CARBOGEN AMCIS

A Dishman Group Company

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Vitamin D, Vitamin D Analogues, Cholesterol and Lanolin Alcohols

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ALFACALCIDOL Ph. Eur./IP/BP

(1α-Hydroxycholecalciferol)

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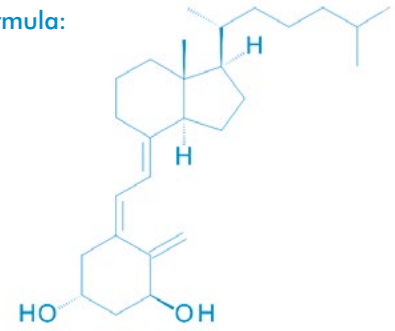
Alfacalcidol is a vitamin D3 analog for the Pharmaceutical and Veterinary industry. Alfacalcidol is especially used to prevent and treat osteoporosis or decalcification of bones. The substance is also active against other bone growth disorders such as osteomalacia, rickets and specific liver and parathyroid glands abnormalities. It is also used for the treatment and prevention of secondary hyperparathyroidism associated with chronic kidney disease (CKD).

CARBOGEN AMCIS manufactures this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Alfacalcidol; 1α-hydroxycholecalciferol; 1α-hydroxyvitamin D3
Content Alfacalcidol (HPLC) is 97.0-102.0%
CAS 41294-56-8

•• **Structural formula:**



CAS no. 41294-56-8

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: CEP/CoS and DMF available.

Application: Pharmaceutical and Veterinary industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

ARS - Working Standard

Alfacalcidol – CAS no. 41294-56-8

Available Impurities

Impurity A (trans-Alfacalcidol) – CAS no. 65445-14-9
Impurity B (Betacalcidol) - CAS no. 63181-13-5
Impurity C (triazoline adduct of pre-Alfacalcidol) – CAS no. 82266-85-1

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CALCIFEDIOL Ph. Eur./USP/IP/BP

(25-Hydroxycholecalciferol)

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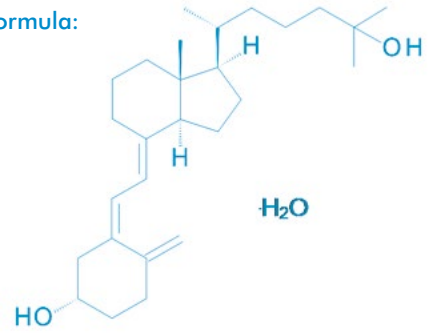
Calcifediol is a vitamin D3 analog for the Pharmaceutical and Veterinary industry. Calcifediol is especially used to prevent and treat osteoporosis or decalcification of bones. The substance is also active against other bone growth disorders such as rickets, osteomalacia and specific liver and parathyroid glands abnormalities. It is also used for the treatment and prevention of secondary hyperparathyroidism associated with chronic kidney disease (CKD).

CARBOGEN AMCIS manufactures this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Calcifediol; 25-hydroxyvitamin D3; 25-hydroxycholecalciferol; 25-HCC
Content Calcifediol (HPLC) is 97.0-102.0%
CAS 63283-36-3 (monohydrate), 19356-17-3 (anhydrous)

•• **Structural formula:**



CAS no. 63283-36-3 (monohydrate), 19356-17-3 (anhydrous)

Toxic classification: Harmful (category Xn). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: CEP/CoS and DMF available.

Application: Pharmaceutical and Veterinary industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

ARS - Working Standard

Calcifediol – CAS no. 63283-36-3

Available Impurities

Impurity A (25-hydroxylumisterol) - CAS no. 61585-29-3

Impurity B (25-hydroxy-7-dehydrocholesterol) - CAS no. 22145-68-2

Impurity C (25-hydroxytachysterol) – CAS no. 39932-44-0

Impurity D (trans-25-hydroxyvitamin D3) – CAS no. 1233749-00-2

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CALCITRIOL Ph. Eur./USP/IP/BP

(1α,25-Dihydroxycholecalciferol)

