



U.S. PHARMACOPEIA
*The Standard of Quality*SM

USAN and INN Process

Andrzej Wilk, Ph. D.

Development of a Freely Distributable Data System for the Registration of
Substances and Related Information Based on ISO 11238

February, 2013



USAN Mission



The purpose of the United States Adopted Names (USAN) Council is to serve the health professions in the United States by selecting simple, informative, and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships.



USAN goals

Aims for global standardization and unification of drug nomenclature and related rules to ensure that drug information is communicated accurately and unambiguously, working closely with the International Nonproprietary Name (INN) Programme of the World Health Organization (WHO), and various national nomenclature groups.



USAN Council

USAN Council

The three organizations that sponsor the USAN program, i.e., the American Medical Association, the American Pharmacists Association, and the U.S. Pharmacopeia, do so through representation on the USAN Council. Members are appointed by their sponsors, subject to acceptance by the other sponsors. In addition, the three organizations jointly select a member-at-large. Members are appointed for one-year terms and may serve no more than ten consecutive terms.



USAN Council – FDA membership

In 1967, negotiations were completed to provide for participation by the U.S. Food and Drug Administration in the program as a means of consolidating the work of selecting suitable nonproprietary names for drugs on the part of the federal government and the existing Council. Thus, a liaison representative of the FDA sits on the Council.



USAN Council – present members

The USAN Council is tri-sponsored by the

- ◆ American Medical Association (AMA)
 - ▶ Peter Rheinstein, M.D., J.D. (Chair)
- ◆ United States Pharmacopeial Convention (USP)
 - ▶ Kent T. Johnson M.S.Pharm
- ◆ American Pharmacists Association (APhA)
 - ▶ Judith K. Jones, M.D., Ph.D.
- ◆ David Lewis, Ph.D., (FDA)
- ◆ Member-at-large – Armen P. Melikian, Ph. D. (APhA)



USAN - Purpose

The Purpose of USAN

- ◆ identify the substance to which it applies and to serve as a designation that may be used without restriction by the public at large
- ◆ teaching in pharmacy and medicine requires a common designation, especially for a drug that is available from several sources or in a combination of two or more drugs



The Purpose of USAN

- ◆ nonproprietary names greatly facilitate communication between health professionals, and most journals demand their use
- ◆ state formularies and hospital and managed care organization formularies generally use nonproprietary names as the titles of the articles recognized.



USAN - Purpose

The Purpose of USAN

- ◆ nonproprietary name is essential to the pharmaceutical manufacturer as a means of preserving trade mark rights to a brand name for the article concerned.
- ◆ federal law obliges the manufacturer to use the “established” nonproprietary name in advertising, labels, and brochures.



USAN - Procedure

USAN Procedure

- ◆ firm or an individual who has developed a substance of potential therapeutic utility
- ◆ submission for a USAN is expected to conform to the established Guiding Principles
 - ▶ reasonably free from conflict with other names
 - ▶ discourage in trademarks the syllables used in an established nonproprietary name



USAN - Procedure

USAN Procedure

- ◆ initial screening
 - ▶ user's fee
 - ▶ form - “Request for a United States Adopted Name (USAN),”
- ◆ results of searches conducted by the Secretary
- ◆ tentative decision



USAN Submission Form

Appendix IX

USAN Submission Forms

1357

Form A

USAN Application for Single Entity Drug and Salt Form

UNITED STATES ADOPTED NAMES COUNCIL
AMERICAN MEDICAL ASSOCIATION
515 N. STATE ST.
CHICAGO, IL 60654
312-464-4046

REQUEST FOR A UNITED STATES ADOPTED NAME (USAN) FOR A SINGLE ENTITY DRUG AND USAN MODIFIED

(for USAN staff use only)

File No. (Single Entity):
File No. (Modified):
INN Status:

Acknowledged:
WHO No.:

SUGGESTED NAME(S) IN ORDER OF PREFERENCE FOR SINGLE ENTITY:

(Please attach verification of the absence of conflicts with existing chemical names, insecticides, other nonproprietary names or trademarks)

1.
2.
3.

