



PT. MERSIFARMA TM
SUKABUMI-INDONESIA

**FORMULIR LATAR BELAKANG
PERMINTAAN BARANG
HABIS PAKAI**

Diisi oleh Pemohon

DEPARTEMEN: QUALITY CONTROL

No. : 025 /LBPBHP/ 11 /20 26

Nama Barang Habis Pakai:

Baku Pembanding Vitamin D3 (Cholecalciferol)

ex. USP Catalog 1131009 / ex. EDQM Catalog C2100000

Berlaku untuk satu jenis barang

1B500102

Rencana Waktu Penggunaan:
9 April 2026

Lead time Purchasing:
60 hari

Masa Waktu Pakai 3-4 tahun

Setiap kali pembakuan WS
Masa Frekuensi Pakai Vitamin D3

☐ Permintaan Item Baru

☐ Permintaan Kebutuhan Jadwal Kerja

☒ Bahan Penunjang

☐ Perlengkapan Listrik

☐ Suku Cadang

☐ Alat Tulis

☐ Bahan Kebersihan

☐ Hardware

☐ Inkjet/Laserjet Print

☐ _____

☐ Innovator

☐ Kalibrasi

☐ Sample Bahan Kemasan

☐ Perbaikan

☐ Sample Bahan Baku

☐ Marketing Promosi

☐ Kualifikasi

☐ _____

SYARAT WAJIB PERMINTAAN BARU

1. Sertakan Foto Barang Baru.
2. Dibatasi hanya sekali untuk awal mendaftarkan ke sistem QAD.
3. Pemesanan selanjutnya menggunakan Analisa Permintaan Barang dengan melampirkan hasil verifikasi stok fisik (kartu stok/bin card).

SYARAT WAJIB PERMINTAAN JADWAL KERJA

1. Formulir Perbaikan (jika dibutuhkan).
2. Setiap pengajuan menyertakan jadwal/timetable.
3. Dibatasi setiap mengajukan kebutuhan untuk memenuhi rencana jadwal kerja, sekalipun barang sudah terdaftar di sistem QAD.

Digunakan
untuk

Pembuatan/standarisasi baku pembanding sekunder Vitamin D3 rutin setiap tahun dengan rencana penggunaan untuk satu kali analisa pembakuan adalah 25-50 mg berdasarkan metode terkini.

Latar
belakang
permintaan

1. Untuk memenuhi kebutuhan pembuatan Working Standard (WS) Vitamin D3 yang nantinya WS akan digunakan untuk analisa produk antara, ruahan, produk jadi, valpro, stabilita produk dan bahan baku Vitamin D3
2. Saat ini stok RS Vitamin D3 sudah habis sehingga perlu dilakukan pengadaan baru.

☐ Perlu Minimum Stock

Tentukan Reorder Point

Dibuat:

DIBIOCA B.D.

Tgl. 09/02/26
(Staf/Koord.)

Diperiksa:

Oktorini S.

Tgl. 10/02/26
(Koord./Spw/Ast. Mgr)

Menyetujui:

Tgl. 10/02/26
(Kepala Departemen)

Nomor
Dokumen : COM-FPT/001A.00

Tanggal
Berlaku : **11 SEP 2023**

Disetujui
oleh :



