
Cropel
Lifesciences Pvt. Ltd.

Cropel Lifesciences Pvt. Ltd.

Mfg. & Exporter of Hormones, Steroids & General API

Factory: Plot No.3203, Phase-III, G.I.D.C. Chhatral-382729

Ta. -Kalol, Dis.-Gandhinagar, Gujarat, India.

TEL.NO.: +919898573384 E-MAIL: sales@cropel.in

BRIEF INFORMATION ABOUT COMPANY'S ACTIVITIES

The company manufacturing of Hormones, steroids and General API started back in 2016 **M/S.Kantam Pharma Chem**, at **Plot No.3203, Phase III, G.I.D.C.**

Chhatral-382729Ta. -Kalol, Dis.-Gandhinagar, Gujarat, India with a desire to provide Quality Bulk Drugs conforming to Indian and International Pharmacopoeias standards, at the best competitive prices possible, to beneficially serve mankind.

Later in year 2020 the Partnership concern was converted to Private Limited Company in the name of **“Cropel Lifesciences Pvt Ltd.”** with an intent of running the company under set of Company Laws as per directives of Financial Institution.

In year 2016, the above said company after producing Hormones, steroids and General API over long 4 years at Chhatral (Gandhinagar) city site felt badly the need to upgrade itself as per new GMP & off-course to cater to ever increasing domestic as well as international demand. Hence a new company in the name of **“Cropel Lifesciences Pvt Ltd.”** was formed on 2020 with intent to take over the existing operations of Kantam Pharma Chem. The decision to form new company was largely driven by the attraction of Government benefits of setting up new facilities on outskirts of city.

With latest equipment's, technology, Quality Control and an active Research and Development Laboratories, equipped with modern instrument, this facility is truly State of the Art. At **Cropel Lifesciences Pvt Ltd**, principles of GMP are strictly adhered to, for all activities & systems, starting from product design and development through production, distribution & marketing for attaining “Total Quality Management” and “Customer Satisfaction” effectively.

The Company is involved in manufacturing different APIs (Hormones), namely Progesterone, Hydroxy Progesterone Caproate, Dydrogesterone, Norethisterone, Norethisterone Acetate, Methyl cobalamin. The products fully comply with IP, BP, EP, USP & and other International Pharmacopoeias specifications

Cropel Lifesciences Pvt. Ltd.

HORMONE COMMERCIAL PRODUCTS:

PRODUCT	PHARMACOPOEIA	CAS No
Progesterone	IP/USP	57-83- 0
Estradiol	IP/USP	50-28- 2
Estradiol Hemi hydrate	BP	35380-71- 3
Levonorgestrel	IP/BP/USP/EP	797-63- 7
Norethisterone	IP/USP/BP	68-22- 4
Nandrolone Decanoate	IP/BP/USP/EP	360-70- 3
Nandrolone	IP	434-22- 0
Nandrolone phenyl propionate	IP/BP/USP/EP	62-90- 8
Testosterone	IP/BP/USP/EP	58-22- 0
Testosterone Decanoate	IP/BP/USP/EP	5721-91- 5
Testosterone Enanthate.	IP/BP/USP/EP	315-37- 7
Testosterone un Decanoate	IP/BP/USP/EP	5949-44- 0
Testosterone isocaproate	IP/BP/USP/EP	58-22- 0
Testosterone Propionate	IP/BP/USP/EP	57-85- 2
Testosterone Cypionate	IP/BP/USP/EP	58-20- 8
Testosterone phenyl propionate.	IP/BP/USP/EP	1255-49- 8
17 α -Hydroxy progesterone Caproate (HPC)	IP/BP/USP/EP	57-83- 0
Melatonin	BP/USP	73-31- 4
Medroxy Progesterone Acetate	BP/USP/EP	71-58- 9
Norethisterone Acetate.	IP/BP/USP/EP	51-98- 9
Norethisterone Enantate.	BP/USP	68-22- 4
Testosterone Acetate.	IP/BP/USP/EP	1045-69- 8
Estradiol Valerate.	USP	979-32- 8
Estradiol Benzoate.	USP	50-50- 0
Mifepristone	IP	84371-65- 3
Danazole	USP	17230-88- 5
Dydrogesterone	IP	152-62-5

GENERAL COMMERCIAL PRODUCTS:

PRODUCT	PHARMACOPOEIA	CAS No
Luliconazole	IH	187164-19-8
Itraconazole	BP/USP	84625-61-6
Montelukast Sodium	IP/BP/USP	151767-02-1

Cropel Lifesciences Pvt. Ltd.

STERIOD COMMERCIAL PRODUCTS:

PRODUCT	PHARMACOPOEIA	CAS No	DMF STATUS
Beclomethasone Dipropionate	IP/BP/USP	5534-09- 8	CTD Available
Betamethasone Dipropionate	IP/BP/USP/EP	5593-20- 4	CTD Available
Betamethasone Valerate	IP/BP/USP/EP	2152-44- 5	In-process
Betamethasone Sodium Phosphate	IP/BP/USP/EP	151-73- 5	CTD Available
Clobetasole Propionate	IP/BP/USP/EP	21522-46- 7	CTD Available
Clobetasole Butyrate	IP/BP	21522-57- 0	In-process
Deflazacort	IH	14484-47- 0	CTD Available
Dexamethasone Sodium Phosphate	IP/BP/USP/EP	2392-39- 4	CTD Available
Hydrocortisone Acetate	IP/BP/USP/EP	50-03- 3	In-process
Methylprednisolone	IP/BP/USP/EP	83-43- 2	CTD Available
Methylprednisolone Acetate	IP/BP/USP	56-36- 1	CTD Available
Mometasone Furoate	IP/BP/USP/EP	83919-23- 7	CTD Available
Prednisolone acetate	IP/BP/USP/EP	52-21- 1	CTD Available
Prednisolone Sodium Phosphate	IP/BP/USP/EP	125-02- 0	CTD Available
Triamcinolone Acetonide	IP/BP/USP/EP	76-25- 5	In-process
Helobetasole Propionate	USP	66852-54- 8	In-process
Fluocinolone Acetonide	IP/BP/USP/EP	67-73- 2	In-process
Dexamethasone	IP/BP/USP/EP	50-02- 2	In-process
Dutasteride	IP/BP/USP	164656-23- 9	In-process

VITAMIN PRODUCT:

PRODUCT	PHARMACOPOEIA	CAS No	DMF STATUS
Methylcobalamin	USP/JP	13422-55-4	CTD Available

FORM 25

(See Rule 70)

Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedules C, C(1) and X

Number of licence and date of issue No: G/25/2106

Date: 16-Dec-2020

1. Director

of M/s. CROPEL LIFESCIENCES PRIVATE LIMITED is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [Schedules C, C(1), and X] to the Drugs & Cosmetics Rules, 1945, on the premises situated at PLOT NO. 3203, PHASE - 3, G.I.D.C., CHHATRAL, TAL. - KALOL, DIST.- GANDHINAGAR - 382 729 under the direction and supervision of the following (competent technical staff):-

(a) Competent technical staff (Names): As Per List Approved & Annexed

(b) Names of Drugs As Per List Approved & Annexed
(each item to be separately specified)

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force From : 16-Dec-2020 To 15-Dec-2025

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Signature : (This Document is Digitally Signed.)

Designation : **Dr. H. G. KOSHIA**
Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 28-Feb-2024

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the [competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5). This licence will be deemed to extend to the categories so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

REMARKS : License amendment due to change in address of Own Firm.
W. E. F. 28-Feb-2024



Reg ID : **738261**

Doc ID: **LI132800002106**

CROPEL LIFESCIENCES PRIVATE LIMITED

Print Date : **26/03/2024 04:22 PM**

Signature valid

Digitally signed by
Date: 2024.03.26
16:25:48 +05:30
Reason: Sign
Location: AHD

FORM 28

(See Rule 76)

Licence to manufacture for sale (or for distribution of) drugs specified in Schedules C, C (1) [excluding those specified in schedule X]

Number of licence and date of issue No G/28/1526 Date: 16-Dec-2020

1. Director

of M/s. CROPEL LIFESCIENCES PRIVATE LIMITED is hereby licence to manufacture at the premises situated at the PLOT NO. 3203, PHASE - 3, G.I.D.C., CHHATRAL, TAL.- KALOL, DIST.- GANDHINAGAR - 382 729 the following drugs being drugs specified in schedules C & C (1) (Excluding those specified in schedule X) to the Drugs and Cosmetics Rules 1945.