DESIGNATION FOR SALT FORM (e.g. hydrochloride, sodium, etc.)

CHEMICAL NAME(S) OR DESCRIPTION FOR SINGLE ENTITY:

(Chemical Abstracts Service Index Name must be supplied)

CHEMICAL NAME(S) OR DESCRIPTION FOR SALT FORM:

(Chemical Abstracts Service Index Name must be supplied)

1358

USAN Submission Forms

Appendix IX

STRUCTURAL FORMULA FOR SINGLE ENTITY:

(Provide stereochemistry)

When naming biologics please take note of the following reminders:

- The complete amino acid sequence is required for proteins, peptides or antibodies, or the nucleotide sequence for oligonucleotides, in an editable MS Word document.*
- For a glycoprotein/glycopeptide, the glycosylation pattern including the sites of glycosylation, type of sugars, etc.*
- Please supply the origin of each chain; sites of disulfide-bridges; Ig-subclass; name/structure of the antigen against which the monoclonal antibody is directed.*
- Include expression system and comparison with the native sequence.*

STRUCTURAL FORMULA FOR SALT FORM:

(Provide stereochemistry)

MOLECULAR FORMULA FOR SINGLE ENTITY:

MOLECULAR FORMULA FOR SALT FORM:

MOLECULAR WEIGHT FOR SINGLE ENTITY:



USAN Procedure

USAN Procedure

- ◆ Suggested USAN
 - ▶ sent to the World Health Organization (WHO)
 - ▶ sent to the Spanish regulatory authorities
- ◆ Tentatively adopted USAN
 - ▶ submitted to the WHO



USAN Objections

USAN Procedure

- ◆ Valid objections
 - ▶ unsuitable for adoption elsewhere
 - ▶ closely similar name accepted (e.g. BAN)



USAN - Approved

USAN Procedure

- ◆ Approved USAN
 - ▶ published electronically on the web site
www.ama-assn.org/go/usan
 - ▶ published in the USP dictionary of USAN and International Drug Names



USAN – Adoption Statement

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

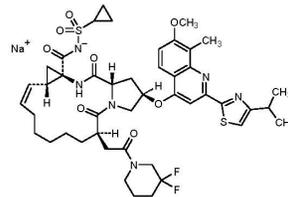
USAN
PRONUNCIATION
THERAPEUTIC CLAIM

NECEPREVIR SODIUM
nes e' pre vir
Treatment of Hepatitis C

CHEMICAL NAMES

1. Cyclopropa[e]pyrrolo[1,2-a][1,4]diazacyclopentadecine-14a(5*H*)-carboxamide, *N*-(cyclopropylsulfonyl)-6-[2-(3,3-difluoro-1-piperidiny)-2-oxoethyl]-1,2,3,6,7,8,9,10,11,13a,14,15,16,16a-tetradecahydro-2-[[7-methoxy-8-methyl-2-[4-(1-methylethyl)-2-thiazolyl]-4-quinolinyl]oxy]-5,16-dioxo-, sodium salt (1:1), (2*R*,6*R*,12*Z*,13*a**S*,14*a**R*,16*a**S*)-
2. Sodium (cyclopropylsulfonyl){[(2*R*,6*R*,12*Z*,13*a**S*,14*a**R*,16*a**S*)-6-[2-(3,3-difluoropiperidin-1-yl)-2-oxoethyl]-2-[(7-methoxy-8-methyl-2-[4-(1-methylethyl)thiazol-2-yl]quinolin-4-yl]oxy]-5,16-dioxo-1,2,3,6,7,8,9,10,11,13*a*,14,15,16,16a-tetradecahydrocyclopropa[e]pyrrolo[1,2-a][1,4]diazacyclopentadecine-14a(5*H*)-yl]formyl]azanide