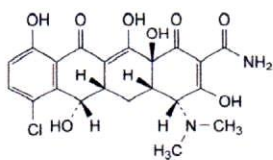
Last Updated On: December 3, 2025

USP Catalog

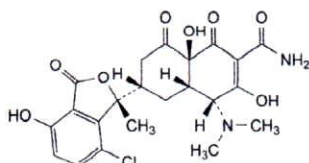
Catalog #	Status	Product Name	Product Type	Current Lot	Previous Lot (VUD)	CAS #	NDC #	Unit Price	Co. Of Origin	Material Origin	UN #	Net Weight	Unit Of Measure	Commodity Codes (HS Codes)*	Special Restriction	Pkg. Type	USMCA Eligible	KORUS Eligible	Base Control Drug	Base Control Drug %	Subcategory
		Heavy Peptide 3 (50 ug) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	Material												Shipment Required						Reference Material
1130796	Active	CHO HCP PLBL2 Heavy Peptide 1 (50 uL) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	Analytical Reference Material	F24400		NA	N/A	\$450.00	US	Chemical Synthesis	UN1648	50	uL	2845900100	International Cold Chain Shipment Required	AMPUL E	Yes	Yes			Analytical Reference Material
1131009	Active	Cholecalciferol (30 mg/ampule; 5 ampules) (Vitamin D3)	Reference Standard	R19690	R07150 (31-OCT-2025)	67-97-0	N/A	\$309.00	CN	Chemical Synthesis	UN2811	150	mg	2936299055		AMPUL E	No	No			Vitamins
1131858	Active	Cholestanol (200 mg)	Reference Standard	F051B0		80-97-7	N/A	\$230.00	US	Plant - Synthetic		200	mg	2906130000		VIAL	No	No			Botanicals-Herbal Medicines
1131960	Active	Cholesterol (125 mg)	Reference Standard	R19500	R112K0 (31-AUG-2025)	57-88-5	N/A	\$318.00	JP	Animal-Sheep		125	mg	2906130000		VIAL	No	No			Surfactants
1132001	Active	Cholesteryl Caprylate (200 mg)	Reference Standard	F1L277	F (31-JUL-2013)	1182-42-9	N/A	\$292.00	US	Chemical Synthesis		200	mg	2915900090		VIAL	No	No			Steroids
1133004	Active	Cholestyramine Resin (500 mg)	Reference Standard	R23210	R06850 (31-MAR-2026)	11041-12-6	N/A	\$245.00	RO	Chemical Synthesis		500	mg	3914002000		VIAL	No	No			Gastrointestinal
1133503	Active	Cholic Acid (200 mg)	Reference Standard	R164S1	R164S0 (30-NOV-2026)	81-25-4	N/A	\$275.00	US	Animal-Cow		200	mg	2918195000		VIAL	No	No			Functional Ingredients
1133536	Active	Choline Bitartrate (200 mg)	Reference Standard	R14340	R05960 (30-NOV-2022)	87-67-2	N/A	\$236.00	ES	Chemical Synthesis		200	mg	2923100000		VIAL	No	No			Others - Dietary Supplements
1133547	Active	Choline Chloride (500 mg)	Reference Standard	R20140	R060C1 (31-JAN-2025)	67-48-1	N/A	\$289.00	CN	Chemical Synthesis		500	mg	2923100000		VIAL	No	No			Others - Dietary Supplements
1133558	Active	Choline Fenofibrate (50 mg) (2-Hydroxy-N,N,N-trimethylethanaminium 2-[4-(4-chlorobenzoyl)phenoxy]-2-	Reference Standard	F088G1	F088G0 (28-FEB-2023)	856676-23-8	N/A	\$457.00	US	Chemical Synthesis		50	mg	2923100000		VIAL	No	No			Antihyperlipidemics