CARBOGEN AMCIS
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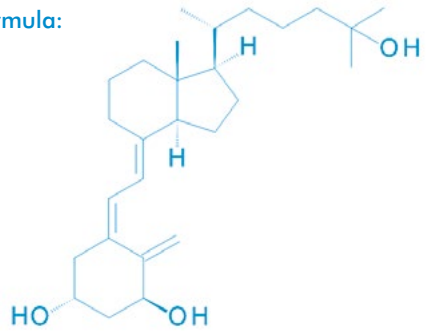
Calcitriol is a vitamin D3 analog for the Pharmaceutical and Veterinary industry. Calcitriol is especially used to prevent and treat osteoporosis or decalcification of bones. The substance is also active against other bone growth disorders such as osteomalacia, rickets and specific liver and parathyroid glands abnormalities. It is also used for the treatment and prevention of secondary hyperparathyroidism associated with chronic kidney disease (CKD).

CARBOGEN AMCIS manufactures this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Calcitriol; 1α,25-dihydroxycholecalciferol; 1α,25-dihydroxyvitamin D3; 1,25 DHCC
Content Calcitriol (HPLC) is 97.0-102.0%
CAS 32222-06-3

•• **Structural formula:**



CAS no. 32222-06-3

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: CEP/CoS and DMF available.

Application: Pharmaceutical and Veterinary industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

ARS - Working Standard

Calcitriol – CAS no. 32222-06-3

Available Impurities

Impurity A (trans-Calcitriol) – CAS no. 73837-24-8
Impurity B (1beta-Calcitriol) – CAS no. 66791-71-7
Impurity C ((Phenyl)triazoline adduct of pre-Calcitriol) – CAS no. 86307-44-0

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CHOLESTEROL HP

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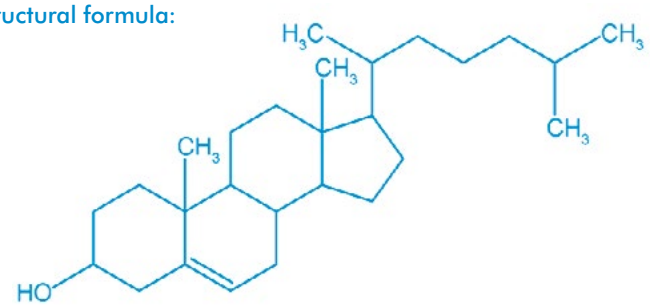
Cholesterol HP is made from wool grease by extraction and refining processes. Cholesterol HP is soluble in most common organic solvents and vegetable oils but insoluble in water.

Specification: Cholesterol HP is a white crystalline powder
Cholesterol (GC), 99.0 - 101.0%
Total sterol (GC), ≥ 99.5%

•• **Structural formula:**



CAS no. 57-88-5

Regulatory: Cholesterol HP is made under cGMP regime. We have an up to date DMF and CoS/CEP. We can also offer a technical package with full regulatory support.

Application: Cholesterol HP is used in liposomal formulations. It enables controlled release by encapsulation of drugs/actives in injectables and it can be used as a carrier for diagnostic substances. Cholesterol HP has excellent emulsifying properties and can be used to enable transdermal transport.

Packing: Aluminum laminated bags of 1 kg, packed under nitrogen.

Storage: To avoid contamination keep the bags well closed.

Stability: Retest after 5 years if kept in the original, unopened packing.

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CHOLESTEROL NF

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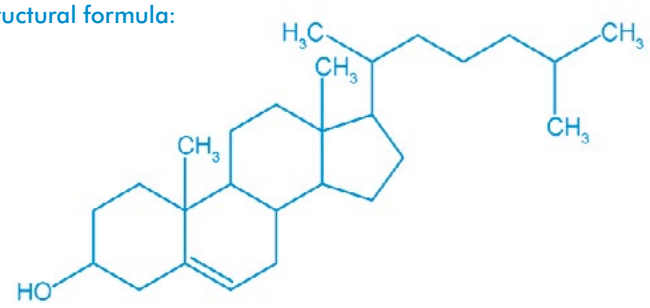
Cholesterol NF is a white, crystalline powder. It is made from wool grease by extraction and refining processes. Cholesterol NF is soluble in most common organic solvents and vegetable oils but insoluble in water.

