

Certificate

DOCETAXEL IDENTIFICATION

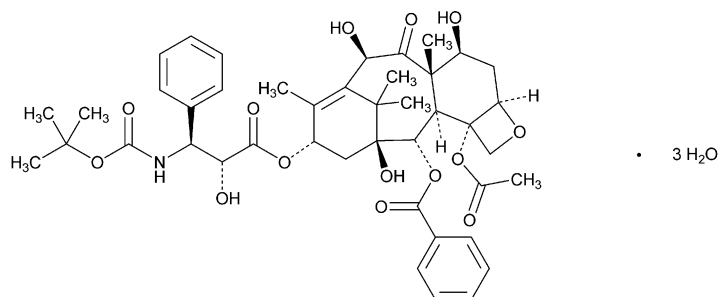
(Contains approximately 98% of docetaxel and approximately 0.5% each of 2-debenzoxyl 2-pentenoyl docetaxel, docetaxel, 6-oxodocetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel)

USP Catalog No.: 1224562

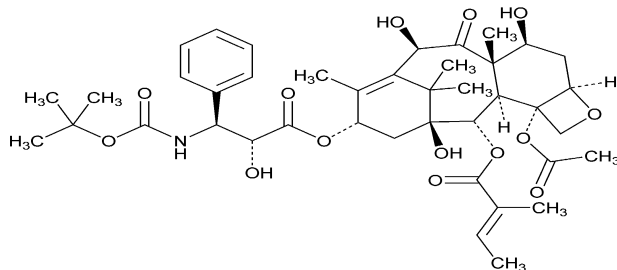
USP Lot No.: R008Q0

Only compendial components as listed in the monograph are shown below

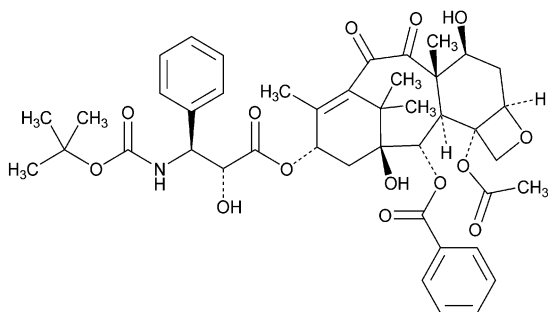
(1) Docetaxel



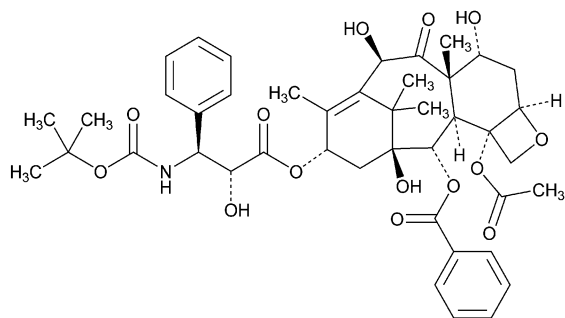
(2) 2-Debenzoxyl 2-pentenoyl docetaxel



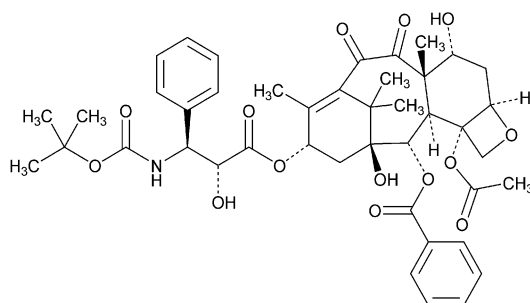
(3) 6-Oxodocetaxel



(4) 4-Epidocetaxel



(5) 4-Epi-6-oxodocetaxel



Only compendial components as listed in the monograph shown below

Only compendial components as listed in the monograph are shown below

Item	Name/Chemical name	CAS	Molecular Weight	Molecular Formula	Content
1	Docetaxel / (2 <i>R</i> ,3 <i>S</i>)- <i>N</i> -Carboxy-3-phenylisoserine, <i>N</i> -tert-butyl ester, 13-ester with 5 <i>B</i> ,20-epoxy-1,2 <i>α</i> ,4,7 <i>B</i> ,10 <i>B</i> ,13 <i>α</i> - hexahydroxytax-11-en-9-one 4-acetate 2-benzoate trihydrate	148408-66-6	861.93	C ₄₃ H ₅₃ NO ₁₄ ·3H ₂ O	97.92%
2	2-Debenzoxyl 2-pentenoyl docetaxel/ (2 <i>aR</i> ,4 <i>S</i> ,4 <i>aS</i> ,6 <i>R</i> ,9 <i>S</i> ,11 <i>S</i> ,12 <i>S</i> ,12 <i>aR</i> ,12 <i>bS</i>)-1,2 <i>a</i> ,3,4,4 <i>a</i> ,6,9,10,11,12,12 <i>a</i> ,12 <i>b</i> -Dodecahydro-4,6,9,11,12,12 <i>b</i> -hexahydroxy-4 <i>a</i> ,8,13,13-tetramethyl-7,11-methano-5 <i>H</i> -cyclodeca[3,4]benz[1,2- <i>b</i>]oxet-5-one 12 <i>b</i> -acetate,12-[(<i>E</i>)-2-methylbut-2-enoate], 9-ester with (2 <i>R</i> ,3 <i>S</i>)- <i>N</i> -tert-butoxycarbonyl-3-phenylisoserine	N/A	785.87	C ₄₁ H ₅₅ NO ₁₄	0.42%
