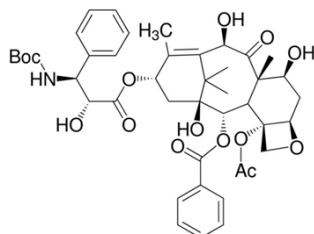


Certificate of Analysis



Product Name	Docetaxel	Batch No.	A22F10156
CAS No.	114977-28-5	MFG. Date	Oct 15, 2022
CAT No.	A000806	Retest Date	Pending
Items	Specification	Results	
Appearance	White or almost white crystalline powder	Conforms	
Identification	IR, HPLC	Conforms	
Optical Rotation	-35 ~ -45° (20°C)	-39.7°	
Water	≤ 1.5%	0.83%	
Residue on Ignition	≤ 0.1%	0.05%	
Related Substances	10-Deacetyl baccatin ≤ 0.15% N-Formyl impurity ≤ 0.15% 2-Debenzoxyl 2-pentenoyl docetaxel ≤ 0.5% 6-Oxodocetaxel ≤ 0.3% 4-Epidocetaxel ≤ 0.3% 4-Epi-6-oxodocetaxel ≤ 0.2% 6-Dichloroethoxycarbonyl docetaxel ≤ 0.15% Any unspecified impurity ≤ 0.10% Total impurities ≤ 1.0%	10-Deacetyl baccatin < 0.01% N-Formyl impurity < 0.01% 2-Debenzoxyl 2-pentenoyl docetaxel < 0.05% 6-Oxodocetaxel 0.05% 4-Epidocetaxel < 0.04% 4-Epi-6-oxodocetaxel < 0.01% 6-Dichloroethoxycarbonyl docetaxel < 0.01% Any unspecified impurity ≤ 0.05% Total impurities 0.21%	

<i>Residue Solvents</i>	Acetone ≤ 5000 ppm Isopropanol ≤ 5000 ppm Dichloromethane ≤ 600 ppm Ethyl acetate ≤ 5000 ppm Tetrahydrofuran ≤ 720 ppm n-Heptane ≤ 5000 ppm Methylcyclohexane ≤ 1180 ppm Pyridine ≤ 200 ppm	Acetone 157ppm Isopropanol 50.20ppm Dichloromethane < 5.95ppm Ethyl acetate <1.5ppm Tetrahydrofuran < 0.36 ppm n-Heptane 24 ppm Methylcyclohexane 11.80ppm Pyridine < 3.90 ppm
<i>Bacterial endotoxins</i>	< 0.4 EU/mg	< 0.3 EU/mg
<i>Microbial Test</i>	Total aerobic microbial ≤ 100 cfu/g Total molds and yeasts ≤ 10 cfu/g	<10cfu/g <10cfu/g
<i>Assay</i>	97.5%~102.0% (Dry basis)	100.3%
<i>Conclusion</i>	The above substance has been tested according to USP standards, and it meets requirements.	
<i>Storage Condition</i>	Dry and Cool	

QC: *Alex Foster*
QA: *Felix Hobart*