



# Excel with us



Fermion is a subsidiary  
of Orion Corporation

# Fermion in brief

Fermion develops, manufactures and markets active pharmaceutical ingredients (APIs) to companies in global generic market as well as under exclusive contracts to companies focusing on new chemical entities (NCEs). Fermion is fully owned subsidiary of Orion Corporation and headquartered in Espoo, Finland. Together with Orion we are a fully integrated contract development and manufacturing organization (CDMO) and offer services covering both drug substances and drug products. All contract manufacturing services of Orion Group are marketed by Fermion.

Our API product portfolio consists of over 25 generic APIs and over 15 NCEs. Fermion's two state-of-the-art manufacturing sites as well as R&D facilities including a modern bench scale operation are all located in Finland. Fermion has systematically invested and expanded capabilities in the production of highly potent compounds (HPAPIs).

Focus areas of drug product contract manufacturing services include hormonal and non-hormonal semi-solids, liquids, cytotoxic oral solids and packaging services. Also small volume parenterals and non-cytotoxic oral solids can be offered. We have three manufacturing sites and one packaging centre for drug products at Orion.

All Fermion and Orion sites operate according to current Good Manufacturing Practice (cGMP) and apply high environmental, health and safety and other sustainability standards. Our facilities are regularly inspected by all the relevant authorities, including the U.S. Food and Drug Administration (FDA), and are frequently audited by our partners and customers.

OVER  
**25**  
GENERIC APIS

OVER  
**15**  
CDMO APIS

OPERATES IN  
FINLAND, EMPLOYS  
**400**  
PROFESSIONALS

## Locations and facility profiles



### SALO SITE

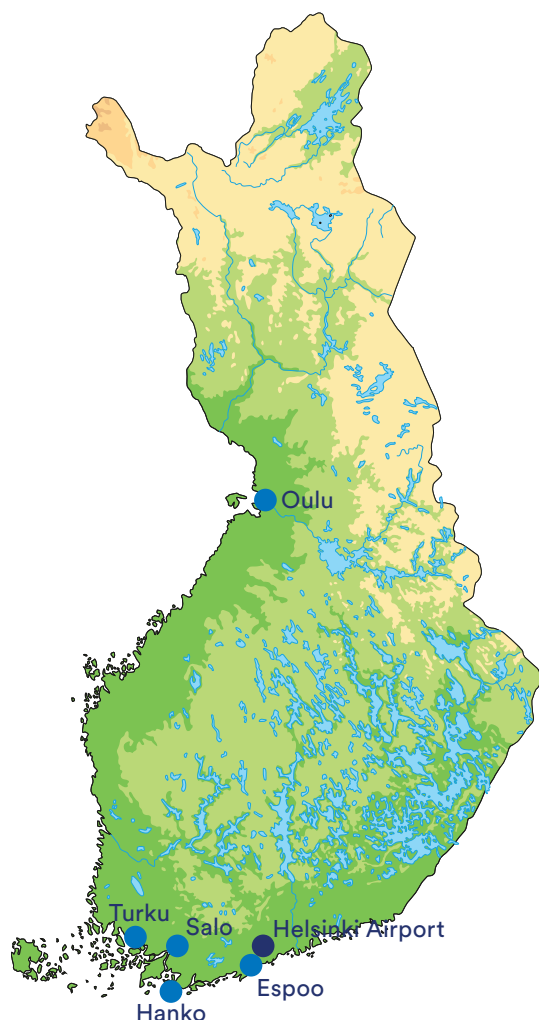
- Centralized warehouse
- Tablet packaging

### TURKU SITE

- Hormone gels & solutions
- Tablets & capsules
- Cytotoxic tablets
- Creams & ointments

### ESPOO SITE

- Tablets & capsules
- Inhalations



### OULU SITE

- Highly potent, OEB4-5 APIs
- Cytotoxic APIs
- OEB5 micronization

### ESPOO SITE

- Kilo-scale R&D API unit
- Corporate functions
- R&D

### HANKO SITE

- Large volume APIs
- Highly potent, OEB4-5 APIs





## CDMO API

Fermion's CDMO API services cover the needs of a customer from Phase I clinical studies until commercial production. Currently there are 12 originally new chemical entities wherein Fermion has had an important role during the development of the drug substance. These molecules are sold on the global market including USA, EU, Japan and China. To secure timely completion of each critical phase of customer's NCE project, we follow a carefully designed process with milestones and deliverables set for Phase I, II, and III, and for moving to commercial phase.