3	6-Oxodocetaxel/ (2 <i>aR</i> ,4 <i>S</i> ,4 <i>aS</i> ,9 <i>S</i> ,11 <i>S</i> ,12 <i>S</i> ,12 <i>aR</i> ,12 <i>bS</i>)-1,2 <i>a</i> ,3,4,4 <i>a</i> ,6,9,10,11,12,12 <i>a</i> ,12 <i>b</i> -Dodecahydro-4, 9,11,12,12 <i>b</i> -pentahydroxy-4 <i>a</i> ,8,13,13-tetramethyl-7,11-methano-5 <i>H</i> -cyclodeca[3,4]benz[1,2- <i>b</i>]oxet-5,6-dione 12 <i>b</i> -acetate, 12-benzoate, 9-ester with (2 <i>R</i> ,3 <i>S</i>)- <i>N</i> -tert-butoxycarbonyl-3-phenylisoserine	N/A	805.86	C ₄₃ H ₅₁ NO ₁₄	0.64%

4	4-Epidocetaxel/ (2 <i>aR</i> ,4 <i>R</i> ,4 <i>aS</i> ,6 <i>R</i> ,9 <i>S</i> ,11 <i>S</i> ,12 <i>S</i> ,12 <i>aR</i> ,12 <i>bS</i>)- 1,2 <i>a</i> ,3,4,4 <i>a</i> ,6,9,10,11,12,12 <i>a</i> ,12 <i>b</i> - Dodecahydro-4,6,9,11,12,12 <i>b</i> -hexahydroxy- 4 <i>a</i> ,8,13,13-tetramethyl-7,11-methano-5 <i>H</i> - cyclodeca[3,4]benz[1,2- <i>b</i>]oxet-5-one 12 <i>b</i> - acetate, 12-benzoate, 9-ester with (2 <i>R</i> ,3 <i>S</i>)- <i>N</i> - <i>tert</i> -butoxycarbonyl-3-phenylisoserine	N/A	807.88	C ₄₃ H ₅₃ NO ₁₄	0.42%
5	4-Epi-6-oxodocetaxel/ (2 <i>aR</i> ,4 <i>R</i> ,4 <i>aS</i> ,9 <i>S</i> ,11 <i>S</i> ,12 <i>S</i> ,12 <i>aR</i> ,12 <i>bS</i>)- 1,2 <i>a</i> ,3,4,4 <i>a</i> ,6,9,10,11,12,12 <i>a</i> ,12 <i>b</i> - Dodecahydro-4, 9,11,12,12 <i>b</i> -pentahydroxy- 4 <i>a</i> ,8,13,13-tetramethyl-7,11-methano-5 <i>H</i> - cyclodeca[3,4]benz[1,2- <i>b</i>]oxet-5,6-dione 12 <i>b</i> - acetate, 12-benzoate, 9-ester with (2 <i>R</i> ,3 <i>S</i>)- <i>N</i> - <i>tert</i> -butoxycarbonyl-3-phenylisoserine	N/A	805.86	C ₄₃ H ₅₁ NO ₁₄	0.61%

LABEL TEXT

For use with specified USP compendial tests.
Not for use as a drug. See SDS prior to use
at www.usp.org/sds.



Lot: R008Q0



USP REFERENCE STANDARD

DOCETAXEL IDENTIFICATION 50 mg

Danger! Causes serious eye irritation. Suspected of causing genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs (bone marrow) through prolonged or repeated exposure.