STRUCTURAL FORMULA



MOLECULAR FORMULA
MOLECULAR WEIGHT
TRADEMARK
SPONSOR
CODE DESIGNATION
CAS REGISTRY NUMBER

C₄₅H₅₅F₂N₆NaO₈S₂
933.1
None as yet
Achillion Pharmaceuticals, Inc.
ACH-0142684.Na, ACH-2684.Na
1298053-61-8



INN at WHO

Address <http://www.who.int/medicines/services/inn/en/>



World Health Organization

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International Nonproprietary Names

Guidance

International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.

:: [General guidance](#)

Mandate

WHO has a constitutional mandate to "develop, establish and promote international standards with respect to biological, pharmaceutical and similar products".

The World Health Organization collaborates closely with INN experts and national nomenclature committees to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical. To avoid confusion, which could jeopardize the safety of patients, trade-marks should neither be derived from INNs nor contain common stems used in INNs.

The selection and publication of INNs falls under the responsibility of the HTP/PSM/QSM team of the INN Programme.

Contact us

[Full text](#)

LATEST NEWS AND EVENTS

21 September 2006
[Health Outcomes and the Poor E-Learning course in English](#)

19 September 2006
[Twentieth Meeting of the WHO International Working Group for Drug Statistics Methodology](#)

15 September 2006
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[Version française](#)



International Nonproprietary Names for Pharmaceutical Substances (INN)

Notice is hereby given that, in accordance with article 3 of the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances, the names given in the list on the following pages are under consideration by the World Health Organization as Proposed International Nonproprietary Names. The inclusion of a name in the lists of Proposed International Nonproprietary Names does not imply any recommendation of the use of the substance in medicine or pharmacy.

Lists of Proposed (1–105) and Recommended (1–66) International Nonproprietary Names can be found in *Cumulative List No. 14, 2011* (available in CD-ROM only). The statements indicating action and use are based largely on information supplied by the manufacturer. This information is merely meant to provide an indication of the potential use of new substances at the time they are accorded Proposed International Nonproprietary Names. WHO is not in a position either to uphold these statements or to comment on the efficacy of the action claimed. Because of their provisional nature, these descriptors will neither be revised nor included in the Cumulative Lists of INNs.

Dénominations communes internationales des Substances pharmaceutiques (DCI)

Il est notifié que, conformément aux dispositions de l'article 3 de la Procédure à suivre en vue du choix de Dénominations communes internationales recommandées pour les Substances pharmaceutiques les dénominations ci-dessous sont mises à l'étude par l'Organisation mondiale de la Santé en tant que dénominations communes internationales proposées. L'inclusion d'une dénomination dans les listes de DCI proposées n'implique aucune recommandation en vue de l'utilisation de la substance correspondante en médecine ou en pharmacie.

On trouvera d'autres listes de Dénominations communes internationales proposées (1–105) et recommandées (1–66) dans la *Liste récapitulative No. 14, 2011* (disponible sur CD-ROM seulement). Les mentions indiquant les propriétés et les indications des substances sont fondées sur les renseignements communiqués par le fabricant. Elles ne visent qu'à donner une idée de l'utilisation potentielle des nouvelles substances au moment où elles sont l'objet de propositions de DCI. L'OMS n'est pas en mesure de confirmer ces déclarations ni de faire de commentaires sur l'efficacité du mode d'action ainsi décrit. En raison de leur caractère provisoire, ces informations ne figureront pas dans les listes récapitulatives de DCI.

Denominaciones Comunes Internacionales para las Sustancias Farmacéuticas (DCI)

De conformidad con lo que dispone el párrafo 3 del "Procedimiento de Selección de Denominaciones Comunes Internacionales Recomendadas para las Sustancias Farmacéuticas", se comunica por el presente anuncio que las denominaciones detalladas en las páginas siguientes están sometidas a estudio por la Organización Mundial de La Salud como Denominaciones Comunes Internacionales Propuestas. La inclusión de una denominación en las listas de las DCI Propuestas no supone recomendación alguna en favor del empleo de la sustancia respectiva en medicina o en farmacia.