Names of Drugs :

As Per List Approved & Annexed

2. Names of approved competent technical staff :

As Per List Approved & Annexed

3. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

4. The licence shall be in force from 16-Dec-2020 To 15-Dec-2025

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Signature : (This Document is Digitally Signed.)

Designation :

Dr. H. G. KOSHIA

Commissioner

**Food & Drugs Control Administration
Gujarat State.**

Date:- 28-Feb-2024

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule C and C(1) (excluding those specified in Schedule X) not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(3). This licence will be deemed to extend to the items so endorsed.
3. Any change in the (competent technical staff) shall be forthwith reported to the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed Constitution.

REMARKS : License amendment due to change in address of Own Firm.
W. E. F. 28-Feb-2024



Reg ID : 734820

Doc ID: LI117200001526

CROPEL LIFESCIENCES PRIVATE LIMITED

Print Date : 26/03/2024 04:23 PM

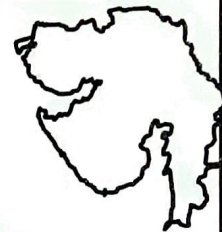
Signature valid

Digitally signed by
Date: 2024.03.26
16:26:34 +05:30
Reason: Sign
Location: AHD



Food & Drugs Control Administration

BLOCK NO. 8, 1st FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : **S-GMP & GLP/24095242**

G.M.P. CERTIFICATE

This is to certify that M/s. CROPEL LIFESCIENCES PRIVATE LIMITED, PLOT NO. 3203, PHASE - 3, G.I.D.C., CHHATRAL, TAL. - KALOL, DIST. - GANDHINAGAR - 382 729 is holding valid drug manufacturing licenses in Form No. 25 & 28 bearing No. G/25/2106 & G/28/1526 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules thereunder. Under the said licenses the firm is permitted to manufacture & sell drugs covered under the following categories.

Dosage Form (s)	Category (ies)
Bulk Drugs (APIs)	General
Bulk Drugs (APIs)	Sex Hormone

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE - M of Drugs & Cosmetics Act 1940 & Rules There under.

The manufacturing plant is subjected to inspection at suitable intervals by competent authority.

This certificate is valid from Dt : 09/09/2024 to 08/09/2026.




(Dr. H. G. KOSHIA)

Commissioner
Food & Drugs Control Administration
Gandhinagar, Gujarat State

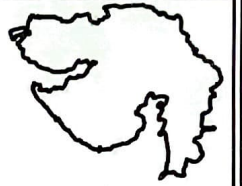
Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400



Food & Drugs Control Administration,

Block No. 8, 1st Floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, India, Pin - 382010



No.: S-GMP & GLP/24095242⁵⁶³³⁷/B, Dt. -

G. L. P. CERTIFICATE

12 SEP 2024

This is to certify that M/s. CROPEL LIFESCIENCES PRIVATE LIMITED, PLOT NO. 3203, PHASE - 3, G.I.D.C., CHHATRAL, TAL. - KALOL, DIST. - GANDHINAGAR - 382 729 is holding Drug Manufacturing License in form No. 25 & 28 bearing No. G/25/2106 & G/28/1526 issued by this administration under Drugs & Cosmetics Act, 1940 & Rules thereunder.

The firm is having its own testing laboratory as per Drugs & Cosmetics Act, 1940. The firm is complying with the Good Laboratory Practices (GLP) requirements of "Schedule - L1" of the Drugs and Cosmetics Rules 1945.

This certificate is issued on the basis of the inspection report and other documents submitted in this office as on today and issued for participation in tender for State and Central Governments.

This Certificate is valid up to: 09/09/2024 to 08/09/2026.



(Mr. H. L. RAVAT)

JOINT COMMISSIONER

Food & Drugs Control Administration
Gujarat State.

Certificate of Registration

This is to Certify that
Environmental Management System of
CROPEL LIFESCIENCES PRIVATE LIMITED

PLOT NO: 3203, PHASE-3, G.I.D.C., CHHATRAL TA: KALOL,
DIST: GANDHINAGAR - 382729, GUJARAT, INDIA.

has been assessed and found to conform to the requirements of
ISO 14001:2015
for the following scope :

MANUFACTURER OF PHARMACEUTICAL BULK DRUGS.
IAF CODE : 13

Certificate No	: 22IEKF79		
Initial Registration Date	: 02/09/2022	Issuance Date	: 02/09/2022
Date of Expiry	: 01/09/2025		
1st Surv. Due	: 02/08/2023	2nd Surv. Due	: 02/08/2024



Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQC MIDDLE EAST LLC

Head Office: Office No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE. e-mail: info@aqcworld.com.

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of AQC Middle East LLC and shall be returned immediately when demanded

Certificate of Registration

This is to Certify that
Occupational Health & Safety Management System of

CROPEL LIFESCIENCES PRIVATE LIMITED

PLOT NO: 3203, PHASE-3, G.I.D.C., CHHATRAL TA: KALOL,
DIST: GANDHINAGAR - 382729, GUJARAT, INDIA.

has been assessed and found to conform to the requirements of

ISO 45001:2018

for the following scope :

MANUFACTURER OF PHARMACEUTICAL BULK DRUGS.
IAF CODE : 13

Certificate No : **22IOKH85**

Initial Registration Date : 02/09/2022

Issuance Date : 02/09/2022

Date of Expiry : 01/09/2025

1st Surv. Due : 02/08/2023

2nd Surv. Due : 02/08/2024



Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQC MIDDLE EAST LLC

Head Office: Office No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE. e-mail: info@aqcworld.com.

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawal).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of AQC Middle East LLC and shall be returned immediately when demanded.

Certificate of Registration

This is to Certify that
Quality Management System of

CROPEL LIFESCIENCES PRIVATE LIMITED

PLOT NO: 3203, PHASE-3, G.I.D.C., CHHATRAL TA: KALOL,
DIST: GANDHINAGAR - 382729, GUJARAT, INDIA.

has been assessed and found to conform to the requirements of

ISO 9001:2015

for the following scope :

MANUFACTURER OF PHARMACEUTICAL BULK DRUGS.

IAF CODE : 13

Certificate No : **22IQKG92**
Initial Registration Date : 02/09/2022
Date of Expiry : 01/09/2025
1st Surv. Due : 02/08/2023

Issuance Date : 02/09/2022
2nd Surv. Due : 02/08/2024



Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQC MIDDLE EAST LLC

Head Office: Office No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE. e-mail : info@aqcworld.com,

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

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Certificate is the property of AQC Middle East LLC and shall be returned immediately when demanded



PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

Branch Office Ahmedabad

7-C, Trade Centre, Near Stadium Cross Road, Navrangpura, Ahmedabad.

AHMEDABAD, GUJARAT, 380009.

Email - boahmedabad@pharmexcil.com, Telephone - 079-40050497 Website - https://pharmexcil.com

REGISTRATION - CUM - MEMBERSHIP CERTIFICATE

(Issued under the provisions of Foreign Trade Policy, Government of India)

Name of the exporter	CROPEL LIFESCIENCES PRIVATE LIMITED				
IEC Number	AAICC9041L	PAN	AAICC9041L	Date of Birth / Incorporation	20/08/2020
Address of the Registered/Head Office	433, GIDC ODHAV, NR. BHIKSHUK GRUH, AHMEDABAD, 382415, AHMEDABAD, GUJARAT				
Nature of Concern	Private Limited				
Description of goods/ services for which registered	API's / Bulk Drugs				
Registration Number	RCMC/PHARMEXCIL/00208/2022-2023				
Issued against File Number	RCMCRENEWPHARMEXC00013137AM26				
Registered as	Manufacturer Exporter				
Name of the Proprietor/ Partner(s)/Director(s)/Karta	Prakash Babubhai Dobariya, Kishorkumar Vallabhbhai Kachhadia, Haresh Vallabhbhai Tadhani, Ghanshyam Kachhadia, Mukeshkumar Vallabhbhai Vekaria, Alkesh Kalubhai Sangani, Jayantilal Dhirubhai Bhuva, Mahendrakumar Jethabhai Patel, Jaysukhbhai Sangani				

This certificate is issued as per the details of our records and is subject to the conditions laid down in the relevant scheme of registration of this council.

