

Certificate

DOCETAXEL SYSTEM SUITABILITY MIXTURE

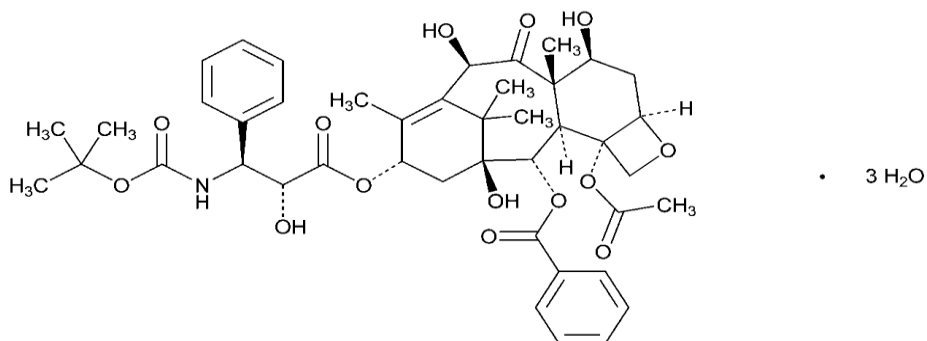
(Contains approximately 92% of docetaxel and approximately 6% total of 6-oxodocetaxel, O-BOC N-pyruvyl docetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel)

USP Catalog No.: 1224573

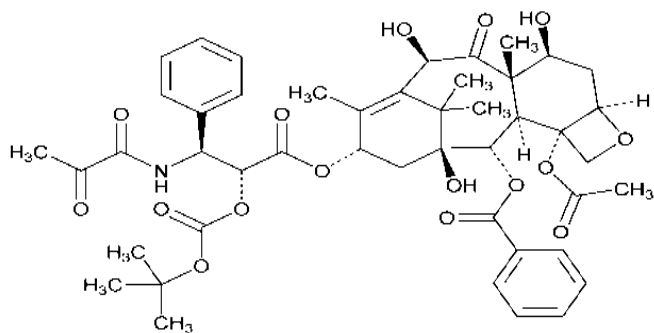
USP Lot No.: R023J0

Only compendial components as listed in the monograph are shown below

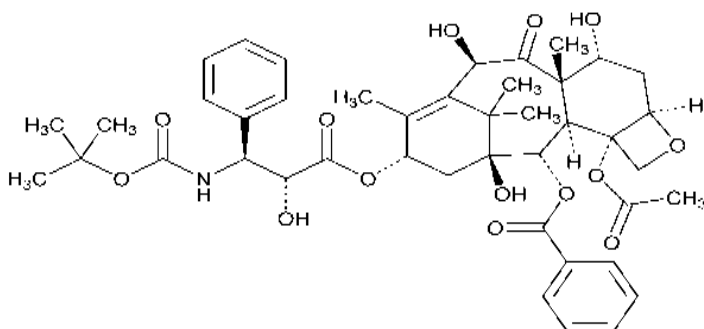
(1)



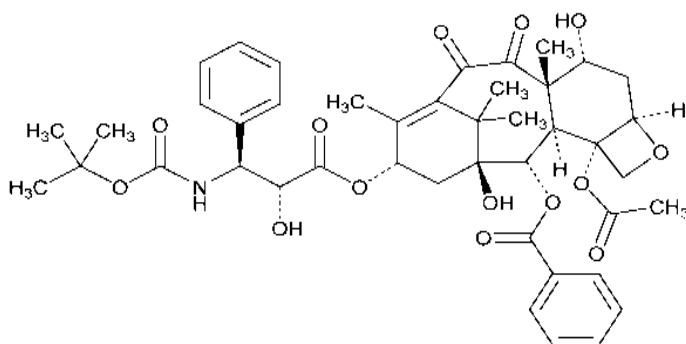
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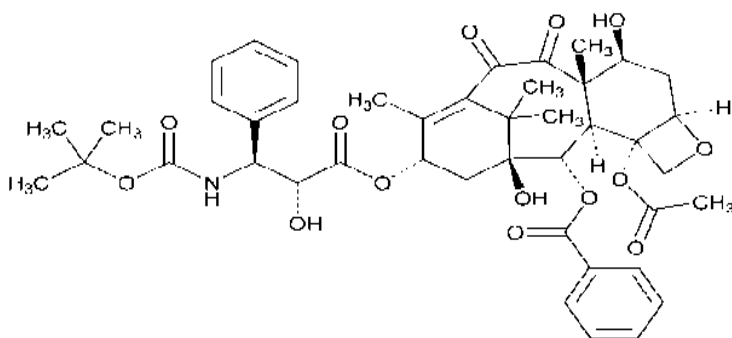
(3)



(4)



(5)