Fermion's R&D organization consists of two groups of synthesis development scientists and two groups process engineers. These teams are supported by 20 laboratory technicians. For scale-up work the R&D department has a kilo scale unit located in Espoo and pilot scale unit located in Oulu. The pilot scale unit can also be utilised in commercial manufacturing. The total headcount of Fermion's R&D is 50 employees. Nearly 30% of the scientists have PhD degree.

Fermion has two commercial USFDA and EMA approved API manufacturing sites. Total volume of reactors is 325 m<sup>3</sup>. Fermion's Hanko site handles production of higher volume products, whereas Fermion's Oulu site focuses more on smaller volume high potency APIs including cytotoxic compounds. We have capabilities to commercially manufacture highly potent OEB5 APIs from a scale of 1–2 kg per batch up to one metric ton. This includes all aspects from chemistry to final handling including micronization and packaging.

All contract manufacturing services of Orion Group are marketed by Fermion. This also applies to finished dosage form (FDF) contract manufacturing where the services, however, are provided by Fermion's mother company Orion. We have over 45 years of experience in pharmaceutical production. Together with drug products Fermion can offer full-service package, one-stop-shop solution. The key dosage forms we can offer are non-sterile hormonal and non-hormonal semi-solids, including OEB4 or 5 classified gels, ointments, solutions and liquids as well as cytotoxic oral solids or conventional tablets or capsules. All drug product manufacturing sites comply the requirements of the major regulatory authorities including USFDA, EMA as well as Japanese, Russian and Brazilian officials. Fermion's marketing and key account management team and Orion's project and technical support team helps a customer all the way from the development and technology transfer to full scale commercial manufacturing.

In hormonal semisolids we have one single dose sachet filling and packaging line and three bottle filling lines. Two bottle filling lines are integrated with secondary packaging lines including serialisation and aggregation capabilities. In non-hormonal semisolids we have one line for oral syringe filling and packaging and two lines for plastic and aluminium tube filling and packaging, and furthermore, one glass and plastic bottle filling and packaging line. Oral solids manufacturing capabilities are integrated with state-of-the-art packaging centre in Salo. Blister and bottle lines with serialisation and aggregation are available both for conventional and cytotoxic formulations.



## CMO Drug product

# Generic API

Fermion has a strong position in global market with a number of its generic APIs.

PRODUCT	USA	EUROPE	JAPAN	BRAZIL/KOREA/CHINA
Alprazolam	DMF	CEP	JMF	
Azathioprine	DMF	CEP	JMF	KDMF
Benserazide		CEP		KDMF
Budesonide		CEP		
Buspirone HCl	DMF	CEP		
Carbidopa	DMF	CEP		BDMF, KDMF
Dabrafenib				
Dexmedetomidine	DMF	ASMF	JMF	BDMF, CDMF, KDMF
Diltiazem HCl	DMF	ASMF		
Entacapone	DMF	ASMF		KDMF
Fluticasone propionate		CEP		
Formoterol fumarate	DMF	CEP	JMF	CDMF
Glipizide	DMF			
Hydroxychloroquine sulphate	DMF	CEP		
Irinotecan HCl	DMF	ASMF	JMF	BDMF, CDMF, KDMF
Levosimendan	DMF	ASMF		
Mercaptopurine	DMF	CEP	JMF	
Methotrexate	DMF	CEP	JMF	BDMF
Methotrexate disodium	DMF	ASMF		
Nadolol	DMF	ASMF	JMF	
Nintedanib	DMF	ASMF		KDMF
Nitrofurantoin Macrocrystals	DMF	CEP		
Nitrofurantoin Monohydrate	DMF	ASMF		
Quetiapine fumarate	DMF	CEP		
Sodium cromoglicate	DMF	CEP	JMF	CDMF
Tolnaftate	DMF	ASMF		
Toremifene Citrate	DMF	ASMF	JMF	
Trazodone HCl	DMF	ASMF		