Issue Date	14/04/2025	Renew upto	31/03/2026
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Additional Remarks from Registering Authority:SSM - RENEWAL

Note: Refer DGFT Website (Services - View IEC Related Details - View Any IEC) for IEC Branch and Director details.

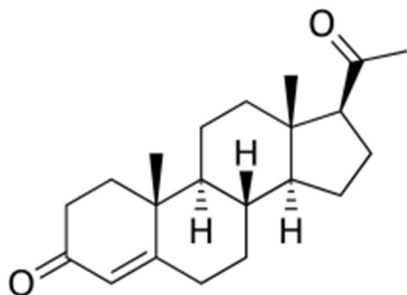
Annexure-1

UDINRCMC00034570AM26

Serial No.	Branch Name
1	1-PL 3 GIDC ,PLOT NO 3203,,CHHATRAL , KALOL,GANDHINAGAR,GUJARAT,GANDHINAGAR,382729

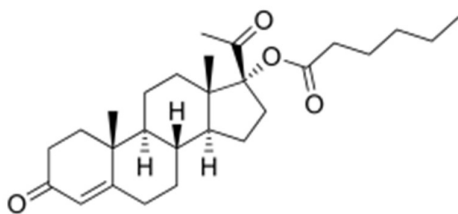
Note:Branch name printed on certificate as requested by exporter. However it may be noted that for latest information on branches, may please refer IEC details on DGFT portal ---> under Services ---> View IEC Related Details ---> View Any IEC.

Progesterone IP/BP/EP/USP



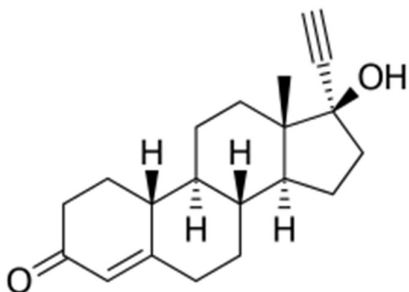
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
(1S,3aS,3bS,9aR,9bS,11aS)-1-Acetyl-9a,11a-dimethyl-1,2,3,3a,3b,4,5,8,9,9a,9b,10,11,11a-tetradecahydro-7H-cyclopenta[a]phenanthren-7-one		Pregnenedione; Pregn-4-ene-3,20-dione	
Identifiers & Properties			
CAS Number	57-83-0	Appearance:	A White or almost white micronized powder
		Odour:	Odourless Powder
Chemical formula	C ₂₁ H ₃₀ O ₂	Specific Optical Rotation:	+186.0° to +194.0°
Molar mass	314.469 g/mol	RS Single Impurity: RS Total Impurity:	NMT 0.5% NMT 0.8%
Melting point	124°C	Assay By UV:	97.0% to 103.0%
Pharmacology			
Routes of administration	By mouth, topical/transdermal, vaginal, intramuscular injection, subcutaneous injection, subcutaneous implant		

Hydroxy Progesterone Caproate IP/USP



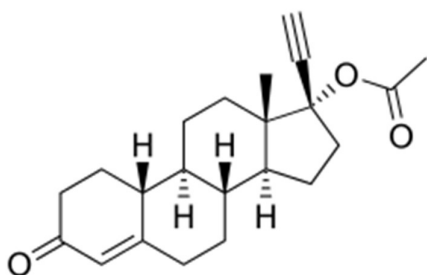
Names			
<div>Preferred IUPAC Name :</div> <div>[(8<i>R</i>,9<i>S</i>,10<i>R</i>,13<i>S</i>,14<i>S</i>,17<i>R</i>)-17-acetyl-10,13-dimethyl-3-oxo-2,6,7,8,9,11,12,14,15,16-decahydro-1<i>H</i>-cyclopenta[<i>a</i>]phenanthren-17-yl] hexanoate</div>		<div>Other Names:</div> <div>Hydroxyprogesterone caproate; Hydroxyprogesterone hexanoate; 17α-Hydroxyprogesterone caproate; 17α-OHPC; 17-Hydroxyprogesterone caproate; 17-OHPC; 17-HPC; 17α-HPC; HPC; LPCN-1107; 17α-Hydroxypregn-4-ene-3,20-dione 17α-hexanoate</div>	
Identifiers & Properties			
CAS Number	630-56-8	Appearance:	A White or almost white powder
Chemical formula	C ₂₇ H ₄₀ O ₄	Odour:	Odourless Powder
Molar mass	428.613 g/mol	Specific Optical Rotation:	+44.0° to +49.0°
Melting point	120°C-124°C	Assay By UV:	97.0% to 103.0%
Pharmacology			
Routes of administration	intramuscular injection, subcutaneous injection.		

Norethisterone IP/BP/EP/USP



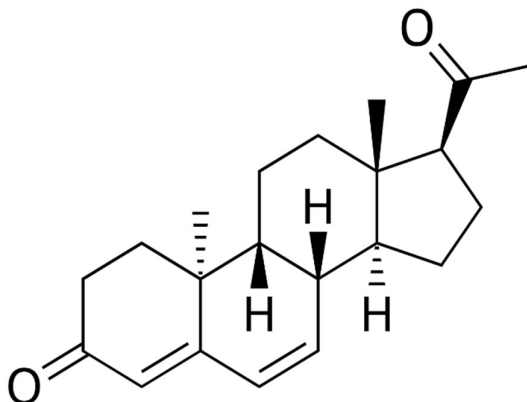
Names			
<u>Preferred IUPAC Name</u> :		Other Names :	
(8 <i>R</i> ,9 <i>S</i> ,10 <i>R</i> ,13 <i>S</i> ,14 <i>S</i> ,17 <i>R</i>)-17-ethynyl-17-hydroxy-13-methyl-1,2,6,7,8,9,10,11,12,14,15,16-dodecahydrocyclopenta[<i>a</i>]phenanthren-3-one		Ethinylnoretestosterone; Norpregneninolone; Anhydrohydroxy-norprogesterone; Ethinylestrenolone; 17α-Ethynyl-19-nortestosterone; 17α-Ethynylestra-4-en-17β-ol-3-one; 17α-Hydroxy-19-norpregn-4-en-20-yn-3-one	
Identifiers & Properties			
CAS Number	68-22-4	Appearance:	A White or almost white micronized powder
		Odour:	Odourless Powder
Chemical formula	C ₂₀ H ₂₆ O ₂	Specific Optical Rotation:	-37° to -33°
Molar mass	298.426 g/mol	RS Single Impurity: RS Total Impurity:	NMT 0.2% NMT 0.3%
Melting point	202°C-208°C	Assay:	98.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, intramuscular injection, subcutaneous injection.		

Norethisterone Acetate BP/EP/USP



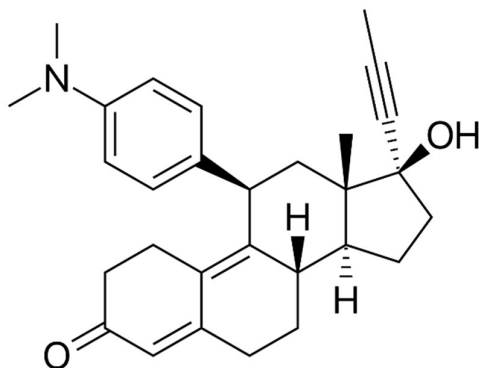
Names			
<u>Preferred IUPAC Name</u> :		Other Names :	
(8 <i>R</i> ,9 <i>S</i> ,10 <i>R</i> ,13 <i>S</i> ,14 <i>S</i> ,17 <i>S</i>)-17-ethynyl-13-methyl-3-oxo-2,3,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-1 <i>H</i> -cyclopenta[<i>a</i>]phenanthren-17-yl acetate		Norethindrone acetate; SH-420; 17α-Ethynyl-19-nortestosterone 17β-acetate; 17α-Ethynylestra-4-en-17β-ol-3-one 17β-acetate	
Identifiers & Properties			
CAS Number	38673-38-0	Appearance:	A White or almost white micronized powder
Chemical formula	C ₂₂ H ₂₈ O ₃	Odour:	Odourless Powder
Molar mass	340.463 g/mol	HPLC :	NLT 99.0%
Specific Optical Rotation:	-32° to -35°	Assay By HPLC:	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth		