Only compendial components as listed in the monograph shown below

Item	Name/Chemical name	CAS	Molecular Weight	Molecular Formula	Content
1	Docetaxel	114977-28-5	807.88	C ₄₃ H ₅₃ NO ₁₄	92.37 %
2	O-BOC N-Pyruvyl Docetaxel	N/A	877.93	C ₄₃ H ₅₁ NO ₁₄	1.62 %
3	4-Epidocetaxel	N/A	807.88	C ₄₃ H ₅₃ NO ₁₄	1.04 %
4	4-Epi-6-oxodocetaxel	N/A	805.86	C ₄₃ H ₅₁ NO ₁₄	2.01 %
5	6-Oxodocetaxel	N/A	805.86	C ₄₃ H ₅₁ NO ₁₄	1.32 %

LABEL TEXT

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



Lot: R023J0

USP REFERENCE STANDARD

DOCETAXEL SYSTEM SUITABILITY MIXTURE 15 mg

(Contains approximately 92 % of docetaxel and approximately 6 % total of 6-oxodocetaxel, O-BOC N-pyruvyl docetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel)



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.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1224573 Material mfd. in Taiwan

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. Toth

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

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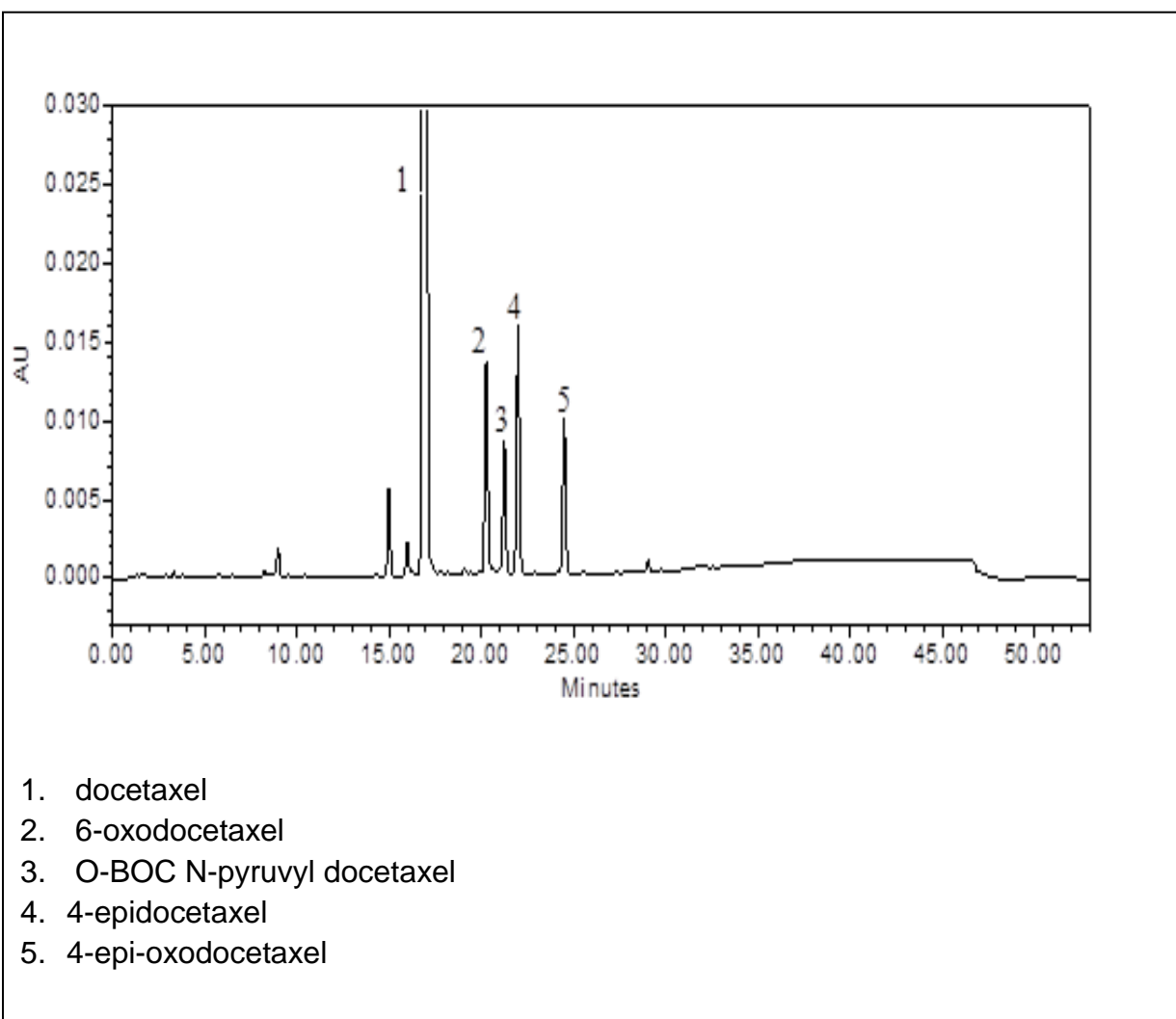
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Typical Chromatogram

Docetaxel System Suitability Mixture

Catalog Number: 1224573
Lot: R023J0
Monograph: Docetaxel
Publication: USP 38
Test: Organic Impurities Procedure 2
Sample: System suitability solution



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