



# Certificate

## DOCETAXEL SYSTEM SUITABILITY MIXTURE

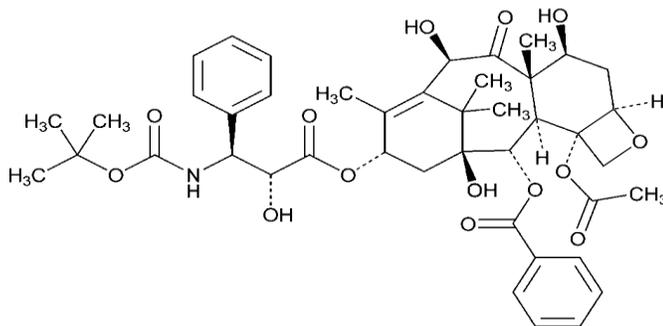
(Contains approximately 96% of docetaxel and approximately 3.9% total of 6-oxodocetaxel, *O*-BOC *N*-pyruvyl docetaxel, 4-epidocetaxel, and 4-epi-6-oxodocetaxel)

USP Catalog No.: 1224573

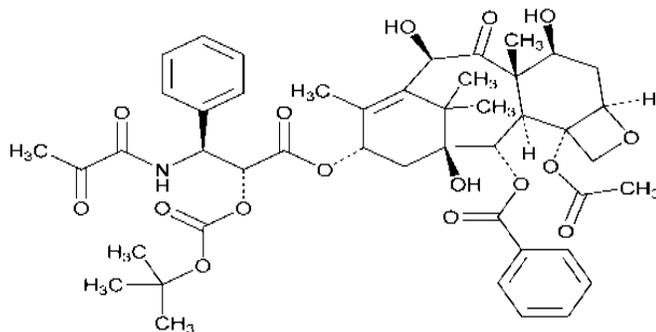
USP Lot No.: R109G0

Only compendial components as listed in the monograph are shown below (Only for more than one component)

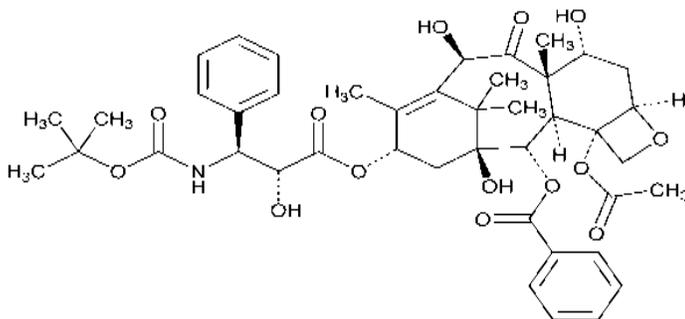
(1)



(2)



(3)



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USP Certificate

USP Template No.: CERT1-06

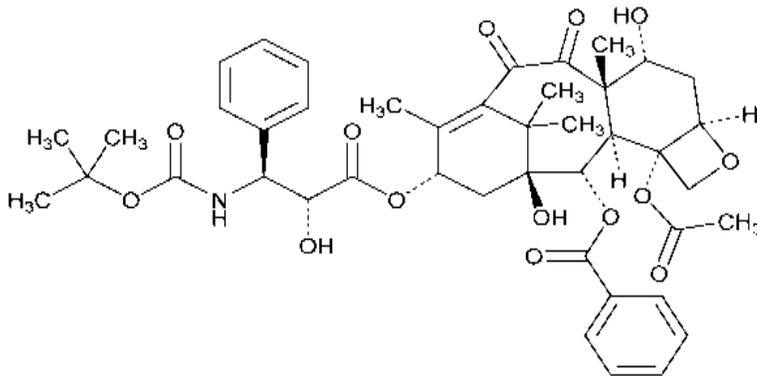
Template Effective Date: September 11, 2018