Dydrogesterone IP/BP/EP/USP



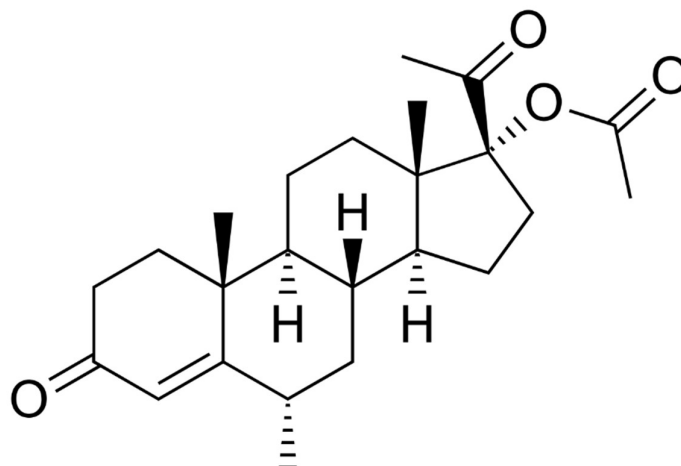
Names			
<u>Preferred IUPAC Name</u> :		Other Names :	
(8 <i>S</i> ,9 <i>R</i> ,10 <i>S</i> ,13 <i>S</i> ,14 <i>S</i> ,17 <i>S</i>)-17-acetyl-10,13-dimethyl-1,2,8,9,11,12,14,15,16,17-decahydrocyclopenta[<i>a</i>]phenanthren-3-one		Isopregnenone; Dehydroprogesterone; Didrogesteron; 6-Dehydroretroprogesterone; 9β,10α-Pregna-4,6-diene-3,20-dione;	
Identifiers & Properties			
CAS Number	152-62-5	Appearance:	A White or almost white crystalline powder
		Odour:	Odourless Powder
Chemical formula	C ₂₁ H ₂₈ O ₂	Specific Optical Rotation:	-485° to -469°
Molar mass	312.446 g/mol	HPLC :	NLT 99.5%
Melting point	167°C to 171°C	Assay By HPLC:	98%-102%
Pharmacology			
Routes of administration	By mouth, sublingual, injection.		

Mifepristone IP



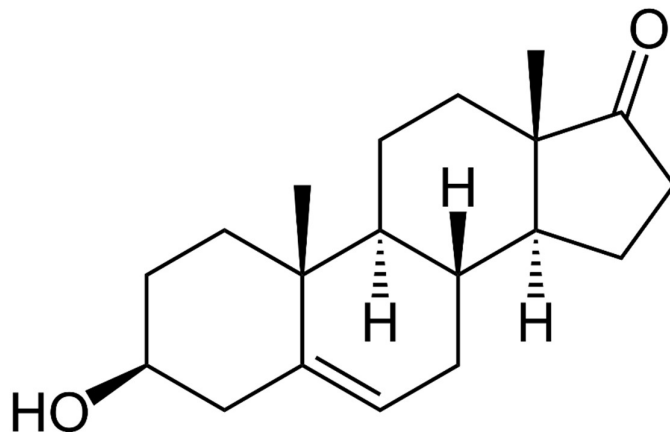
Names			
<p><u>Preferred IUPAC Name</u> :</p> <p>(8S,11R,13S,14S,17S)-11-[4-(dimethyl lamino) phenyl]-17-hydroxy-13-methyl-17-prop-1-ynyl-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[a]phenanthren-3-one</p>		<p>Other Names:</p> <p>11β- [p-(Dimethyl amino) phenyl]-17α-(1-propynyl) estro-4,9-dien-17β-ol-3-one</p>	
Identifiers & Properties			
CAS Number	84371-65-3	Appearance:	A slightly yellow crystalline powder.
Chemical formula	C ₂₉ H ₃₅ NO ₂	Odour:	Odourless Powder
Molar mass	429.604 g/mol	HPLC :	NLT 99.0%
Specific Optical Rotation:	+124° to +135°	Assay:	98% - 102%
Pharmacology			
Routes of administration	By mouth		

Medroxyprogesterone Acetate IP/BP/EP/USP



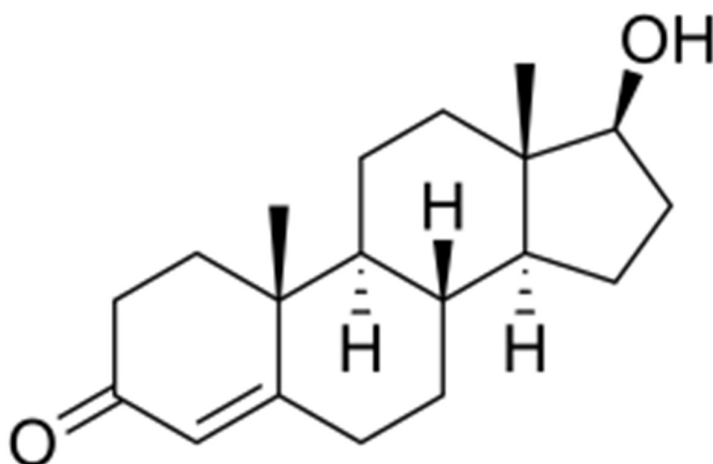
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
[(6S,8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-3-oxo-2,6,7,8,9,11,12,14,15,16-decahydro-1H-cyclopenta[a]phenanthren-17-yl] acetate		MPA; DMPA; Methyl hydroxyprogesterone acetate; Methyl acetoxy progesterone; MAP; Methypregnone; Metipregnone; 6α-Methyl-17α-hydroxyprogesterone acetate; 6α-Methyl-17α-acetoxyprogesterone;	
Identifiers & Properties			
CAS Number	71-58-9	Appearance: Odour:	A white or almost white, crystalline powder. Odourless Powder
Chemical formula	C ₂₄ H ₃₄ O ₄	RS Single Impurity: RS Total Impurity:	NMT-1.0 % NMT-1.5 %
Molar mass	386.532 g/mol	HPLC :	NLT 98.5%
Specific Optical Rotation:	+45° to +51°	Assay:	97.0% to 103.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection. intramuscular injection, subcutaneous injection		

Dehydroepiandrosterone IH



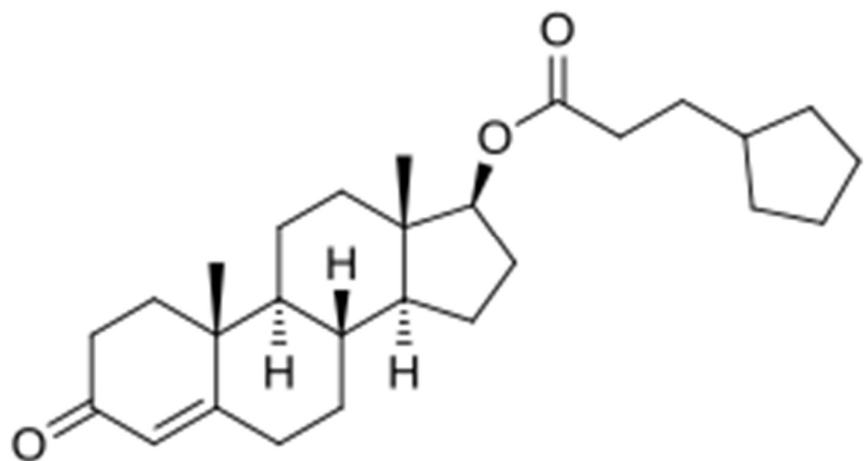
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
(3a <i>S</i> ,3b <i>R</i> ,7 <i>S</i> ,9a <i>R</i> ,9b <i>S</i> ,11a <i>S</i>)-7-Hydroxy-9a,11a-dimethyl-2,3,3a,3b,4,6,7,8,9,9a,9b,10,11,11a-tetradecahydro-1 <i>H</i> -cyclopenta[<i>a</i>]phenanthren-1-one		Androst-enolone; Prasterone; Androst-5-en-3β-ol-17-one	
Identifiers & Properties			
CAS Number	53-43-0	Appearance:	A White or almost white Crystalline Powder
Chemical formula	C ₁₉ H ₂₈ O ₂	Specific Optical Rotation:	+11.0° to +14.0°
Molar mass	288.4 g·mol ^{−1}	Assay :	98.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, vaginal (insert), intramuscular injection, injection		