Do not dry. Keep container tightly closed. Protect from light. Store in a refrigerator. See accompanying Certificate for additional information.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1224562 Material mfd. in France

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If exposed or concerned: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth

Quality Assurance

Calculation Value

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

LEGAL NOTICE

USP WARRANTS GOOD TITLE TO USP REFERENCE STANDARDS ON DISPATCH FROM USP. THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY WARRANTY THAT THE PRODUCTS, INCLUDING THIS CERTIFICATE, ARE OF MERCHANTABILITY QUALITY. USP'S LIABILITY ARISING OUT OF OR RELATING TO THE SUPPLY OF USP REFERENCE STANDARDS AND THIS CERTIFICATE SHALL IN NO EVENT INCLUDE LOSS OF PROFITS, COST OF PROCURING SUBSTITUTE GOODS OR SERVICES, OR ANY INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, EVEN IF USP IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, USP DOES NOT WARRANT THAT THE USE OR RESALE OF USP REFERENCE STANDARDS, INCLUDING THEIR USE TO PERFORM TESTS AND ASSAYS PUBLISHED BY USP, WILL NOT INFRINGE UNITED STATES OR ANY OTHER PATENTS.

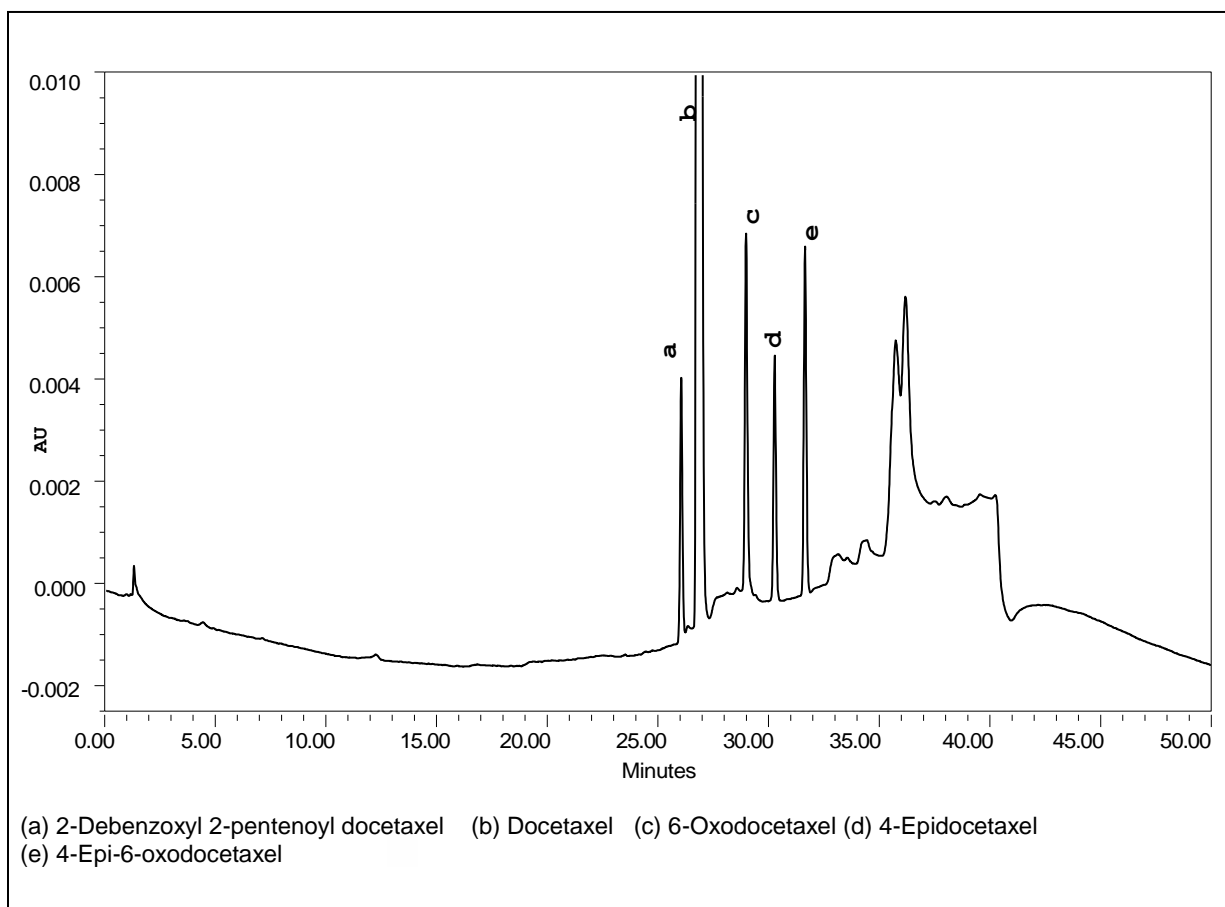
USP Reference Standards are not intended for use as drugs, dietary supplements, or as medical devices.

This certificate may not be reproduced without the express written permission of USP.

Typical Chromatogram

USP Docetaxel Identification RS

Catalog Number: 1224562
Lot: R008Q0
Monograph: Docetaxel
Publication: USP37/NF32
Test: Assay & Organic Impurities
Sample: System Suitability Solution



This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.