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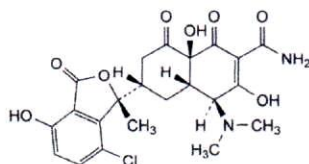
	Order Code	Reference Standard	Batch n°	Quantity per vial	Sale Unit	Information	Monograph	Storage	Shipping group	Price
	Y0002088	CHLORPROTHIXENE FOR SYSTEM SUITABILITY CRS	1	1 MG	1		0815, 1365	+5°C+/-3°C	A1A	90 €
	C1915000	CHLORPROTHIXENE HYDROCHLORIDE CRS	6	50 MG	1		0815	+5°C+/-3°C	A1A	90 €
	C1950000	CHLORTALIDONE CRS	4	150 MG	1		0546	+5°C+/-3°C	A1A	90 €
	Y0002129	CHLORTALIDONE FOR SYSTEM SUITABILITY CRS	2	1.017 MG	1	batch 1 : validity until 31 January 2026	0546	+5°C+/-3°C	A1A	90 €
	Y0001451	CHLORTETRACYCLINE FOR SYSTEM SUITABILITY CRS	4	10 MG	1		0173	+5°C+/-3°C	A1A	90 €
	C2000000	CHLORTETRACYCLINE HYDROCHLORIDE CRS	6	100 MG	1		0173	+5°C+/-3°C	A1A	90 €
	C2100000	CHOLECALCIFEROL CRS	11	260 MG	1	Synonym : Vitamin D3	0072, 0574, 0575, 1192, 2398	-20°C +/-5°C	C1A	90 €
	Y0002328	CHOLECALCIFEROL IMPURITY A CRS	4	0.06 MG	1		0072, 0574, 0575	-20°C +/-5°C	C1A	90 €
	C2155000	CHOLESTEROL CRS	5	80 MG	2		0593, 0993, 2397	+5°C+/-3°C	A1A	90 €
	C2158000	CHOLIC ACID CRS	3	60 MG	1		1189	+5°C+/-3°C	A1A	90 €
	Y0000593	CHONDROITIN SULFATE SODIUM (MARINE) CRS	1	100 MG	1		2064	+5°C+/-3°C	A1A	90 €
	Y0000280	CHONDROITIN SULFATE SODIUM CRS	3	350 MG	1		2064, 2090	+5°C+/-3°C	A1A	90 €
	Y0002395	CHRYSANTHEMUM FLOWER FOR SYSTEM SUITABILITY CRS	1	520 MG	1		3162	+5°C+/-3°C	A1A	150 €
	C2160000	CHYMOTRYPSIN BRP	3	100 MG	1		0476, 0694	+5°C+/-3°C	A1A	110 €
	Y0001554	CICLESONIDE CONTAINING IMPURITY A CRS	2	15 MG	1		2703	+5°C+/-3°C	A1A	90 €
	Y0001553	CICLESONIDE CRS	2	150 MG	1		2703	+5°C+/-3°C	A1A	90 €
	Y0001555	CICLESONIDE IMPURITY B CRS	2	10 MG	1		2703	+5°C+/-3°C	A1A	90 €
	Y0001556	CICLESONIDE IMPURITY C CRS	2	10 MG	1		2703	+5°C+/-3°C	A1A	90 €
	Y0000040	CICLOPIROX CRS	2	75 MG	1		1407	+5°C+/-3°C	A1A	90 €
	C2162701	CICLOPIROX IMPURITY A CRS	5	40 MG	1		1302, 1407	+5°C+/-3°C	A1A	90 €
	C2162702	CICLOPIROX IMPURITY B CRS	5	40 MG	1		1302, 1407	-20°C +/-5°C	C1A	90 €
	C2162700	CICLOPIROX OLAMINE CRS	2	150 MG	1		1302	+5°C+/-3°C	A1A	90 €
	C2163000	CICLOSPORIN CRS	5	100 MG	1		0994	+5°C+/-3°C	A1A	90 €
	Y0002292	CICLOSPORIN FOR SYSTEM SUITABILITY A CRS	2	1 MG	1	batch 1 : validity until 31 March 2026	0994	+5°C+/-3°C	A1A	90 €
	Y0001651	CILASTATIN FOR SYSTEM SUITABILITY 1 CRS	2	5 MG	1		1408	+5°C+/-3°C	A1A	90 €
	Y0001652	CILASTATIN FOR SYSTEM SUITABILITY 2 CRS	1	5 MG	1		1408	+5°C+/-3°C	A1A	90 €



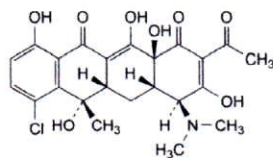
- E. (4*R*,4*aS*,5*aS*,6*S*,12*aS*)-7-chloro-4-(dimethylamino)-3,6,10,12,12*a*-pentahydroxy-1,11-dioxo-1,4,4*a*,5,5*a*,6,11,12*a*-octahydrotetracene-2-carboxamide (4-epidemethylchlortetracycline),



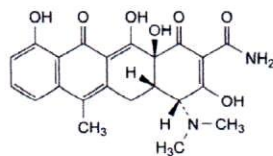
- F. (4*R*,4*aS*,6*S*,8*aS*)-6-[(1*R*)-7-chloro-4-hydroxy-1-methyl-3-oxo-1,3-dihydro-2-benzofuran-1-yl]-4-(dimethylamino)-3,8*a*-dihydroxy-1,8-dioxo-1,4,4*a*,5,6,7,8,8*a*-octahydronaphthalene-2-carboxamide (4-epiisochlortetracycline),