Testosterone BP/EP/USP



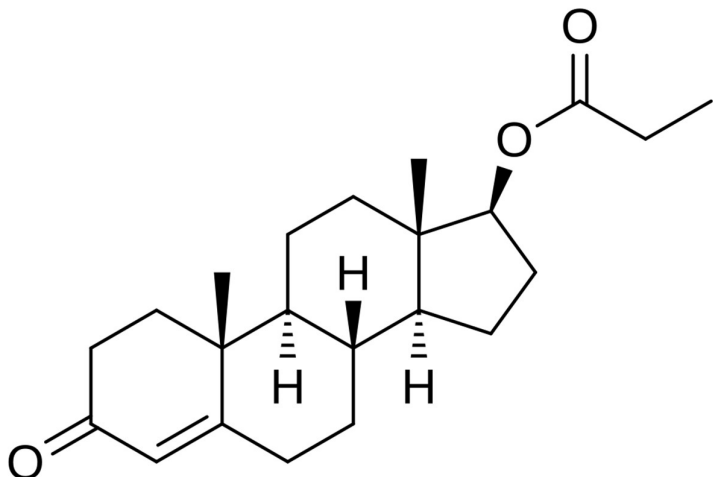
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
(1S,3aS,3bR,9aR,9bS,11aS)-1-Hydroxy-9a,11a-dimethyl-1,2,3,3a,3b,4,5,8,9,9a,9b,10,11,11a-tetradecahydro-7H-cyclopenta[a]phenanthren-7-one		Androst-4-en-17β-ol-3-one, 17β-Hydroxyandrost-4-en-3-one	
Identifiers & Properties			
CAS Number	58-22-0	Appearance:	White or almost white crystalline powder, or colourless or yellowish-white crystals
Chemical formula	C ₁₉ H ₂₈ O ₂	Melting point	About 155 °C
Molar mass	288.4 g·mol ^{−1}	HPLC	Total Impurities: NMT 0.6 %
Specific Optical Rotation:	+106.0° to +114.0°	Assay :	98.0% to 102.0%
Pharmacology			
Routes of administration	Transdermal, by mouth, in the cheek, intranasal, intramuscular injection, subcutaneous pellets		

Testosterone Cypionate USP



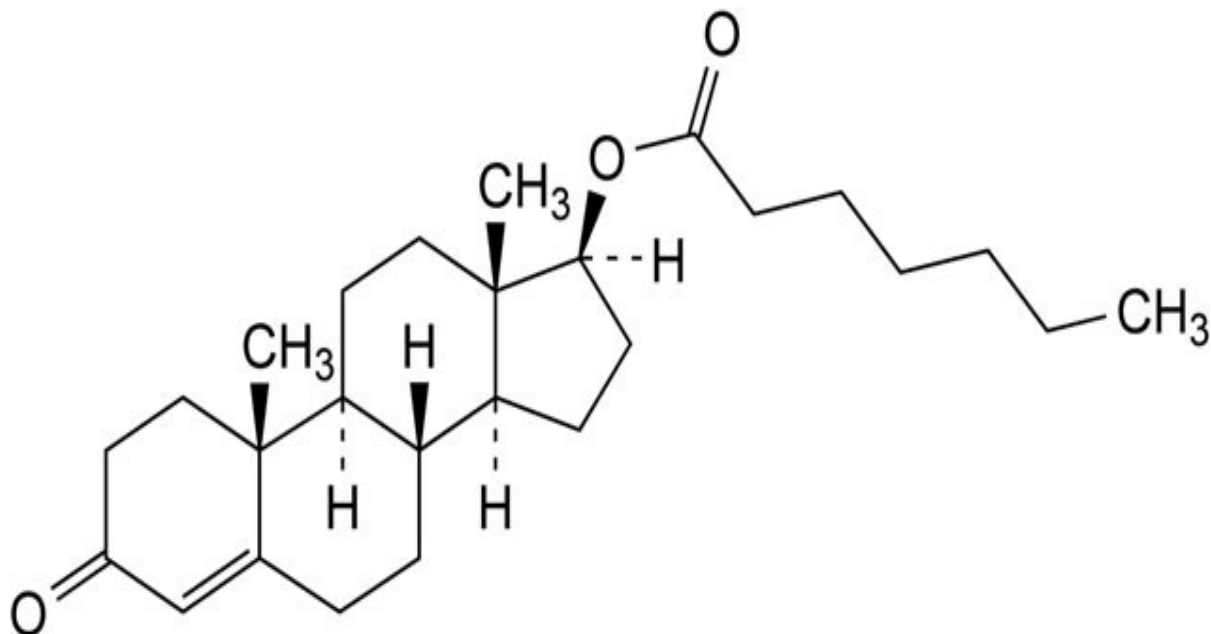
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopr opoxy)-, (17β)-		Testosterone cipionate; Testosterone cyclopentylpropionate; Testosterone cyclopentanepropionate; Testosterone 17β- cyclopentylpropionate	
Identifiers & Properties			
CAS Number	58-20-8	Appearance:	White or creamy white, crystalline powder.
Chemical formula	C ₂₇ H ₄₀ O ₃	Odour:	odorless or has a slight odor
Molar mass	412.6 g·mol−1	Melting point	Between 98° and 104°.
Specific Optical Rotation:	+85.0° to +92.0°	Assay :	97.0% to 103.0%
Pharmacology			
Routes of administration	Intramuscular injection		

Testosterone Propionate IP/BP/EP/USP



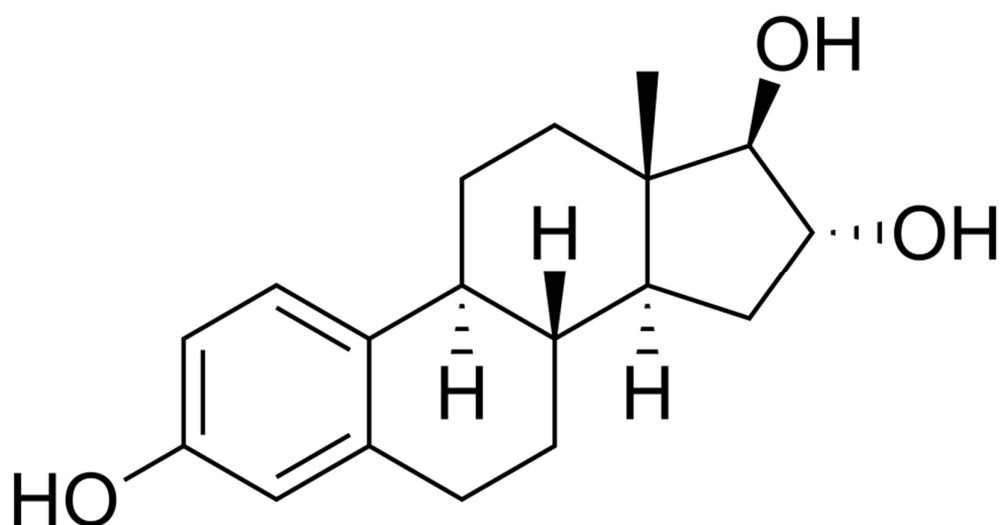
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
3-Oxoandrost-4-en-17β-yl propanoate.		Testosterone propanoate; Testosterone 17β-propanoate Propionyltestosterone	
Identifiers & Properties			
CAS Number	57-85-2	Appearance:	A white or almost white powder or colourless crystals.
Chemical formula	C ₂₂ H ₃₂ O ₃	Melting point	Between 118 °C and 123 °C.
Molar mass	344.5 g·mol ^{−1}	HPLC	Total Impurities: NMT 1.0 %
Specific Optical Rotation:	+83.0° to +90.0°	Assay :	97.0% to 103.0%
Pharmacology			
Routes of administration	Intramuscular injection, buccal		

Testosterone Enanthate BP/EP/USP



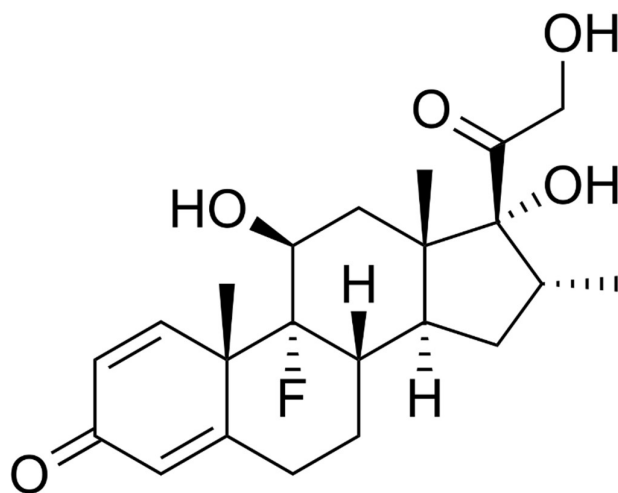
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
3-Oxoandrost-4-en-17β-yl heptanoate.		Testosterone heptanoate; Testosterone 17β-heptanoate;	
Identifiers & Properties			
CAS Number	315-37-7	Appearance:	White or yellowish-white, crystalline powder
Chemical formula	C ₂₆ H ₄₀ O ₃	Melting point	34 °C to 39 °C.
Molar mass	400.6 g·mol ^{−1}	HPLC	Total Impurities: NMT 0.7 %
Specific Optical Rotation:	+81.0° to +86.0°	Assay :	97.0% to 103.0%
Pharmacology			
Routes of administration	Intramuscular injection, Subcutaneous Injection		

