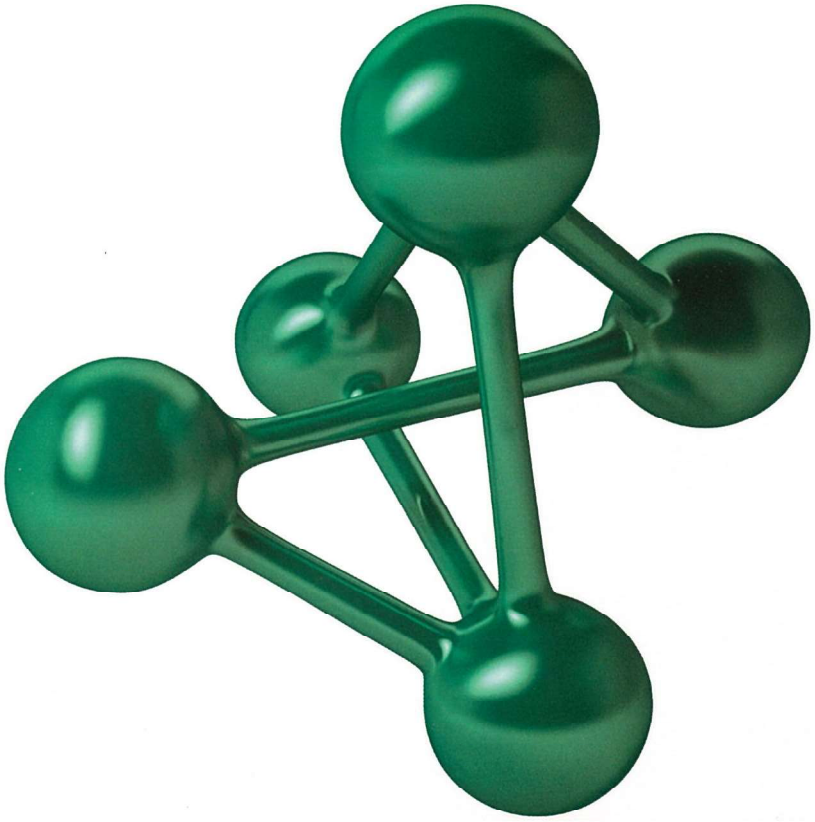
OlainFarm

Your Health is Our Passion!



DKSH

DKSHジャパン株式会社　生産資材事業部門　化学品ビジネスライン

〒108-8360 東京都港区三田 3-4-19　Phone 03-5441-4526, Fax 03-5441-4528
〒542-0081 大阪市中央区南船場 4-3-11 豊田ビル　Phone 06-6282-0174, Fax 06-6282-1718
www.dksh.jp

Company Profile

- Located 25 km of Riga, Latvia
- Company established in 1972
- Olainfarm is an innovative manufacturer of Finished dosage forms, Original and Generic APIs, API intermediates, Specialty organic chemicals
- Site area 430 000 sq. meter, multipurpose plant
- Full cGMP compliance
- Products offered in gram to tons quantities

Research and Development

- Synthetic route scouting
- Technology optimization/upscale
- Development and Validation of analytical methods
- Determination and characterization of impurities
- Degradation studies and stability testing

Our Chemistry Know-how

- Quinuclidine chemistry
- Adamantane chemistry
- Chiral amino acids
- Hydrogenations
- Handling of hazardous chemicals
- Metalorganic chemistry

Contract Manufacturing

- APIs and Intermediates manufacturing
  We offer full cycle API and Intermediates development/upscale/manufacturing under cGMP

QC/QA and Regulatory Documentation Support

- Compilation of Active Substance Master File (ASMF) and Dossiers in CTD and eCTD formats
- Qualification and Validation (facility, equipment and process validation)
- Conducting internal audits as part of self-inspection program to ensure compliance to GMP standards and also vendor audits
- Preparation of Quality Reviews (PQR)
- Change control, deviation investigation and handling of market complaints
- QC of Raw materials, in-process samples and finished products

Equipment

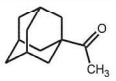
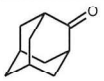
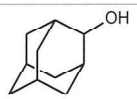
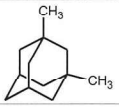
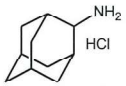
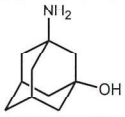
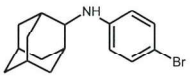
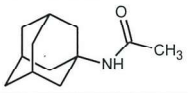
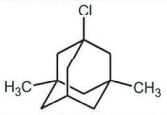
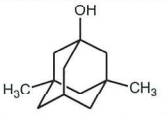
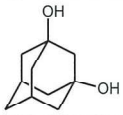
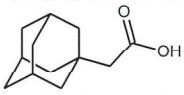
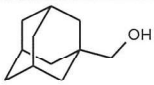
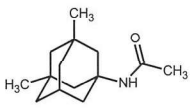
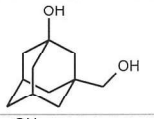
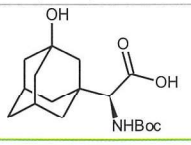
1. HPLC/UPLC (UV, MS, LSD, RI)
2. GC, GC-MS
3. Particle size analysis
4. IR, UV, Optical rotation, mp, XRPD, NMR
5. Solubility determination
6. Automatic titrators