Certificate Date: 26Aug2019

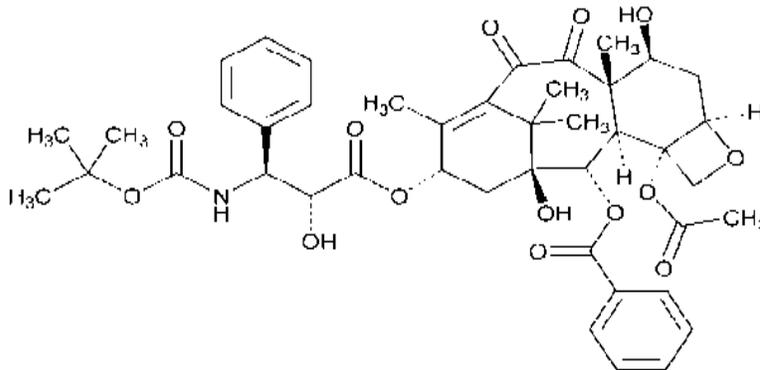
Certificate Version: 00

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(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 <sub>43</sub> H <sub>53</sub> NO <sub>14</sub>	96.1%
2	O-BOC N-Pyruvyl Docetaxel	N/A	877.93	C <sub>43</sub> H <sub>51</sub> NO <sub>14</sub>	0.7%
3	4-Epidocetaxel	N/A	807.88	C <sub>43</sub> H <sub>53</sub> NO <sub>14</sub>	1.2%
4	4-Epi-6-oxodocetaxel	N/A	805.86	C <sub>43</sub> H <sub>51</sub> NO <sub>14</sub>	0.5%
5	6-Oxodocetaxel	N/A	805.86	C <sub>43</sub> H <sub>51</sub> NO <sub>14</sub>	1.5%



**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: R109G0

**USP REFERENCE STANDARD**

**DOCETAXEL SYSTEM SUITABILITY MIXTURE 15 mg**

(Contains approximately 96% of docetaxel and approximately 3.9% 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.

Labeled for qualitative use. Keep container tightly closed. Protect from light. Store in a refrigerator.

**See certificate for any additional information.**

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. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. 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. If exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

*Jeri L. Joth*

Quality Assurance

**Assigned Value**

Please refer to the USP Reference Standard label for the assigned value of the specific lot. If the lot was developed for qualitative use, it will not have an assigned value.

**Valid Use Date**

It is the responsibility of the user to ascertain that a particular lot of a USP Reference Standard has official status either as a "Current lot" or as a "Previous lot" within the assigned valid use date. The online USP Reference Standards Catalog and the online USP Store at [www.usp.org](http://www.usp.org) are updated daily. USP recommends referring to one of these sources prior to using a USP Reference Standard to make sure the lot is valid for use.

**Storage**

Storage conditions are lot-specific and may change from one lot to another. If no specific directions or limitations are provided on the USP Reference Standard label, the conditions of storage shall include storage at room temperature and protection from moisture, light, freezing, and excessive heat.

**Instructions for Use**

Follow the instructions provided on this Certificate, on the label of the USP Reference Standard, and in the associated USP documentary standard(s). Please refer to General Chapter <11> for additional information.

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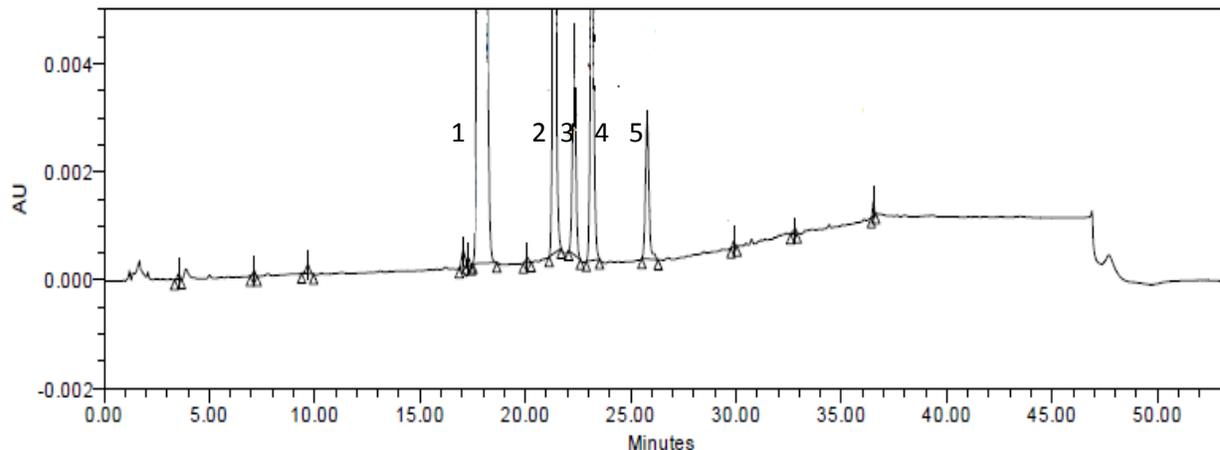


# Typical Chromatogram

## USP Docetaxel System Suitability Mixture RS

<b>Catalog Number:</b> Docetaxel System Suitability Mixture
<b>Lot:</b> R109G0
<b>Monograph:</b> Docetaxel
<b>Publication:</b> USP42/NF37
<b>Test:</b> Organic Impurities, Procedure 2
<b>Sample:</b> System Suitability solution

Only compendial components as listed in the monograph shown below



1. Docetaxel
2. 6-Oxodocetaxel
3. O-BOC N-pyruvyl docetaxel
4. 4-Epidocetaxel
5. 4-Epi-6-oxodocetaxel

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