# Welcome



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## Substances in the USP and the USP Dictionary

Andrzej Wilk, Ph. D. USP

## USP – drug substances



#### **Paclitaxel**

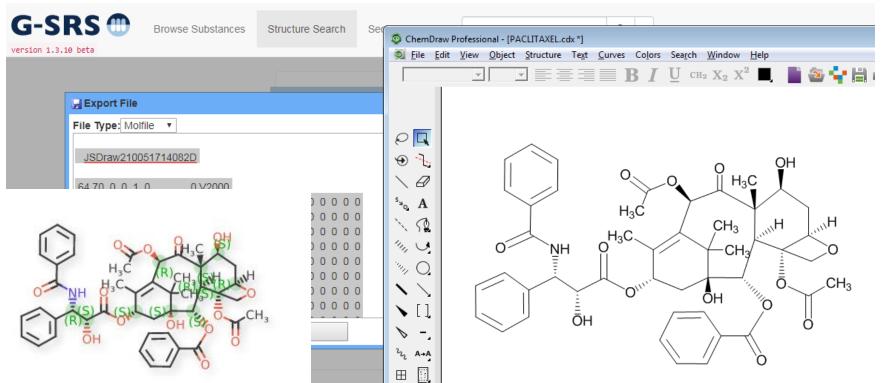
C<sub>47</sub>H<sub>51</sub>NO<sub>14</sub> 853.91

Benzenepropanoic acid,  $\beta$ -(benzoylamino)- $\alpha$ -hydroxy-, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10, 11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13, 13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca [3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2a $\alpha$ ,4 $\beta$ ,4a $\beta$ ,6 $\beta$ , 9 $\alpha$ ( $\alpha R^*$ , $\beta S^*$ ),11 $\alpha$ ,12 $\alpha$ ,12a $\alpha$ ,12b $\alpha$ ]]-.

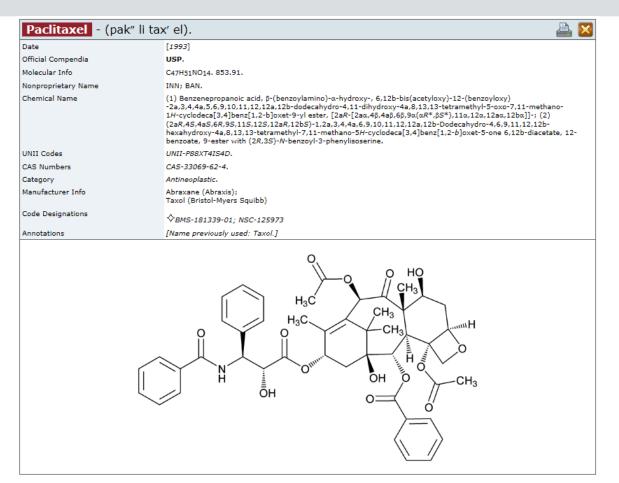
(2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-1,2a,3,4,4a,6,9, 10,11,12,12a,12b-Dodecahydro-4,6,9,11,12,12b-hexahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5*H*-cyclodeca[3,4]-benz[1,2-*b*]oxet-5-one 6,12b-diacetate, 12-benzoate, 9-ester with (2*R*,3*S*)-*N*-benzoyl-3-phenylisoserine [33069-62-4].

