

# Chem-Impex International, Inc.

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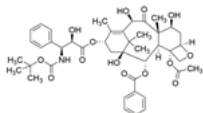
Web site: www.chemimpex.com

Manufacturing site:

825 Dillon Drive

Wood Dale, IL 60191

## Product Specifications



Catalogue Number 37802

Product **Docetaxel**

*N*-Debenzoyl-*N*-tert-butoxycarbonyl-10-deacetyltaxol

CAS Number 114977-28-5

Molecular Formula C<sub>43</sub>H<sub>53</sub>NO<sub>14</sub>

Molecular Weight 807.89

Appearance White or almost white crystalline powder

Solubility Freely soluble in acetone. Soluble in methanol. Practically insoluble in water

Heavy Metals ≤ 10 ppm

Water Content (Karl Fisher) ≤ 1.5%

Yeast and Mold ≤ 8 cfu/g

Optical Rotation [α]<sub>D</sub><sup>20</sup> = -45 to -35 ° (on as-is basis)

Residual Solvents Pyridine:≤200 ppm; Toluene:≤890 ppm; Ethyl acetate:≤4500 ppm  
Methylene chloride:≤600 ppm; Methanol:≤3000 ppm;  
n-Hexane:≤290 ppm; Acetone:≤4500 ppm

Bacterial Endotoxins ≤ 0.2 EU/mg

Microbial Count ≤ 80 cfu/g (TAMC)

Related Substances 10-Deacetyl baccatin:≤0.15%; 2-Debenzoxyl 2-pentenoyl docetaxel:≤0.45%  
6-Oxodocetaxel:≤0.25%; 4-Epidocetaxel:≤0.25%; 4-Epi-6-oxodocetaxel:≤0.15%  
Any unspecified impurities:≤0.10%; Total impurities:≤1%

Residue On Ignition ≤ 0.1%

Assay (anhydrous basis) 97.8 - 102.0% (Solvent free basis)

Storage Store at 2 - 8 °C

Additional Information Identification A : Infrared Spectrum : Conforms to structure  
Identification B : The retention time of the principal peak in the chromatogram obtained with the test solution corresponds to that of principal peak in the chromatogram obtained with the standard solution in the test for assay.

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**For Laboratory Use Only**