
- Capacity to produce grams to hundred kilograms of API
  - Two production sites supporting R&D, lab scale, pilot scale, and commercial scale requirements

### **NANOPARTICLE TECHNOLOGY**

- Accessibility to various "nano" technologies that cover a wide range of products and particle sizes
- Two proven proprietary advanced technologies
- Regulatory expertise



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## Quality and Support

Quality is the cornerstone upon which Teva's API Division is built. We make it our mission, at every level of the organization, to promote top quality products and services. This mission is nurtured and fulfilled through extensive employee training programs.

### CUSTOMER SERVICE

Teva's API Division adds a new dimension to the concept of customer service. The Division provides uniquely specialized services, tailored and designed to aid customers in reducing their time to market. A dedicated customer service team is geared to provide full technical and scientific support to the customer including worldwide shipments and customs clearance.

### CORPORATE SUPPORT

Teva's API Division is a standalone unit of Teva Pharmaceutical Industries Limited, a leading global generic and innovative pharmaceutical company. Both Teva's API Division and Teva Pharmaceuticals Industries Limited are fast-growing, financially sound organizations. By working with Teva's API Division, the customer will benefit from a partnership with a stable, long-term supplier who will be there to support them when their products are launched. We have comprehensive pharmaceutical knowledge and a flexible framework adaptable to changing requirements and market conditions.

### CONTACTS

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