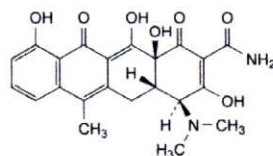
- G. (4*S*,4*aS*,6*S*,8*aS*)-6-[(1*R*)-7-chloro-4-hydroxy-1-methyl-3-oxo-1,3-dihydro-2-benzofuran-1-yl]-4-(dimethylamino)-3,8*a*-dihydroxy-1,8-dioxo-1,4,4*a*,5,6,7,8,8*a*-octahydronaphthalene-2-carboxamide (isochlortetracycline),



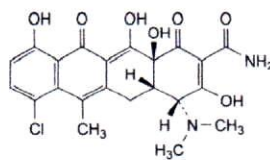
- H. (4*S*,4*aS*,5*aS*,6*S*,12*aS*)-2-acetyl-7-chloro-4-(dimethylamino)-3,6,10,12,12*a*-pentahydroxy-6-methyl-4*a*,5*a*,6,12*a*-tetrahydrotetracene-1,11(4*H*,5*H*)-dione (2-acetyl-2-decarboxamidochlortetracycline),



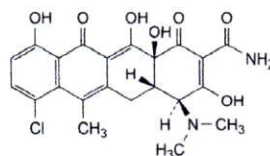
- I. (4*R*,4*aS*,12*aS*)-4-(dimethylamino)-3,10,12,12*a*-tetrahydroxy-6-methyl-1,11-dioxo-1,4,4*a*,5,11,12*a*-hexahydrotetracene-2-carboxamide (4-epianhydrotetracycline),



- J. (4*S*,4*aS*,12*aS*)-4-(dimethylamino)-3,10,12,12*a*-tetrahydroxy-6-methyl-1,11-dioxo-1,4,4*a*,5,11,12*a*-hexahydrotetracene-2-carboxamide (anhydrotetracycline),



- K. (4*R*,4*aS*,12*aS*)-7-chloro-4-(dimethylamino)-3,10,12,12*a*-tetrahydroxy-6-methyl-1,11-dioxo-1,4,4*a*,5,11,12*a*-hexahydrotetracene-2-carboxamide (4-epianhydrochlortetracycline),



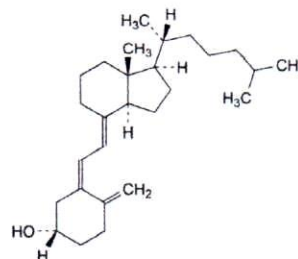
- L. (4*S*,4*aS*,12*aS*)-7-chloro-4-(dimethylamino)-3,10,12,12*a*-tetrahydroxy-6-methyl-1,11-dioxo-1,4,4*a*,5,11,12*a*-hexahydrotetracene-2-carboxamide (anhydrochlortetracycline).



01/2023:0072

CHOLECALCIFEROL

Cholecalciferolum



$C_{27}H_{44}O$
[67-97-0]

M_r 384.6

DEFINITION

(3*S*,5*Z*,7*E*)-9,10-Secocholesta-5,7,10(19)-trien-3-ol.

Content: 97.0 per cent to 102.0 per cent.

A reversible isomerisation to pre-cholecalciferol takes place in solution, depending on temperature and time. The activity is due to both compounds (see Assay).

1 mg of cholecalciferol is equivalent to 40 000 IU of antirachitic activity (vitamin D) in rats.

CHARACTERS

Appearance: white or almost white crystals.

Solubility: practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in trimethylpentane and in fatty oils.

It is sensitive to air, heat and light. Solutions in solvents without an antioxidant are unstable and are to be used immediately.

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison: cholecalciferol CRS.

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OR

TESTS

Specific optical rotation (2.2.7): + 105 to + 112, determined within 30 min of preparing the solution.

Dissolve 0.200 g rapidly in *aldehyde-free alcohol R* without heating and dilute to 25.0 mL with the same solvent.

Related substances. Liquid chromatography (2.2.29). Prepare the solutions immediately before use, avoiding exposure to actinic light and air.

Test solution. Dissolve 10.0 mg of the substance to be examined in *trimethylpentane R* without heating and dilute to 10.0 mL with the same solvent.

Reference solution (a). Dissolve 10.0 mg of *cholecalciferol CRS* in *trimethylpentane R* without heating and dilute to 10.0 mL with the same solvent.