## **USP** in labeling

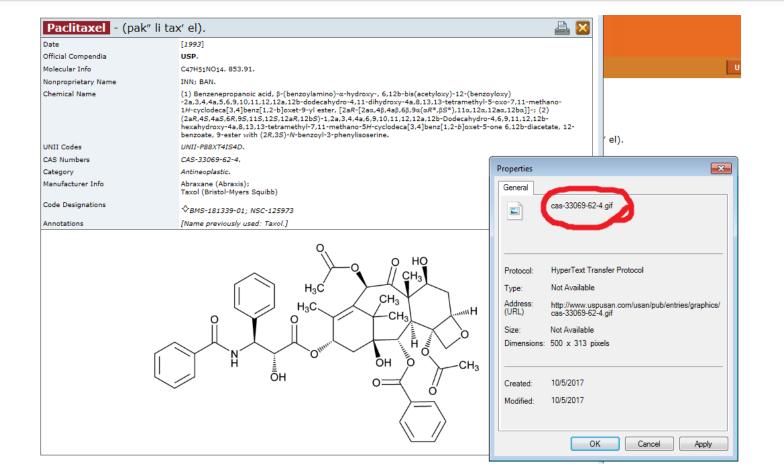




## **USP Dictionary of USAN and International Drug Names**

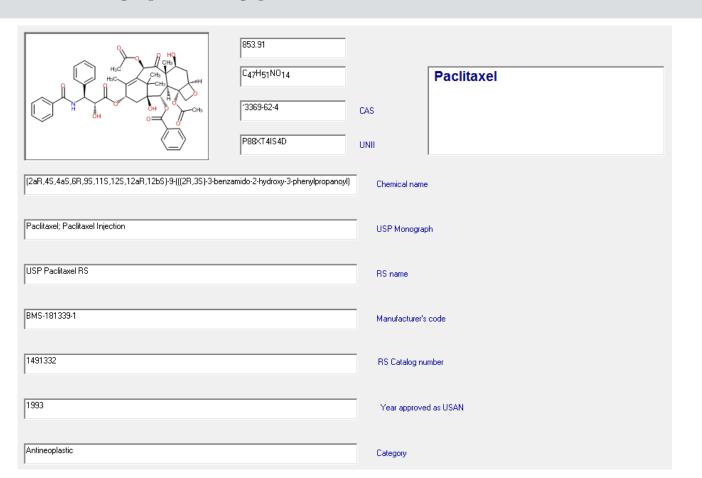


## **USP Dictionary of USAN and International Drug Names**



## **Dictionary prototype**

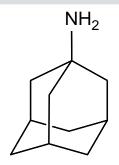






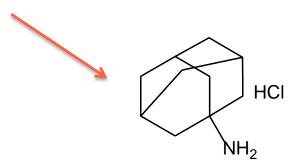
A	R	L	U	E	F	6	Н	1	J	K	L	IVI	N
tructure	USP_Monograph	RS_name	Manufacturer's	Chemical_na me	Category	RS Catalog Number	Codes	Year approved as USAN	MolWeig	Formula	CAS	UNII	USAN
C1(C)[C@@]{[C@@H](OC(C2=CC=CC=C2)=O)[C@@]3([H])[C@@]4(C)[C@@H](O)C -@]5{[H]][C@@]3(OC(C]=O)CO5)(O)C[C@H](OC[C@H](O)[C@H](O5C=CC=CC=C6)N													
	Paclitaxel; Paclitaxel Injection	USP Paclitaxel RS	BMS-181339-1		Antineoplastic	1491332		1993	853.91	C47H51NO14	'3369-62-4	P88XT4IS4D	Paclitaxel
:C1(c)[c@@][(c@@H](OC(C2=CC=CC=C2)=O][c@@]3[[H])[c@@]4(c)[c@@H](O)C c@]5[[H]](c@@]3(OC(O=O)CO5](O)[c@H](OC([c@H](OC(CC[c@@H](cN[c@@ f](CCC(O)=O)C(O)=O)=O)PO([c@H](CCC(O)=O)N)=O)=O)[c@H](C6=CC=CC=C6)PO(C =CC=CC=C7)=O]=O)C(O]=C1[(c@@H](OC(O]=O)C4=O									1241 26	C62H72N4O23			Paclitaxel Poliglumex
, , , , , , === 1, , , ,													
C1(c)[C@@]{[C@@H](OC(/C(c)=C/C)=O)[C@@]2[[H])[C@@]3(C)[C@@H](O)[C e]4[[H]][C@@]2[OC(C)=O)CO4](O)[C[@H](OC(C@H](O)[C@H](C5=CC=CC=C5)NC( 6=CC=CC=C6)=O)=O)C(C]=C1[C@@H](OC(C)=O)C3=O									831.91	C45H53NO14			Paclitaxel Debenzyl- Pentenoat
C1(C)[C@@][[C@@H](OC(C2=CC=CC2)=O][C@@]3[[H])[C@@]4(C)[C@@H](O) -@]5[[H]][C@@]3[OC(C]=O]CO5](OC(C)=O]C[C@H](OC[[C@H](O)[C@H](OECC=C =C6]NC(C7=CC=CC=C7]=O]=O]C(C]=C1[C@@H](OC(C)=O]C4=O									895.95	C49H53NO15			Paclitaxel Acetyl
C1(C)[C@@  [C@@H](OC(C2=CC=CC=C2)=0)[C@@]3{[H])[C@@]4(C)[C@@H](O)C C@]5{[H])[C@@]3(OC(C)=0)C05}(O)C[C@H](OC([C@H](O)[C@H](C6=CC=CC=C6)N (C/C=C\CC)=0)=0)C(C)=C1[C@@H](OC(C)=0)C4=0									845.93	C46H55NO14			Paclitaxel Dehydro
:c:(c)[c@@H](O)[c@@J2([H])[c@@J3(c)[c@@H](O)c[c@H](Oc(c)=0)[c @@J2(O)cOc(c4=CC=CC4)=O)(O)c[c@H](Oc([c@H](O)[c@H](C5=CC=CC=CS)NC( !6=CC=CC=C6)=O)=O)c(c]=C:1[c@@H](Oc(c)=O)C3=O									871.93	C47H53NO15			Paclitaxel Oxetane