Las listas de Denominaciones Comunes Internacionales Propuestas (1–105) y Recomendadas (1–66) se encuentran reunidas en *Cumulative List No. 14, 2011* (disponible sólo en CD-ROM). Las indicaciones sobre acción y uso que aparecen se basan principalmente en la información facilitada por los fabricantes. Esta información tiene por objeto dar una idea únicamente de las posibilidades de aplicación de las nuevas sustancias a las que se asigna una DCI Propuesta. La OMS no está facultada para respaldar esas indicaciones ni para formular comentarios sobre la eficacia de la acción que se atribuye al producto. Debido a su carácter provisional, esos datos descriptivos no deben incluirse en las listas recapitulativas de DCI.



USAN Dictionary

USP Dictionary





USAN Dictionary – entry

Cephalexin [1967] (sef' a lex' in). **USP.** C₁₆H₁₇N₃O₄S.H₂O. 365.40. [Cephalexin is INN, IAN and JAN.] (1) 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-(2-phenylacetylamino)-8-methoxy-, monohydrate (SR 7R)-7-(R)-2-Amino-2-phenylacetyl-1-azabicyclo[4.2.0]octane-2-carboxylic acid (3) 7-(2-phenylacetylamino)-8-methoxy-3-cephem-4-carboxylic acid; 578-78-1 CAS- (Keflex orally); component of Cephalexin

US Name

Chemical formula

International nonproprietary names

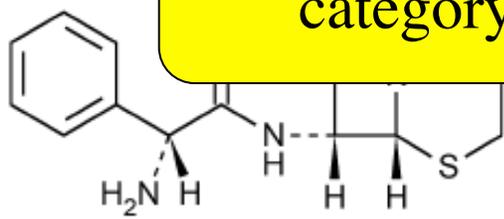
Molecular weight

Brand name(s)

Therapeutic category

Manufacturer(s)

Code designation



66873



Challenges

Nabiximols - (nab ix' i mols).



Date	[2008]
Molecular Info	$C_{21}H_{30}O_2$ (A) THC . 314.46 (A) THC; $C_{21}H_{30}O_2$ (B) CBD. 314.46 (B) CBD.
Chemical Name	(A) Delta-9-tetrahydrocannabinol (THC): (1) 6 <i>H</i> -Dibenzo[<i>b,d</i>]pyran-1-ol, 6 <i>a</i> ,7,8,10 <i>a</i> -tetrahydro-6,6,9-trimethyl-3-pentyl-, (6 <i>aR</i> ,10 <i>aR</i>)-; (2) (6 <i>aR</i> ,10 <i>aR</i>)-6,6,9-Trimethyl-3-pentyl-6 <i>a</i> ,7,8,10 <i>a</i> -tetrahydro-6 <i>H</i> -dibenzo[<i>b,d</i>]pyran-1-ol; (3) Highly characterized botanical extract of a defined chemotype of <i>Cannabis sativa</i> L. The major chemical constituent is the cannabinoid, delta-9-tetrahydrocannabinol (THC). Important minor constituents are related cannabinoids and non-cannabinoid components alpha- and trans-caryophyllenes. (B) Cannabidiol (CBD): (1) 1,3-Benzenediol, 2-[(1 <i>R</i> ,6 <i>R</i>)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-; (2) 2-[(1 <i>R</i> ,6 <i>R</i>)-3-Methyl-6-(1-methylethenyl)cyclohex-2-enyl]-5-pentylbenzene-1,3-diol; (3) Highly characterized botanical extract of a defined chemotype of <i>Cannabis sativa</i> L. The major chemical constituent is the cannabinoid cannabidiol (CBD). Important minor constituents are related cannabinoids and non-cannabinoid components alpha- and trans-caryophyllenes.
CAS Numbers	CAS-1972-08-3 [(A) THC]; CAS-13956-29-1 [(A) CBD].
Category	<i>Relief of pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy.</i>
Manufacturer Info	Sativex (GW Pharma Ltd)
Code Designations	◇GW-1000