Reference solution (b). Dissolve 5.0 mg of *cholecalciferol CRS* in *trimethylpentane R* and dilute to 5.0 mL with the same solvent. Dilute 2.0 mL of the solution to 5.0 mL with the mobile phase. Heat in a water-bath at 90 °C under a reflux condenser for 45 min and cool (formation of pre-cholecalciferol). Dissolve the contents of a vial of *cholecalciferol impurity A CRS* in 1.0 mL of this solution.

Reference solution (c). Dilute 10.0 mL of reference solution (a) to 100.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 100.0 mL with the mobile phase.

Column:

- size: $l = 0.25$ m, $\varnothing = 4.6$ mm;
 - stationary phase: silica gel for chromatography R (5 μ m).
- Mobile phase:** *pentanol R*, *hexane R* (0.3:99.7 V/V).

Flow rate: 2 mL/min.

Detection: spectrophotometer at 265 nm.

Injection: 5 μ L of the test solution and reference solutions (b) and (c).

Run time: twice the retention time of cholecalciferol.

Relative retention with reference to cholecalciferol (retention time = about 19 min): pre-cholecalciferol = about 0.5; impurity A = about 0.6.

System suitability: reference solution (b):

- resolution: minimum 1.5 between the peaks due to pre-cholecalciferol and impurity A.

Limits:

- **impurity A:** not more than the area of the principal peak in the chromatogram obtained with reference solution (c) (0.1 per cent);
- **unspecified impurities:** for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (c) (0.10 per cent);
- **total:** not more than 10 times the area of the principal peak in the chromatogram obtained with reference solution (c) (1.0 per cent);
- **disregard limit:** 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (c) (0.05 per cent); disregard the peak due to pre-cholecalciferol.

ASSAY

Liquid chromatography (2.2.29) as described in the test for related substances with the following modification.

Injection: test solution and reference solution (a).

Calculate the percentage content of $C_{27}H_{44}O$ taking into account the assigned content of *cholecalciferol CRS* and, if necessary, the peak due to pre-cholecalciferol.

STORAGE

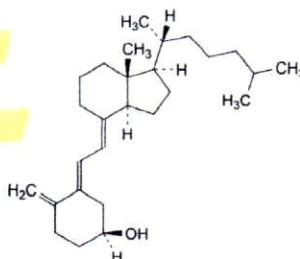
Under nitrogen, in an airtight container, protected from light, at a temperature of 2 °C to 8 °C.

The contents of an opened container are to be used immediately.

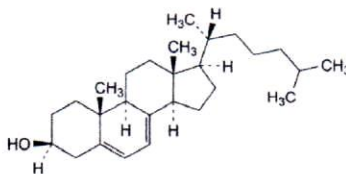
IMPURITIES

Specified impurities: A.

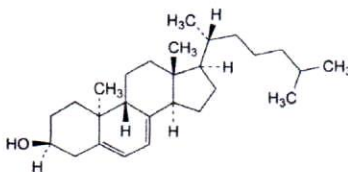
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use* (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. *Control of impurities in substances for pharmaceutical use*): B, C, D, E.



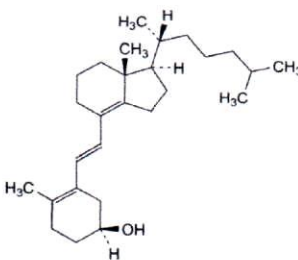
A. (3*S*,5*E*,7*E*)-9,10-secocholesta-5,7,10(19)-trien-3-ol (*trans*-cholecalciferol, *trans*-vitamin D₃),



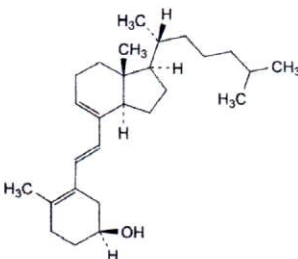
B. cholesta-5,7-dien-3 β -ol (7,8-didehydrocholesterol, provitamin D₃),



C. 9 β ,10 α -cholesta-5,7-dien-3 β -ol (lumisterol₃),



D. (3*S*,6*E*)-9,10-secocholesta-5(10),6,8(14)-trien-3-ol (iso-tachysterol₃),



E. (3*S*,6*E*)-9,10-secocholesta-5(10),6,8-trien-3-ol (tachysterol₃).