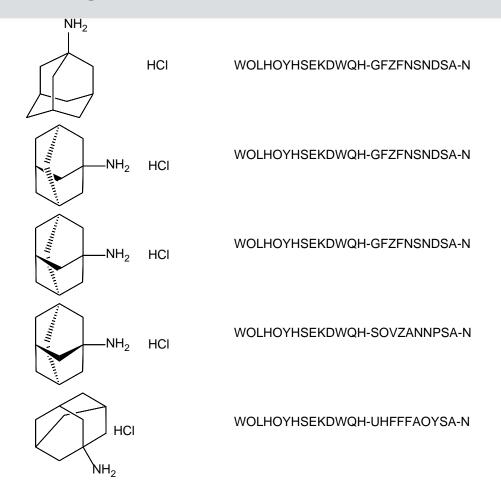




NC1(C2)C[C@@H]3C[C@H]2C[C@H](C1)C3.Cl Cl.NC12CC3CC(CC(C3)C1)C2









#### **Betamethasone Acetate** - (bay" ta meth' a sone as' e tate).





Official Compendia USP.

C24H31FO6, 434,50,

Nonproprietary Name

JAN.

Chemical Name

Molecular Info

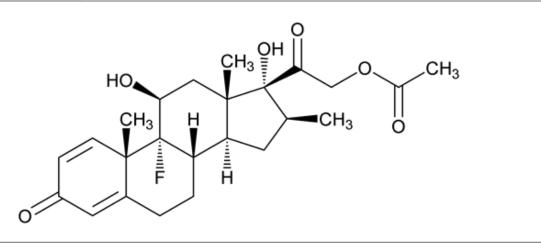
(1) Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(acetyloxy)-, (11β,16β)-;

(2) 9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-acetate.

UNII Codes UNII-TI05AO53L7.

CAS Numbers CAS-987-24-6. Category

Glucocorticoid.