Kilo Lab/Pilot plant/Production plant

- Plant area — 45000 sq. meters
- Operating volume — 219 000 liters
- Operating temperature — -10 to +200 deg. C (-50 to +200 deg. C for the Kilo lab)
- Operating vaccum — 3–5 mBar

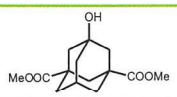
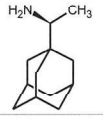
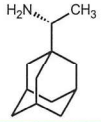
Intermediates

Adamantane derivatives

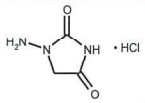
No.	Chemical name	Structural formula	Molecular formula	CAS No.	Key use	Stage
1.	1– Adamantyl methyl ketone (1– Acetyladamantane)		$C_{12}H_{18}O$	[1660–04–4]	Rimantadine hydrochloride	C
2.	2– Adamantanone		$C_{10}H_{14}O$	[700–58–3]		C
3.	2– Adamantanol (2– Hydroxyadamantane)		$C_{10}H_{16}O$	[700–57–2]		P
4.	1,3– Dimethyladamantane		$C_{12}H_{20}$	[702–79–4]	Memantine hydrochloride	C
5.	2– Aminoadamantane hydrochloride		$C_{10}H_{17}N \cdot HCl$	[10523-68-9]		P
6.	3– Amino – 1– hydroxy– adamantane		$C_{10}H_{17}NO$	[702–82–9]	Vildagliptin	C
7.	N– (2– Adamantyl)– N– (4– bromophenyl)amine		$C_{16}H_{20}BrN$	[87913–26–6]		P
8.	1– Acetylamidoadamantane		$C_{12}H_{19}NO$	[880–52–4]		L
9.	1– Chloro– 3,5– dimethyladamantane		$C_{12}H_{19}Cl$	[707–36–8]	Memantine hydrochloride	C
10.	1– Hydroxy– 3,5– dimethyladamantane		$C_{12}H_{20}O$	[707–37–9]	Memantine hydrochloride	C
11.	1,3– Dihydroxyadamantane (1,3– Adamantanediol)		$C_{10}H_{16}O_2$	[5001–18–3]		L
12.	1– Adamantaneacetic acid (1– Adamantylacetic acid)		$C_{12}H_{18}O_2$	[4942–47–6]		P
13.	1– Adamantanemethanol (1– Adamantylmethanol)		$C_{11}H_{18}O$	[770–71–8]		P
14.	1– Adamantaneethanol [2– (1– Adamantylethanol)]		$C_{12}H_{20}O$	[6240–11–5]		P
15.	1– Acetylamido– 3,5– dimethyladamantane		$C_{14}H_{23}NO$	[19982–07–1]	Memantine hydrochloride	L
16.	3– (Hydroxy– methyl)adamant – 1 – ol		$C_{11}H_{18}O_2$	[38584–37–1]		I
17.	(2S)– [(tert – Butoxycarbonyl)amino](3 – hydroxyadamant – 1 – yl)ethanoic acid		$C_{17}H_{27}NO_5$	[361442–00–4]	Saxagliptin	L