Specification: Cholesterol (GC), ≥ 95%
Total sterol (GC), ≥ 97-102%
A-tocopherol, 50-350ppm (anti-oxidant)

•• Structural formula:



CAS no. 57-88-5

Application: Cholesterol NF is widely used as an emulsifying agent in cosmetic preparations. Cholesterol functions as an excellent moisturizer in skin conditioning cosmetics and is used as a raw material for the synthesis of vitamin D3 and liquid crystals.

Packing: Fibre drums containing 10, 25 or 50 kg net in plastic foil. We can also provide Cholesterol NF-one, packed in 1kg plastic containers.

Storage: To avoid contamination keep the drums well closed.

Stability: Retest after 3 years, if stored at ambient temperature in original undamaged packing.

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CHOLESTEROL SF

CARBOGEN AMCIS
A Dishman Group Company

Cholesterol SF is a slightly off-white powder. It is made from wool grease by extraction and refining processes. Cholesterol SF is insoluble in water. The product consists of cholesterol and approximately 1% Aerosil to improve flowability.

Specification: Cholesterol (GC), ≥ 91%
Total sterol (GC), ≥ 97%
A-tocopherol, ≥ 50ppm (anti-oxidant)

CAS no. 57-88-5

Application: As an ingredient for shrimp feed Cholesterol is an essential molecule for the synthesis of molting hormones, sex hormones, bile acids, vitamin D and is a building block of shrimp tissues. Cholesterol cannot be metabolized by the shrimp and has therefore to be added to the shrimp feed.

Particle size: 100% < 1000 microns
98% < 500 microns
80% < 250 microns

Formulation: Recommended inclusion rate:
-Larval feed: 1%
-Shrimp feed: 0.3-0.5% depending on growth stage
Cholesterol should be added before extrusion, together with other fatty compounds.

Packing: Fibre drums containing 25 kg or 50 kg net, lined with plastic foil.

Storage: To avoid contamination keep the drums well closed.

Stability: Retest after 3 years, if stored at ambient temperatures in original undamaged packing.

DIHYDROTACHYSTEROL
Ph. Eur. (DHT-2 or Dihydrotachysterol-2)

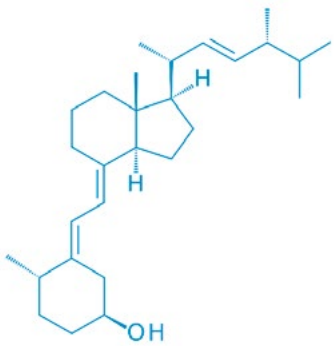
CARBOGEN AMCIS
A Dishman Group Company

Dihydrotachysterol-2 (DHT-2) is a vitamin D2 analog for the Pharmaceutical industry. DHT2 is used in the prevention and treatment of several bone growth disorders such as osteoporosis. Besides this the substance is also used to treat several abnormalities of the parathyroid glands such as hypoprathyroidism.

Our Dihydrotachysterol-2 is made under cGMP regime. CARBOGEN AMCIS supplies this API from Veenendaal, the Netherlands.

Specification: Chemical name: Dihydrotachysterol-2; DHT-2; DHT Content Dihydrotachysterol-2 (HPLC) is 97.0-102.0%
CAS 67-96-9

•• Structural formula:



CAS no. 67-96-9

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: CEP/CoS and DMF available.

Application: Pharmaceutical industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

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ERCALCIDIOL

CARBOGEN AMCIS
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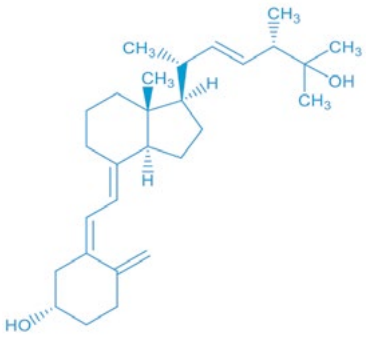
Ercalcidiol is an active Vitamin D2 analog for the Pharmaceutical industry. Ercalcidiol can be used for the treatment of disorders in Calcium and Phosphor homeostasis. It can also be used as a marker for Vitamin D3 catabolism and a predictor of serum 25-hydroxycholecalciferol response to Vitamin D3 supplementation.