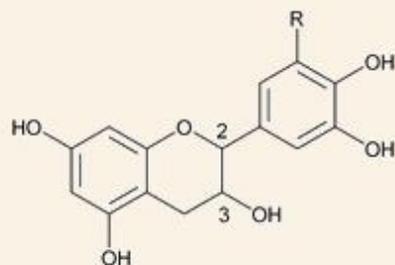


Challenges

Sinecatechins - (sin' e kat' e kins).

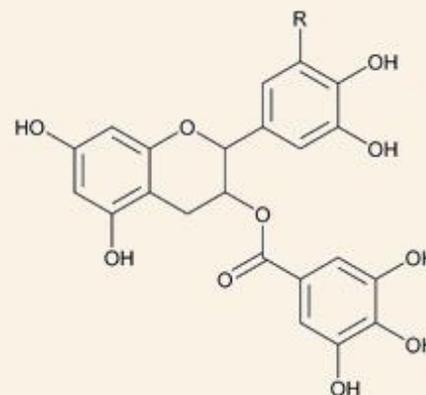


Date	[2006]
Chemical Name	(1) Tea (<i>Camellia sinensis</i>), ext; (2) Major chemical constituents are (-)-Epicatechin, (-)-Epigallocatechin with their corresponding 3-gallate esters, and their corresponding epimers.
UNII Codes	UNII-W2ZU1RY8B0.
CAS Numbers	CAS-811420-59-4.
Category	Treatment of external genital and perianal warts.
Manufacturer Info	Veregen (Medigene)



R = H C₁₅H₁₄O₆ 290.27
R = OH C₁₅H₁₄O₆ 306.27

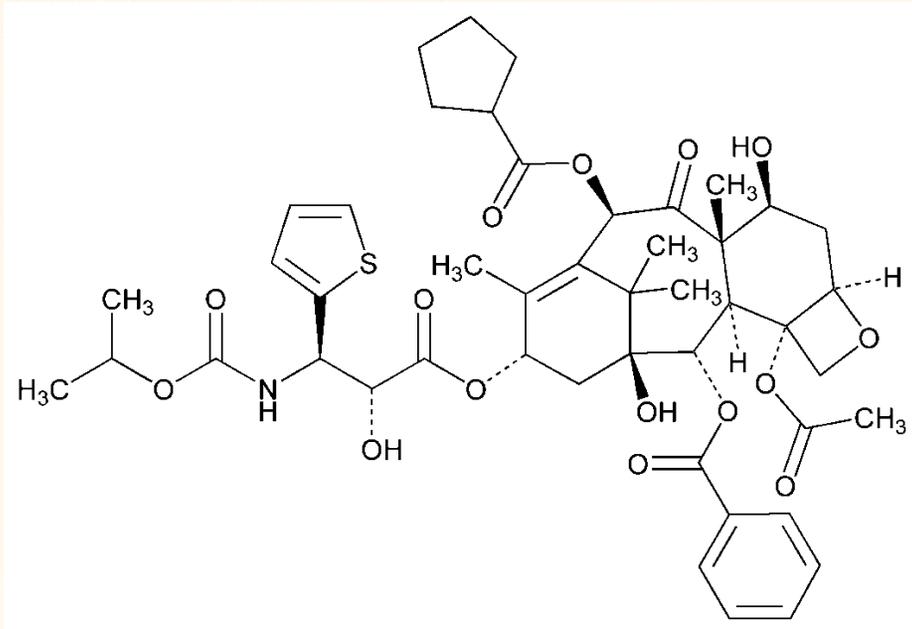
R = H (-)-Epicatechin [cis-, 2R,3R]
R = OH (-)-Epigallocatechin [cis-, 2R,3R]
R = H (+)-Catechin [trans-, 2R,3S]
R = H (-)-Catechin [trans-, 2S,3R]
R = OH (+)-Gallocatechin [trans-, 2R,3S]
R = OH (-)-Gallocatechin [trans-, 2S,3R]