Intermediates

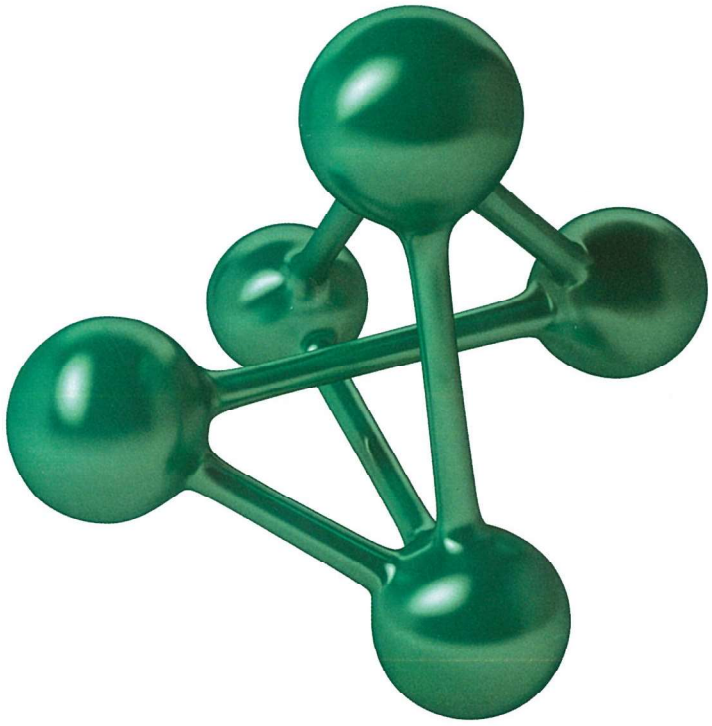
Adamantane derivatives

No.	Chemical name	Structural formula	Molecular formula	CAS No.	Key use	Stage
18.	Dimethyl-5-hydroxy-1,3-Adamantane dicarboxylate		$C_{14}H_{20}O_5$	[213274-64-7]		P
19.	S-Rimantadine		$C_{12}H_{21}N$	[887336-06-3]		P
20.	R-Rimantadine		$C_{12}H_{21}N$	[887336-05-2]		P

Miscellaneous

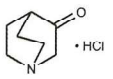
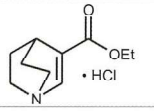
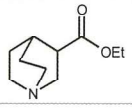
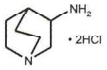
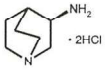
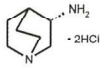
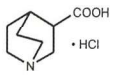
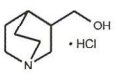
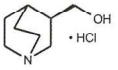
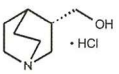
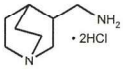
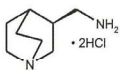
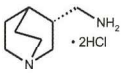
No.	Chemical name	Structural formula	Molecular formula	CAS No.	Key use	Stage
1.	1– Aminohydantoin hydrochloride		$C_3H_5N_3O_2 \cdot HCl$	[2827–56–7]	Dantrolene Nitrofurantoin	C

C – Commercial, P – Pilot, L – Laboratory



Intermediates

Quinuclidine derivatives

No.	Chemical name	Structural formula	Molecular formula	CAS No.	Key use	Stage
1.	3-Quinuclidinone hydrochloride		$C_7H_{11}NO \cdot HCl$	[1193-65-3]	Aceclidine Azasetron Cevimeline Clidinium Mequitazine Quifenadine	C
2.	3-Carbethoxy-dehydro-quinuclidine hydrochloride		$C_{10}H_{15}NO_2 \cdot HCl$	[50790-85-7]		C
3.	3-Carbethoxyquinuclidine		$C_{10}H_{17}NO_2$	[6238-33-1]	Quifenadine	C
4.	3-Quinuclidinol		$C_7H_{13}NO$	[1619-34-7]	Aceclidine Clidinium Quinupramine Aclidinium	C
5.	S-(+)-3-Quinuclidinol ee 99.5%		$C_7H_{13}NO$	[34583-34-1]		C
6.	R-(-)-3-Quinuclidinol ee 99.9%		$C_7H_{13}NO$	[25333-42-0]	Solifenacin Aclidinium	C
7.	3-Aminoquinuclidine dihydrochloride		$C_7H_{14}N_2 \cdot 2HCl$	[6530 09 2]		C
8.	R-(+)-3-Aminoquinuclidine dihydrochloride ee up to 99.5%		$C_7H_{14}N_2 \cdot 2HCl$	[123536-14-1]		C
9.	S-(-)-3-Aminoquinuclidine dihydrochloride ee 99.5%		$C_7H_{14}N_2 \cdot 2HCl$	[119904-90-4]	Palonosetron	C
10.	3-Quinuclidine carboxylic acid hydrochloride		$C_8H_{13}NO_2 \cdot HCl$	[6238-34-2]		L
11.	3-hydroxymethyl quinuclidine hydrochloride		$C_8H_{15}NO \cdot HCl$	[79221-75-3]		L
12.	R-3-hydroxymethyl quinuclidine hydrochloride		$C_8H_{15}NO \cdot HCl$	Free base [138874-55-2]		L
13.	S-3-hydroxymethyl quinuclidine hydrochloride		$C_8H_{15}NO \cdot HCl$	Free base [88644-21-7]		L
14.	3-aminomethyl-quinuclidine dihydrochloride		$C_8H_{16}N_2 \cdot 2HCl$	[865887-14-5]		L
15.	S-3-aminomethyl-quinuclidine dihydrochloride		$C_8H_{16}N_2 \cdot 2HCl$			L
16.	R-3-aminomethyl-quinuclidine dihydrochloride		$C_8H_{16}N_2 \cdot 2HCl$			L