Estriol BP/EP/USP



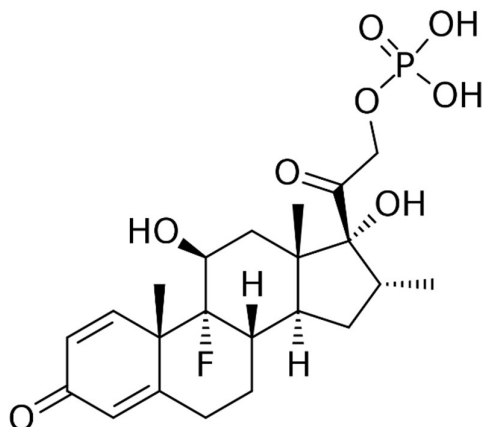
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
Estra-1,3,5(10)-triene-3,16 α ,17 β -triol.		Oestriol; Estratriol; Trihydroxyestrin; Trihydroxyoestrin; 16 α -Hydroxyestradiol	
Identifiers & Properties			
CAS Number	50-27-1	Appearance:	A white or almost white, crystals powder
Chemical formula	C ₁₈ H ₂₄ O ₃	Residue on Ignition:	NMT 0.1 %
Molar mass	288.4 g·mol ⁻¹	HPLC	Total Impurities: NMT 1.0 %
Specific Optical Rotation:	+60.0° to +65.0°	Assay :	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, vaginal, intramuscular injection		

Dexamethasone IP/BP/EP/USP



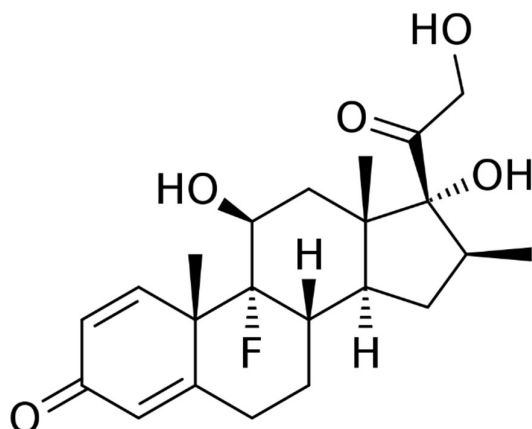
Names			
<p><u>Preferred IUPAC Name</u> :</p> <p>(8S,9R,10S,11S,13S,14S,16R,17R)-9-Fluoro-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-3-one</p>		<p>Other Names:</p> <p>Dexamethasone corticosteroid</p>	
Identifiers & Properties			
CAS Number	50-02-2	Appearance:	A White or almost white powder
		Odour:	Odourless Powder
Chemical formula	C ₂₂ H ₂₉ FO ₅	RS Single Impurity: RS Total Impurity:	NMT-0.5 % NMT-1.0 %
Molar mass	392.467 g·mol ⁻¹	HPLC :	NLT 99.0 %
Specific Optical Rotation:	+72.0° to +80.0°	Assay By HPLC:	96.0% to 104.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection, Drops, spray.		

Dexamethasone Sodium Phosphate IP/BP/EP/USP



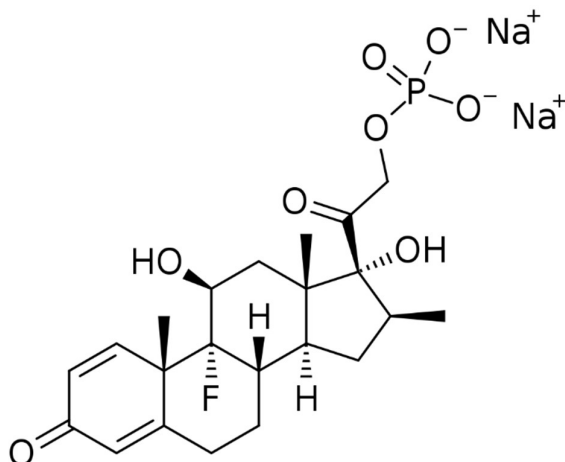
Names			
<p><u>Preferred IUPAC Name</u> :</p> <p>(8S,9R,10S,11S,13S,14S,16R,17R)-9-Fluoro-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-3-one</p>		<p>Other Names :</p>	
		<p>Hexadrol Phosphate</p>	
Identifiers & Properties			
<p>CAS Number</p>	<p>2392-39-4</p>	<p>Appearance:</p> <p>Odour:</p>	<p>A White or almost white powder</p> <p>Odourless Powder</p>
<p>Chemical formula</p>	<p>C₂₂H₂₈FN₂O₈P</p>	<p>RS Total Impurity:</p>	<p>NMT 1.0 %</p>
<p>Molar mass</p>	<p>516.4 g·mol⁻¹</p>	<p>HPLC :</p>	<p>NLT 99.0 %</p>
<p>Specific Optical Rotation:</p>	<p>+75.0° to +83.0°</p>	<p>Assay By HPLC:</p>	<p>97.0% to 102.0%</p>
Pharmacology			
<p>Routes of administration</p>	<p>By mouth, sublingual, injection, Drops, spray.</p>		

Betamethasone IP/BP/EP/USP



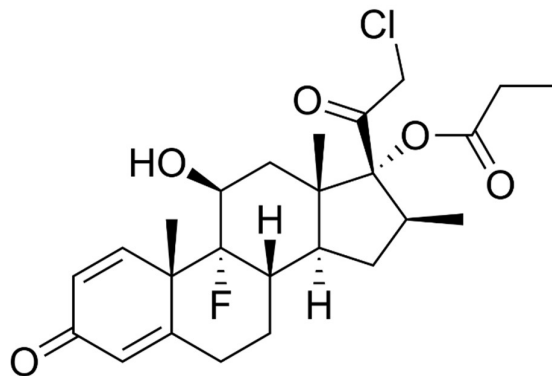
Names			
<p><u>Preferred IUPAC Name</u> :</p> <p>(8S,9R,10S,11S,13S,14S,16S,17R)-9-Fluoro- 11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl- 6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro- 3H-cyclopenta[a]phenanthren-3-one</p>		<p>Other Names:</p>	
		Betamethasonum	
Identifiers & Properties			
<p>CAS Number</p>	378-44-9	<p>Appearance:</p> <p>Odour:</p>	<p>A White or almost white powder</p> <p>Odourless Powder</p>
<p>Chemical formula</p>	C ₂₂ H ₂₉ FO ₅	<p>RS Total Impurity:</p>	<p>NMT 2.0 %</p>
<p>Molar mass</p>	392.46 g·mol ⁻¹	<p>HPLC :</p>	<p>NLT 98.0 %</p>
<p>Specific Optical Rotation:</p>	+118.0° to +126.0°	<p>Assay:</p>	<p>96.0% to 104.0%</p>
Pharmacology			
<p>Routes of administration</p>	<p>By mouth, topical, intramuscular</p>		