Specification: Chemical name: Ercalcidiol; 25-hydroxyergocalciferol; 25-hydroxy D2
Content Ercalcidiol (HPLC) is ≥ 90%
CAS 21343-40-8

•• Structural formula:



CAS no. 21343-40-8

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: Non-GMP material

Application: Pharmaceutical industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

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LANOLIN ALCOHOL

Dusoran

CARBOGEN AMCIS
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Dusoran® is a yellowish, waxy solid. Dusoran® is a purified mixture of sterols (Cholesterol, Lanosterol, Desmosterol and numerous other sterols) and aliphatic alcohols and diols (C18-C32), branched and non-branched. Dusoran® is soluble in mineral oils, ethanol, chloroform, diethylether, light petroleum ether and toluene. It is insoluble in water. Dusoran® is obtained by molecular distillation of saponified Lanolin. Supplied in pellet format.

Specification:

Saponification value (mgKOH/g):	≤ 10
Acid value (mgKOH/g):	≤ 5
Color (Gardner) 22.5 g/100 ml:	≤ 10
Cholesterol (GC):	8 – 13%
Dropping point:	50 - 80°C
Melt behaviour:	clear melt at 90 °C

Use:

Dusoran is ideal for use in hair colourants, hair conditioners, hair treatment (relaxing and perming), 2 in 1 hair combination products etc. In skincare applications, Dusoran can be used in both facial and body care.

Benefits:

Dusoran contributes to the performance for hair colourants, hair conditioners, hair treatment - (relaxing and perming), 2 in 1 hair combination products etc. Its key products benefits for haircare are:

- Volume
- Gloss
- Prevention (premature oily hair)
- Protection - head irritation
- Excellent Sensory properties

In skincare applications, Dusoran can be used in both facial and body care. For skincare its key product benefits are:

- Moisture control
- Controlled transdermal transport
- Protection
- Convenience
- Sensory characteristics

Packing:

Carton box with inliner containing 20 kg net.

Stability:

Dusoran is stable for at least one year.

PARICALCITOL USP

(19-NOR-1α,25-dihydroxyergocalciferol)

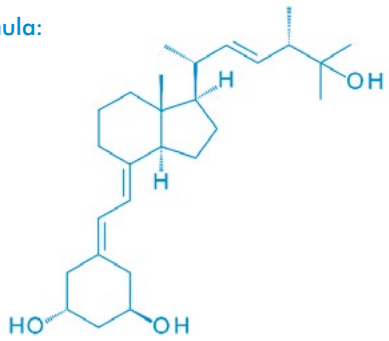
CARBOGEN AMCIS
A Dishman Group Company

Paricalcitol is an active Vitamin D2 analog for the Pharmaceutical industry. Paricalcitol is used for the treatment and prevention of secondary hyperparathyroidism associated with chronic kidney disease (CKD). It has been shown to reduce parathyroid hormone levels by inhibiting its synthesis and secretion.

CARBOGEN AMCIS manufactures this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Paricalcitol; 19-NOR-1α,25-dihydroxyergocalciferol; 19-NOR-1α,25-dihydroxy D2
Content Paricalcitol (HPLC) is 97.0-103.0%
CAS 131918-61-1

•• **Structural formula:**



CAS no. 131918-61-1

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: DMF available. An ASMF has been filed and accepted in several European countries.

Application: Pharmaceutical industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

ARS - Working Standard

Paricalcitol – CAS no. 131918-61-1

Available Impurities

22Z-Paricalcitol – CAS no. 1884139-61-0

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SECALCIFEROL

(24R, 25-Dihydroxycholecalciferol)

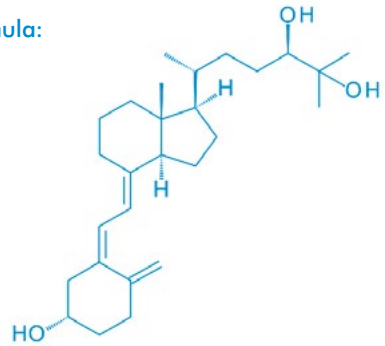
CARBOGEN AMCIS
A Dishman Group Company

Secalciferol is an active Vitamin D analog for the Pharmaceutical industry. Secalciferol can be used for the treatment of disorders in Calcium and Phosphor homeostasis. It can also be used as a marker for Vitamin D3 catabolism and a predictor of serum 25-hydroxycholecalciferol response to Vitamin D3 supplementation.