C – Commercial, P – Pilot, L – Laboratory

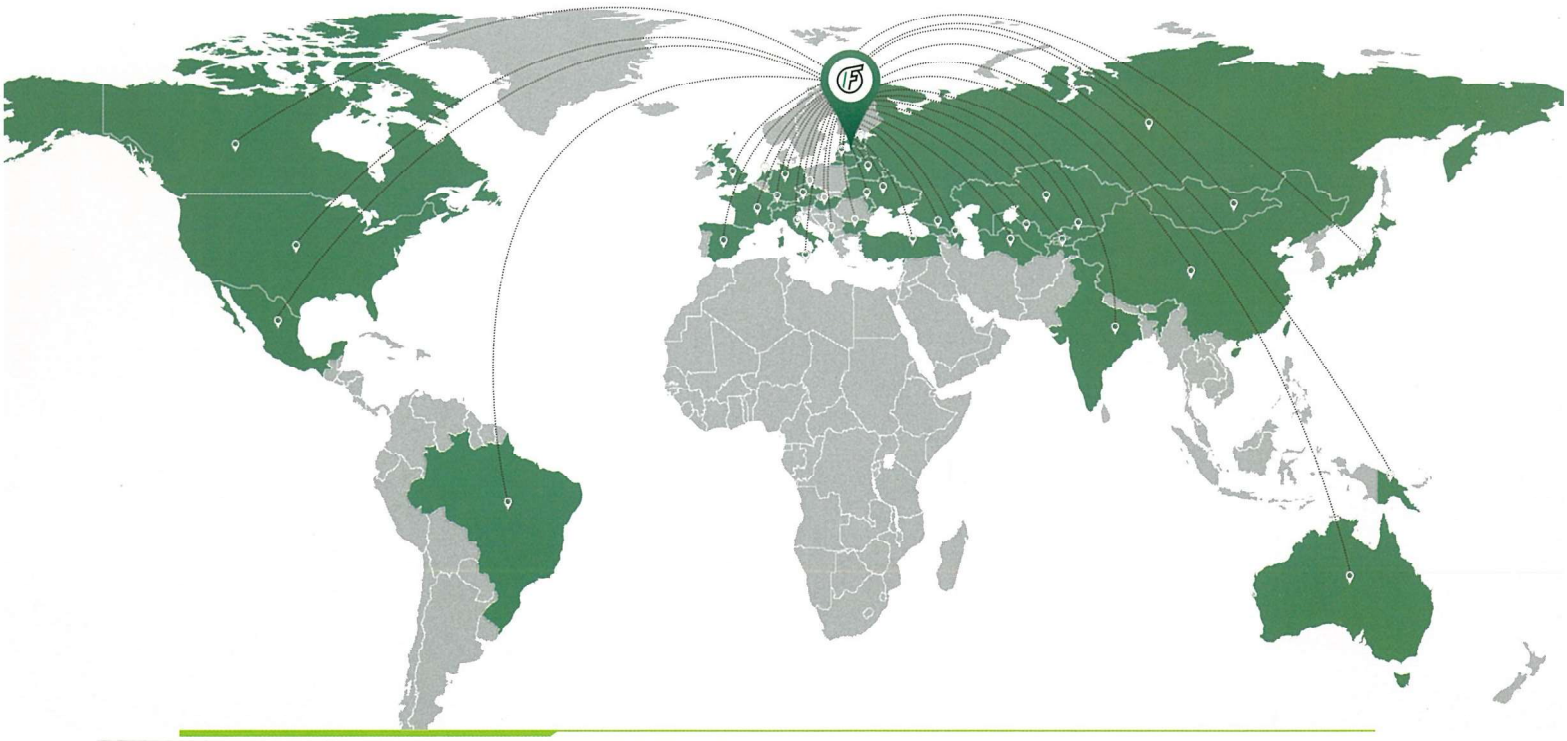
YOUR HEALTH IS OUR PASSION SINCE 1972

Olainfarm is the leading manufacturer in the chemical and pharmaceutical sector of the Baltic States with more than 40 years of experience.

Certificates

- EU GMP for APIs and FDFs
- US cGMP for certain APIs (FDA)
- TGA for FDFs (Australia)
- ISO 14001 Environmental Management System
- ISO 17025 Laboratory Management System

Export to more than 40 countries



DKSH

DKSHジャパン株式会社　生産資材事業部門　化学品ビジネスライン
〒108-8360 東京都港区三田 3-4-19　Phone 03-5441-4526, Fax 03-5441-4528
〒542-0081 大阪市中央区南船場 4-3-11 豊田ビル　Phone 06-6282-0174, Fax 06-6282-1718
www.dksh.jp