Betamethasone Sodium phosphate IP/BP/EP/USP



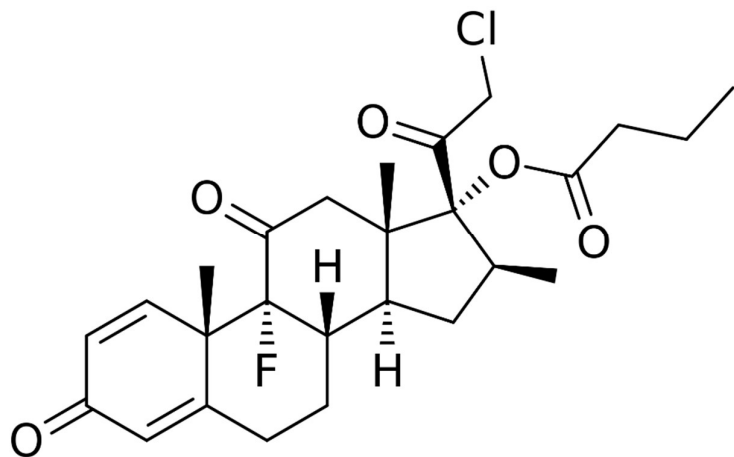
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
Disodium; [2-[(8 <i>S</i> ,9 <i>R</i> ,10 <i>S</i> ,11 <i>S</i> ,13 <i>S</i> ,14 <i>S</i> ,16 <i>S</i> ,17 <i>R</i>)-9-fluoro-11,17-dihydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[<i>a</i>]phenanthren-17-yl]-2-oxoethyl] phosphate		Betamethasone 21-phosphate disodium	
Identifiers & Properties			
CAS Number	151-73-5	Appearance:	A White or almost white powder
		Odour:	Odourless Powder
Chemical formula	C ₂₂ H ₂₈ FNa ₂ O ₈ P	RS Total Impurity:	NMT 3.0 %
Molar mass	516.4 g/mol	HPLC :	NLT 97.0 %
Specific Optical Rotation:	+98.0° to +104.0°	Assay By HPLC:	96.0% to 103.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection, Drops, spray.		

Clobetasol Propionate IP/BP/EP/USP



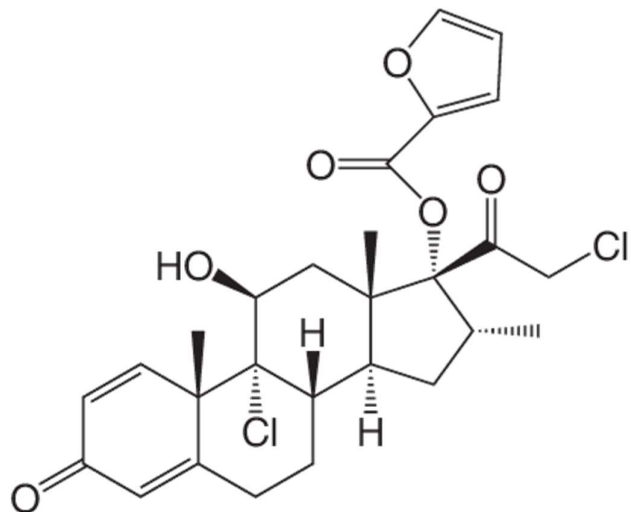
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
[17-(2'-Chloroacetyl)-9-fluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] propanoate		Clobetasol 17-propanoate	
Identifiers & Properties			
CAS Number	25122-46-7	Appearance:	White or almost white, crystalline powder
		Odour:	Odourless Powder
Chemical formula	C ₂₅ H ₃₂ ClFO ₅	RS Total Impurity:	NMT 2.0 %
Molar mass	466.97 g·mol ⁻¹	HPLC :	NLT 98.0 %
Specific Optical Rotation:	+112.0° to +118.0°	Assay By HPLC:	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection, Drops, spray.		

Clobetasone butyrate BP/EP



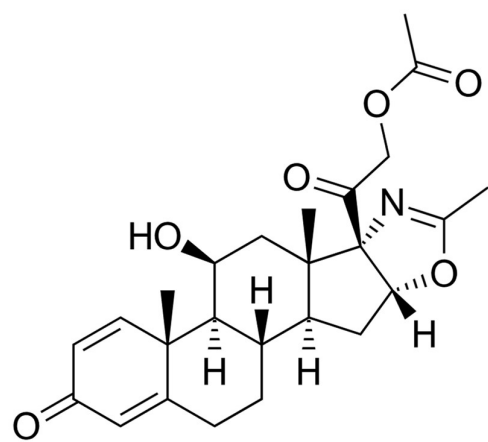
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
(16β)-21-Chloro-9-fluoro-16-methyl-3,11,20-trioxopre gna-1,4-dien-17-yl butyrate		Clobetasone 17-butyrate	
Identifiers & Properties			
CAS Number	25122-57-0	Appearance:	A White or almost white powder
		Odour:	Odourless Powder
Chemical formula	C ₂₆ H ₃₂ ClFO ₅	RS Single Impurity: RS Total Impurity:	NMT-0.1% NMT-0.5%
Molar mass	478.99 g·mol ⁻¹	HPLC :	NLT 99.5 %
Specific Optical Rotation:	+131.0° to +138.0°	Assay By UV:	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection, Drops, spray.		

Mometasone Furoate IP/BP/EP/USP



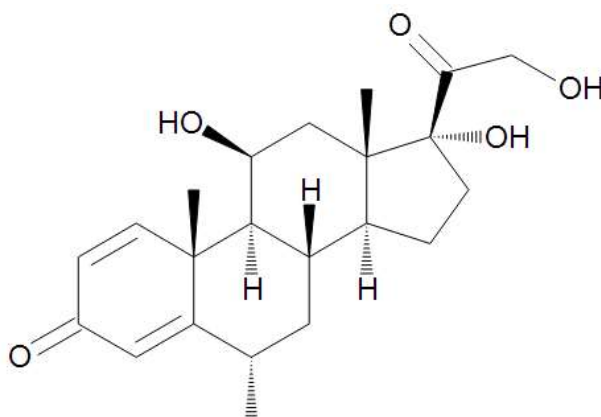
Names			
<div>Preferred IUPAC Name :</div> <div>[(8S,9R,10S,11S,13S,14S,16R,17R)-9-chloro-17-(2-chloroacetyl)-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] furan-2-carboxylate</div>		<div>Other Names:</div> <div>mometasone 17-furoate, Mometasone furoate anhydrous</div>	
Identifiers & Properties			
CAS Number	83919-23-7	Appearance:	A White or almost white powder
		Odour:	Odourless Powder
Chemical formula	C ₂₇ H ₃₀ Cl ₂ O ₆	RS Total Impurity:	NMT 0.3%
Molar mass	521.43 g·mol ^{−1}	HPLC :	NLT 99.4 %
Specific Optical Rotation:	+50.0° to +55.0°	Assay By HPLC:	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection, Drops, spray.		

Deflazacort IH



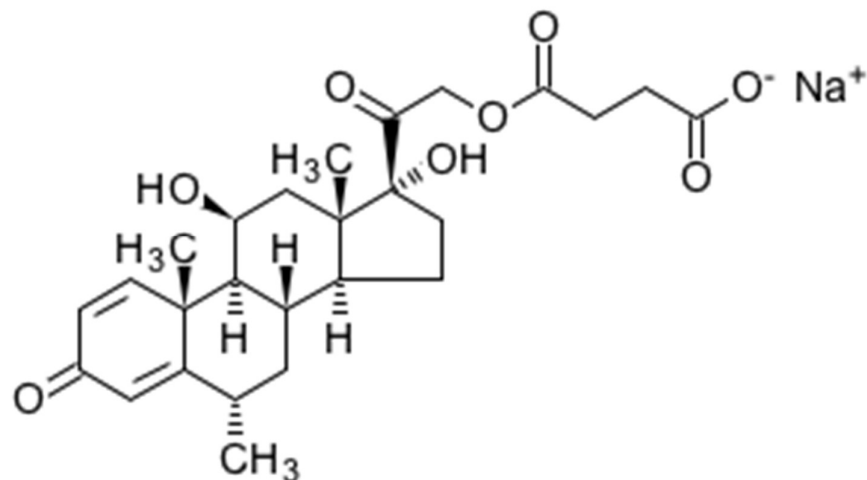
Names			
<div><div><div><div><div></div><div></div></div></div><div><div><div><u>Preferred IUPAC Name</u> :</div><div><div>(11β,16β)-21-(Acetyloxy)-11-hydroxy-2'-methyl-5'H-pr egna-1,4-dieno[17,16-d] oxazole-3,20-dione</div></div></div></div></div></div>		<div><div><div><div>Other Names:</div><div><div>Deflazacort</div></div></div></div></div>	
Identifiers & Properties			
<div><div><div><div></div><div></div></div></div><div><div><div>CAS Number</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>14484-47-0</div></div></div></div>	<div><div><div><div>Appearance:</div><div>Odour:</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>White to creamy white crystalline powder.</div></div></div></div>
<div><div><div><div></div><div></div></div></div><div><div><div>Chemical formula</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>C₂₅H₃₁NO₆</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>RS Total Impurity:</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>NMT 2.0%</div></div></div></div>
<div><div><div><div></div><div></div></div></div><div><div><div>Molar mass</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>441.52 g·mol−1</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>HPLC :</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>NLT 98.0 %</div></div></div></div>
<div><div><div><div></div><div></div></div></div><div><div><div>Specific Optical Rotation:</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>+57.0° to +65.0°</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>Assay By HPLC:</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>97.0% to 102.0%</div></div></div></div>
Pharmacology			
<div><div><div><div></div><div></div></div></div><div><div><div>Routes of administration</div></div></div></div>	<div><div><div><div></div><div></div></div></div><div><div><div>By mouth</div></div></div></div>		

