

Drug Status Report

Drug: Progesterone related substances

A client requested the status of the following fifteen progesterone related substances.

Drug Name Status: I - (6 β)-6-hydroxyprogesterone

II - 6-Ketoprogesterone

III - 1-Dehydroprogesterone

IV - 23, 24-Bisnorchol-4-enic acid-3-one

V - 20-Hydroxy bisnorldehyde

VI - 9-Dehydroprogesterone

VII - 23,24-22-Hydroxychol-4-en-3-one (22-Hydroxy-23,24-Bisnorchol-4-en-3-one)

VIII and IX - Alpha and beta-bisnorldehyde (17alpha and beta isomers)

X and XI - (20R)- and (20S)-20-Hydroxypregna-4-en-3-one

XII - Pregna-4,14-diene-3,20-dione

XIII - (20R)-3-Oxopregn-4-en-20-yl acetate

XIV - 21-(Cyclohex-1-en-1-yl)-pregn-4-en-3,20-dione

XV - 21-Cyclohexylidene-pregn-4-en-3,20-dione

These names are a mixture of trivial names, common names and chemical names.

Chemical Name: I - (6-beta)-6-Hydroxy-pregn-4-ene-3,20-dione

II - 6-Oxo-pregn-4-ene-3,20-dione

III - Pregna-1,4-diene-3,20-dione

IV - 3-Oxo-pregn-4-ene-20-carboxylic acid

V - 20-Hydroxy-3-oxo-pregn-4-ene-20-carboxaldehyde

VI - Pregna-4,9-diene-3,20-dione

VII - 21-Hydroxy-20-methyl-pregn-4-en-3-one

VIII and IX - (17alpha) and (17beta)-3-Oxo-pregn-4-ene-20-carboxaldehyde

X and XI - (20R)- and (20S)-20-Hydroxypregn-4-en-3-one

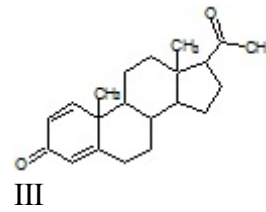
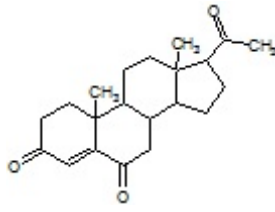
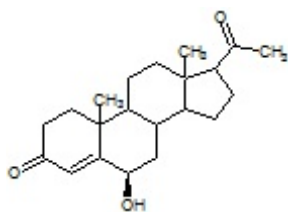
XII - Pregna-4,14-diene-3,20-dione

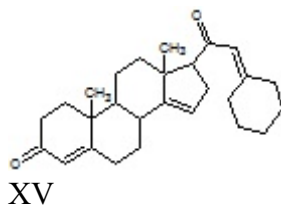
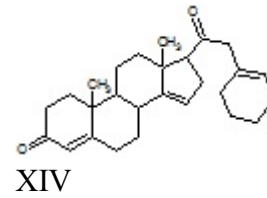
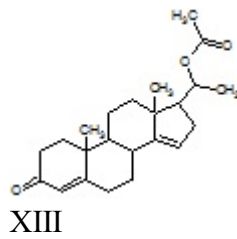
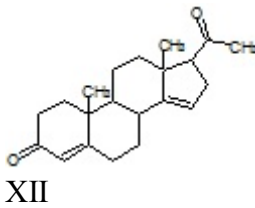
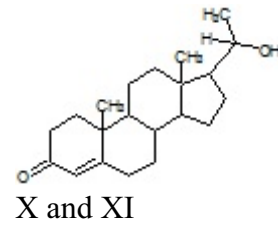
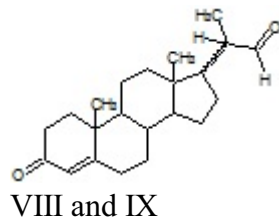
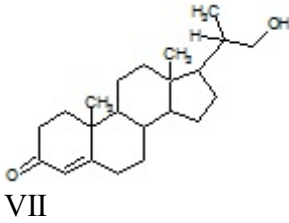
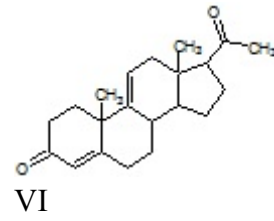
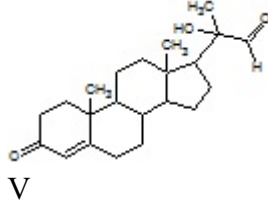
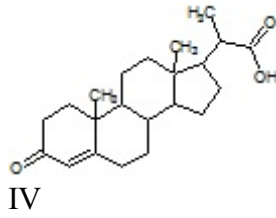
XIII - (20R)-3-Oxopregn-4-en-20-yl acetate

XIV - 21-(Cyclohex-1-en-1-yl)-pregn-4-en-3,20-dione

XV - 21-Cyclohexylidene-pregn-4-en-3,20-dione

Chemical structure:





Molecular Formula: I - $C_{21}H_{30}O_3$

II - $C_{21}H_{28}O_3$

III - $C_{21}H_{28}O_2$

IV - $C_{22}H_{32}O_3$

V - $C_{22}H_{32}O_3$

VI - $C_{21}H_{28}O_2$

VII - $C_{22}H_{34}O_2$

VIII and IX - $C_{22}H_{32}O$

X and XI - $C_{21}H_{32}O_2$

XII - $C_{21}H_{28}O_2$

XIII - $C_{23}H_{32}O_3$

XIV - $C_{27}H_{36}O_2$

XV - $C_{27}H_{36}O_2$

Pharmacological/chemical class / Application: Drug related substances

International status:

US: These substances are not listed on the schedules to US Controlled Substances Act and are not mentioned on the DEA website.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: These substances appear to be a list of related substances to be found in a raw material. Pfizer provides a similar listing for its Progesterone USP (http://www.pfizercentresource.com/sites/centresource/products/Pages/progesterone_USP.pdf). Some of the substances are EP impurities. For example, substances XII-XV are EP Impurities A, E, F, and G. Others, such as I¹, II² and III³ are recognized metabolites of progesterone. Substance IV⁴ is a starting material for the synthesis of many steroids. The remaining substances have structures consistent with their being progesterone related substances.

None of the substances are structurally similar to the anabolic steroids listed in item 23 of Schedule IV to the CDSA. There are no reports that the substances have anabolic activity.

Recommendation: Substances I to XV are not included in the schedules to the CDSA and are not controlled substances.

December 2, 2008

¹ Yamada A, Yamada M, Fujita Y, Nishigami T, Nakasho K, Uematsu K., J Biol Chem. 2001 Feb 16;276(7):4604-10.

² Swinney DC, Ryan DE, Thomas PE, Levin W., Biochemistry. 1988 Jul 26;27(15):5461-70.

³ Clemons KV, Stover EP, Schär G, Stathis PA, Chan K, Tökès L, Stevens DA, Feldman D., J Biol Chem. 1989 Jul 5;264(19):11186-92.

⁴ Hill, F, Preuss, W, Schindler, J, Schmid, R, Struve, A, US Patent 4,320,195 (1982).