This product is in development. CARBOGEN AMCIS can already supply non-GMP R&D material of this API. CARBOGEN AMCIS can produce this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Secalciferol; 24R, 25-dihydroxycholecalciferol; 24R, 25-dihydroxyvitamin D3; 24R 25 DHCC Content Secalciferol (HPLC) is ≥ 95%
CAS 55721-11-4

•• Structural formula:



CAS no. 55721-11-4

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: Non-GMP material.

Application: Pharmaceutical industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

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TRIAZOLINEDIONE

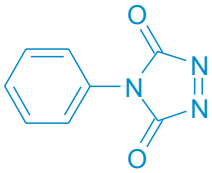
CARBOGEN AMCIS
A Dishman Group Company

We produce Triazolinedione (TAD) for captive use. We use TAD as auxiliary in our syntheses of vitamin D analogs. TAD are also widely used in organic and polymer chemistry, especially valued in their role in “click chemistry” due to their rapid and catalyst-free reactions under mild conditions.

TADs are employed for ultrafast modification and crosslinking of polymers, creation of self-healing materials, and in bioconjugation for selectively labeling amino acids in peptides and proteins. TAD reagents are used for selective modification of specific amino acids (notably tyrosine and tryptophan) in peptides and proteins, which finds applications in chemical biology and proteomics through “tyrosine-click” or “tryptophan labeling” reactions depending on pH..

Specification: Chemical name: 4-phenyl-3H-1,2,4-triazole-3,5(4H)-dione
Content Triazolinedione: ≥ 95%

•• **Structural formula:**



Toxic classification: Harmful (category Xn). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: Non-GMP

Application: Auxiliary

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VITAMIN D2 PURE

Ergocalciferol Ph. Eur./USP/BP

CARBOGEN AMCIS
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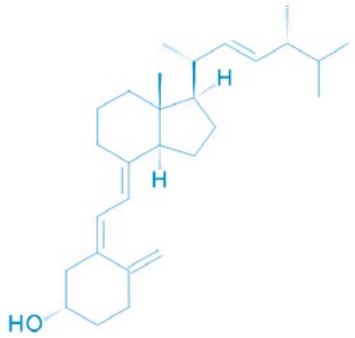
Vitamin D2 is used to ensure the right concentration of calcium and phosphorus in the blood. Ergocalciferol is used to treat and prevent bone growth disorders such as osteomalacia, rickets and osteoporosis. Recent research shows that vitamin D2 can also be of paramount importance to prevent other abnormalities and diseases as well. Several forms of cancer and auto-immune diseases are targeted by several research companies. Vitamin D2 can also be used as starting material for APIs.

The Ergocalciferol Ph. Eur./USP/BP is made under cGMP regime in the European Union. CARBOGEN AMCIS supplies this API from Veenendaal, the Netherlands.

Specification: Chemical name: Vitamin D2 pure; Ergocalciferol; Calciferol Content Ergocalciferol is 97.0-102.0%; 1 gram is equivalent to 40,000,000 IU of Vitamin D2
CAS 50-14-6

•• **Structural formula:**



CAS no. 50-14-6

Toxic classification: Very toxic (category T+). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: DMF available. An ASMF has been filed and accepted in several European countries.

Application: Pharmaceutical and Veterinary industry. Suitable for drug formulation including tablets, injectables, oral solutions and soft gel capsules.

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CARBOGEN AMCIS is a leading service provider, offering a portfolio of drug-development and commercialization services to the pharmaceutical and biopharmaceutical industry at all stages of drug development. The integrated services provide innovative chemistry solutions to support timely and safe drug development allowing customers to make the best use of available resources. CARBOGEN AMCIS is also active in the marketing/sales and manufacture of Vitamin D analogues, Vitamin D, Cholesterol and lanolin related products for key markets as pharmaceutical, cosmetic, food, feed as well as industry applications.