R = H C₂₂H₁₈O₁₀ 442.37
R = OH C₂₂H₁₆O₁₁ 458.37

R = H (-)-Epicatechin gallate [cis-, 2R,3R]
R = OH (-)-Epigallocatechin gallate [cis-, 2R,3R]
R = H (-)-Catechin gallate [trans-, 2S,3R]
R = OH (-)-Gallocatechin gallate [trans-, 2S,3R]

International considerations

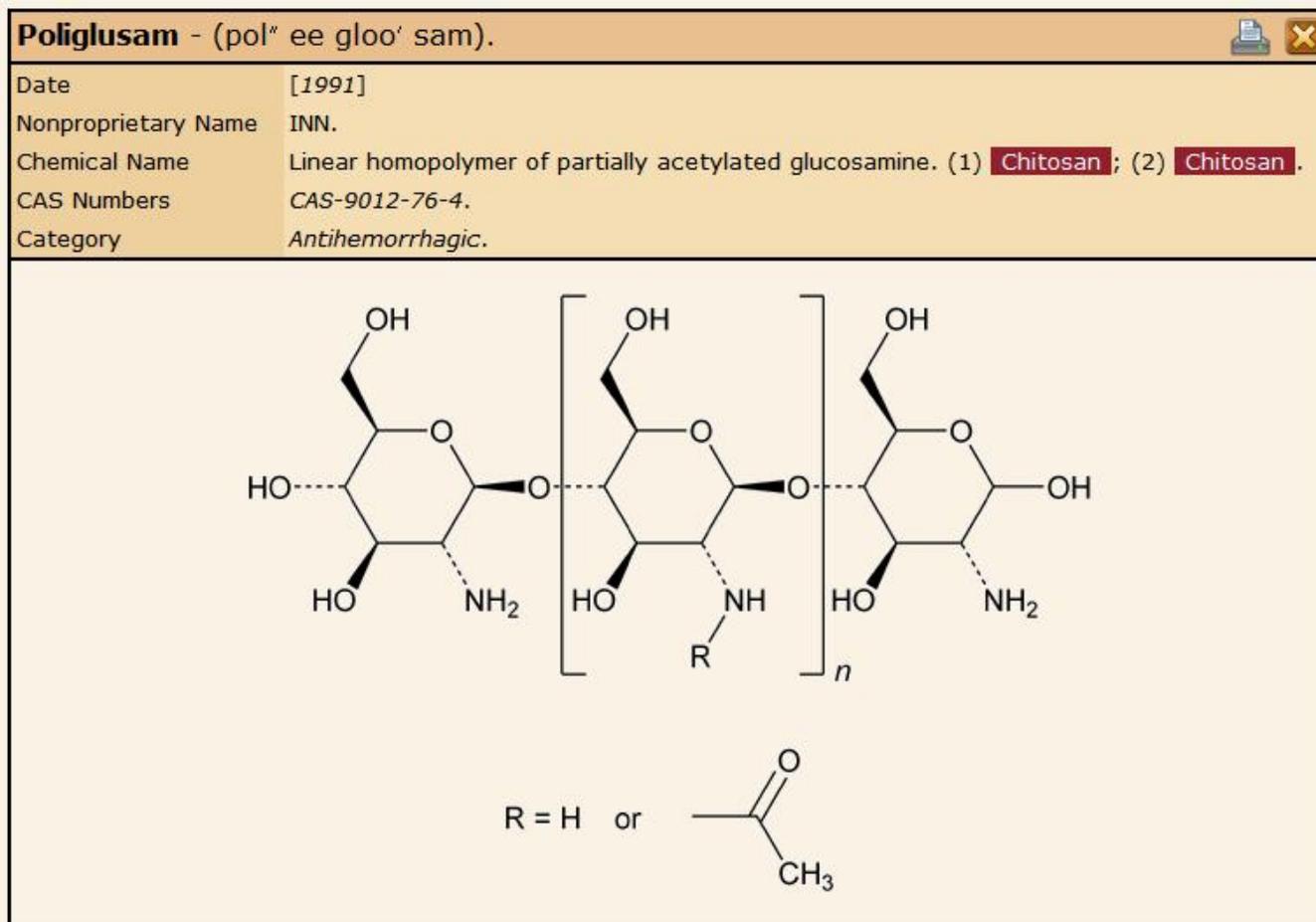


Simotaxel

(sim'' oh tax' el)

- Peridotaxel (Spanish)
- Sukataxel (Russian)
- Bakataxel (Japanese)

Common, trivial, and historical names





Challenges

Search : { metoprolol } in 'Drug Name'

Found : 9 Documents

Displaying results: 1 - 9

1

	Document Title	Sort  
1	USP Monographs: Metoprolol Tartrate Oral Suspension	
2	USP Monographs: Metoprolol Tartrate Oral Solution	
3	USP Monographs: Metoprolol Fumarate	
4	USP Monographs: Metoprolol Succinate	
5	USP Monographs: Metoprolol Succinate Extended-Release Tablets	
6	USP Monographs: Metoprolol Tartrate	
7	USP Monographs: Metoprolol Tartrate Injection	
8	USP Monographs: Metoprolol Tartrate Tablets	
9	USP Monographs: Metoprolol Tartrate and Hydrochlorothiazide Tablets	



NDC 62037-831-10

Metoprolol Succinate