<font face="Symbol">b</font>



### 9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-acetate

<font face="Symbol">b</font>

9-Fluoro-11b,17,21-trihydroxy-16b-methylpregna-1,4-diene-3,20-dione 21-acetate

#### **GINAS**

9-FLUORO-11.BETA.,17,21-TRIHYDROXY-16.BETA.-METHYLPREGNA-1,4-DIENE-3,20-DIONE 21-ACETATE

ChemSpider

xmlns:msxsl="urn:schemas-microsoft-com:xslt"

(11β,16β)-9-Fluoro-11,17-dihydroxy-16-methyl-3,20-dioxopregna-1,4-dien-21-yl acetate





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#### INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

Recommendations on Organic & Biochemical Nomenclature, Symbols & Terminology etc.

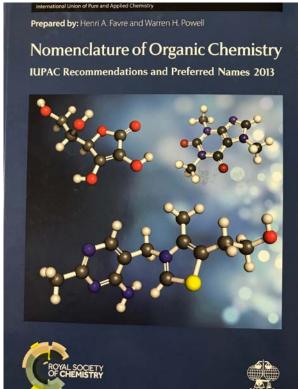
http://www.sbcs.qmul.ac.uk/iupac/

World Wide Web material prepared by G. P. Moss

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Glossary of Organic Class Names	Glossary of Terms in Physical Organic Chemistry	<u>B</u>							
Hantzsch-Widman Nomenclature for Heteromonocyclic Rings	Non-standard Valence States (Lambda Convention)	Cyclic compounds w							
Fused Ring Nomenclature	Phane Nomenclature								
Glossary of Terms in Bioinorganic Chemistry	Glossary of Medicinal Chemistry Terms	Nomenclature							
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Natural product nomenclature (Section F)	Radicals, Ions & Radical Ion Nomenclature								
Fullerene nomenclature	Numbering of Fullerenes								
Regular single-strand organic polymers nomenclature		Watch this space.							





Working document QAS/17.726

July 2017

Document for comments



1

3

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8

GUIDANCE FOR THE GRAPHIC REPRESENTATION OF PHARMACEUTICAL SUBSTANCES IN THE PUBLICATIONS OF INTERNATIONAL NONPROPRIETARY NAMES AND THE INTERNATIONAL PHARMACOPOEIA (July 2017)

DRAFT FOR COMMENTS

\*



EUROPEAN PHARMACOPOEIA 9.0

**European Pharmacopoeia Commission** 

# III. EUROPEAN PHARMACOPOEIA COMMISSION

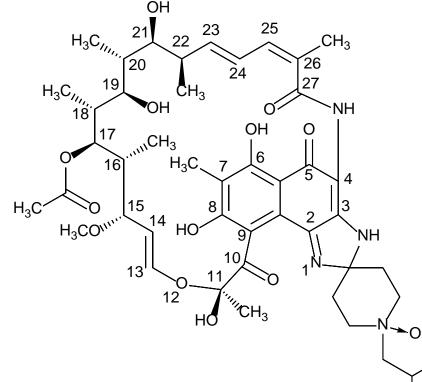
COMPOSITION OF THE COMMISSION, LIST OF EXPERTS AND OF THE SECRETARIAT (2015)

Dr. Armand Blommaert



$$\begin{array}{c} \text{OH} \\ \text{H}_{3}\text{C}_{\text{Im}} \\ \text{OH} \\$$





#### Chem Draw:

 $CH_3$ 

A name could not be generated for this structure.

 $(11R,13E,16S,17R,18S,19R,20R,21S,22S,23E,25Z)-17-acetyloxy-6,8,11,19,21-pentahydroxy-15-methoxy-7,11,16,18,20,22,26-heptamethyl-1'-(2-methylpropyl)-5,10,27-trioxo-3,5-dihydrospiro[4,9-(epiminopentadeca[2,4,14]trienoxyethano) naphtho[1,2-d]imidazole-2,4'-piperidine] <math>N^{1'}$ -oxide

(9R)-9-hydroxy-8,9-secorifabutin N-oxide

# **Thank You**



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# **Questions?**



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