Methyl Prednisolone IP/BP/EP/USP



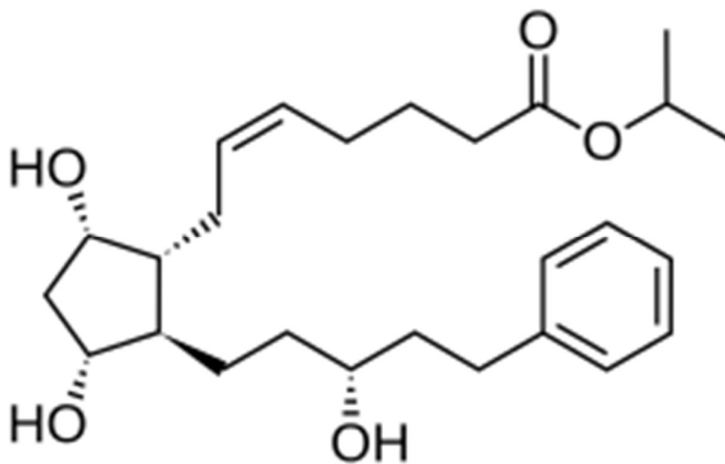
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
6α-Methylprednisolone; 11β,17,21-trihydroxy-6α-methyl-δ ¹ -progesterone; 11β,17,21-Trihydroxy-6α-methylpregna-1,4-diene-3,20-dione		11β,17,21-trihydroxy-6α-methylpregna-1,4-diene-3, 20-dione	
Identifiers & Properties			
CAS Number	83-43-2	Appearance: Odour:	A white or almost white, crystalline powder.
Chemical formula	C ₂₂ H ₃₀ O ₅	RS Total Impurity:	NMT 2.0 %
Molar mass	374.5 g·mol ^{−1}	HPLC :	NLT 98.0 %
Specific Optical Rotation:	+79.0° to +86.0°	Assay By HPLC:	97.0% to 102.0%
Pharmacology			
Routes of administration	By mouth, intramuscular, intra-articular, intravenous		

Methyl Prednisolone Sodium Succinate USP



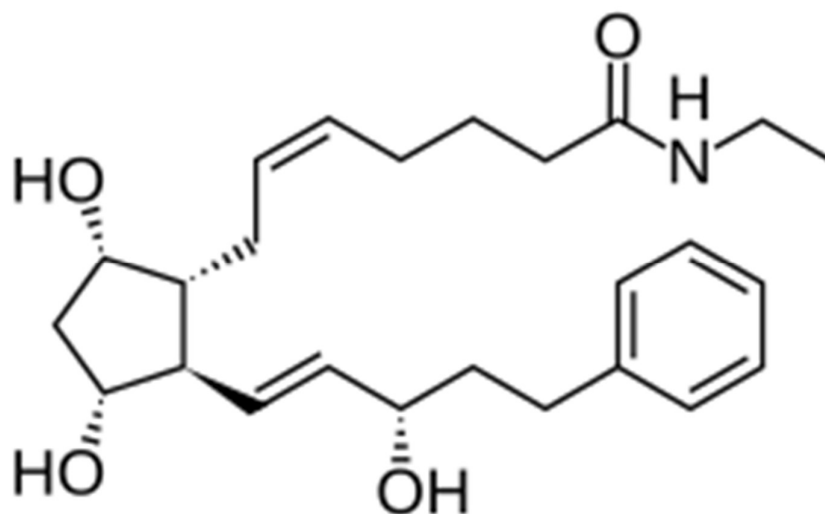
Names			
<u>Preferred IUPAC Name</u> :		Other Names:	
4-[2-[(6S,8S,9S,10R,11S,13S,14S,17R)-11,17-dihydr oxy-6,10,13-trimethyl-3-oxo-7,8,9,11,12,14,15,16-oct ahydro-6H-cyclopenta[a]phenanthren-17-yl]-2-oxoeth oxy]-4-oxobutanoic acid			
Methylprednisolone 21-succinate sodium salt			
Identifiers & Properties			
CAS Number	2375-03-3	Appearance: Odour:	White or nearly white, odourless, hygroscopic, amorphous solid Powder
Chemical formula	C ₂₆ H ₃₃ NaO ₈	Specific Optical Rotation:	+96.0° to +104.0°
Molar mass	496.5 g·mol ^{−1}	Assay :	97.0% to 103.0%
Pharmacology			
Routes of administration	Intravenous, intramuscular injection.		

Latanoprost IP/BP/EP/USP



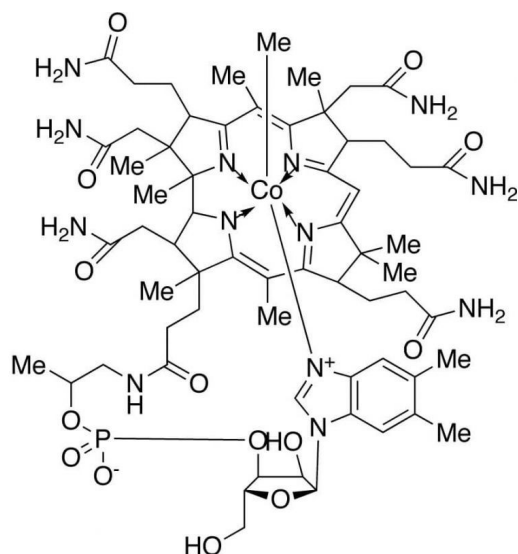
Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
propan-2-yl (Z)-7-[(1 <i>R</i> ,2 <i>R</i> ,3 <i>R</i> ,5 <i>S</i>)-3,5-dihydroxy-2-[(3 <i>R</i>)-3-hydroxy-5-phenylpentyl]cyclopentyl]hept-5-enoate		Latanoprost (isopropyl ester)	
Identifiers & Properties			
CAS Number	130209-82-4	Appearance:	Clear, colourless or yellow, viscous, oily liquid
Chemical formula	C ₂₆ H ₄₀ O ₅	Specific Optical Rotation:	+31.0° to +38.0°
Molar mass	432.6 g·mol−1	Assay :	94.0% to 102.0%
Pharmacology			
Routes of administration	Topical eye drops		

Bimatoprost IH



Names			
<u>Preferred IUPAC Name</u> :		<u>Other Names:</u>	
(Z)-7-[(1R,2R,3R,5S)-3,5-Dihydroxy-2-[(1E,3S)-3-hydroxy-5-phenyl-1-pentenyl]cyclopentyl]-N-ethyl-5-heptenamide		Bimatoprost	
Identifiers & Properties			
CAS Number	155206-00-1	Appearance:	White or almost white powder
Chemical formula	C ₂₅ H ₃₇ NO ₄	Residue on Ignition:	NMT 0.2 %
Molar mass	415.6 g·mol ^{−1}	HPLC	Total Impurities: NMT 1.0 %
Specific Optical Rotation:	+33.0° to +39.0°	Assay :	97.0% to 101.0%
Pharmacology			
Routes of administration	Eye drops		

Methylcobalamin IP/JP



Names			
<u>Preferred IUPAC Name</u> : Carbanide; cobalt(3+);		Other Names : Mecobalamin	
Identifiers & Properties			
CAS Number	13422-55-4	Appearance:	A Saffron or Red Colour Crystals
Chemical formula	C ₆₃ H ₉₁ CoN ₁₃ O ₁₄ P	Odour:	Odourless Powder
Molar mass	1344.405 g/mol	RS Single Impurity : RS Total Impurity :	NMT-0.5% NMT-2.0%
HPLC :	NLT 98.0%	Assay By HPLC:	NLT 98.0%
Pharmacology			
Routes of administration	By mouth, sublingual, injection.		



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