Extended-release Tablets, USP

50 mg* 

 1000 Tablets Rx only

Manufactured By:
Watson Laboratories, Inc.
Corona, CA 92880 USA 7511 (0408)

Distributed By: Watson Pharma, Inc.

*Each tablet contains 47.5 mg metoprolol succinate equivalent to 50 mg metoprolol tartrate, USP.
Dosage: See package insert.
WARNING: As with all medications, keep out of the reach of children.
Store at controlled room temperature, 20°-25°C (68°-77°F). [See USP.]

 62037-831-10 2

LOT: _____
EXP: _____





Challenges

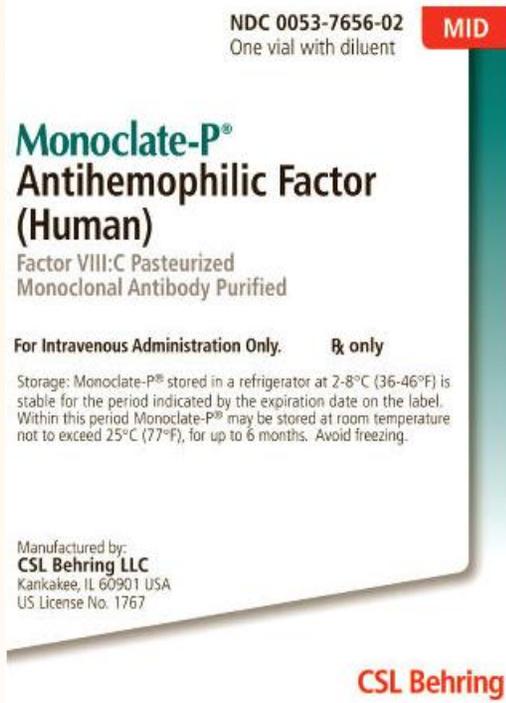
Chemical identity

Epoetin	USAN	INN	BAN	JAN
Alpha	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Beta	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Delta	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Epsilon		<input checked="" type="checkbox"/>		
Gamma		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Kappa		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Omega		<input checked="" type="checkbox"/>		
Theta		<input checked="" type="checkbox"/>		
Zeta		<input checked="" type="checkbox"/>		



Challenges

Labeling





Challenges

Teva Announces FDA Grants Approval for Tbo-filgrastim for the Treatment of Chemotherapy-Induced Neutropenia

*First New Treatment for Neutropenia Approved in the United States in 10 Years
Marks First Supportive Care Therapy for Cancer Patients from Teva Oncology*

JERUSALEM--([BUSINESS WIRE](#))--Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) announced today that the U.S. Food and Drug Administration (FDA) has granted approval for tbo-filgrastim (XM02 filgrastim), the **first new** granulocyte colony-stimulating factor (G-CSF) to be approved in the United States in more than 10 years. Tbo-filgrastim is a **short-acting** recombinant form of G-CSF, indicated to reduce the duration of severe neutropenia in patients with certain types of cancer (non-myeloid malignancies) who are receiving chemotherapy that affects the bone marrow. Neutropenia is a condition in which the number of white blood cells is decreased, leaving patients more susceptible to potentially life-threatening bacterial infections.



Challenges

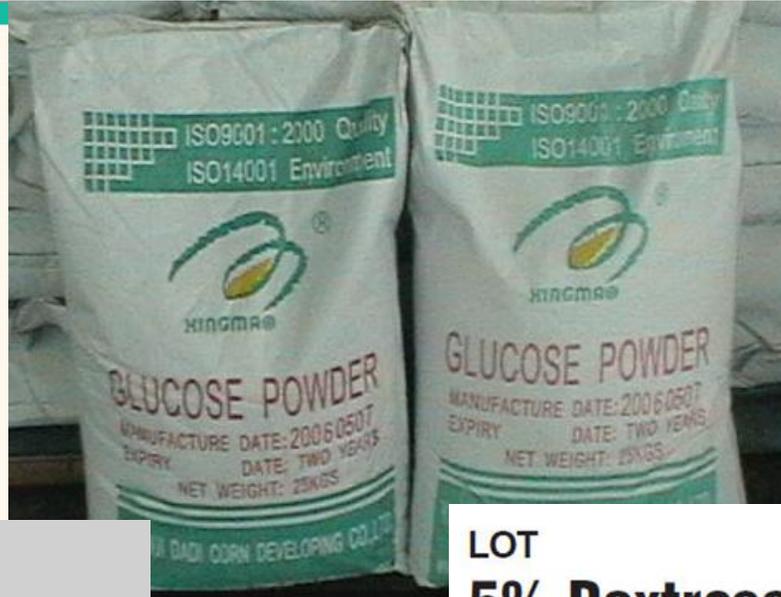


PURE FINEST FOOD GRADE COCONUT OIL

- Virgin
- Organic
- Cold-pressed
- Unrefined
- Unbleached
- **Unhydrogenated**
- Undeodorized



Challenges



LOT

EXP

5% Dextrose Injection USP

2B0040
NDC 0338-0551-11

MINI-BAG Plus Container

50 mL EACH 50 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
pH 4.0 (3.2 TO 6.5) OSMOLARITY 252 mOsmol/L (CALC) STERILE NONPYROGENIC READ PACKAGE INSERT FOR FULL INFORMATION ADDITIVES MAY BE INCOMPATIBLE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT ADMINISTER SIMULTANEOUSLY WITH BLOOD DO NOT USE UNLESS SOLUTION IS CLEAR **Rx ONLY**
US Pat Nos 4 340 049 4 607 671 5 304 163

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

VIAFLEX SINGLE DOSE CONTAINER
PL 146 PLASTIC
BAXTER VIAFLEX MINI-BAG
AND PL146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC

BREAK SEAL AND MIX BEFORE USE

Supplement

U.S. PHARMACOPEIA
The Standard of QualitySM

Thank You

Quality Standards for Medicines | Dietary Supplements | Food Ingredients

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