



Bioman Pharma Limited. (Shanghai-Jiangxi)
 Office: Room 2015, No. 28, Yuanwen Road, Minhang District, Shanghai.
 R&D Center: No. 20, Lane 1500, Xinfei Road, Songjiang District, Shanghai.
 Factory: Chemical Industrial Park, Yanshan County, Shangrao City, Jiangxi Province.
 Tel: 021-33738120 Fax: 021-23025272 Mobile: 15000110506
 Web Site: <http://www.bioman.com.cn>

CERTIFICATE OF ANALYSIS

Product Name: Docetaxel Trihydrate
 Batch No.: 1911003
 Manufacturing Date: Nov.30, 2019
 Retest Date: Nov.29, 2022
 Storage: Preserve in well-closed, light resistant containers, and store at room temperature

Tests and Methods	Specifications	Results	
Description	White or almost white, crystalline powder	Conforms	
Solubility	Soluble in ethanol; insoluble in water	Conforms	
Identification A: IR B: HPLC	Both the test sample and the reference standard exhibit the same intensity of absorption at the same wave number (wavelengths)	Conforms	
	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Conforms	
Optical rotation	$[\alpha]_D^{20}$: $-39^{\circ} \sim -41^{\circ}$	-40.3°	
Heavy metals	Not more than 20ppm	Conforms	
Water Determination	5.0% ~ 7.0%	6.45%	
Residue on ignition	Not more than 0.1%	0.04%	
Microbial enumeration tests	The total aerobic microbial count does not exceed 10^2 cfu/g.	Conforms	
	The total molds and yeasts count does not exceed 10 cfu/g	Conforms	
Bacterial Endotoxins Test	Not more than 0.3 USP EU/mg	Conforms	
Organic Impurities	10-Deacetyl baccatin	N.M.T. 0.15%	Not detected
	2-Debenzoxyl 2-pentenoyl docetaxel	N.M.T. 0.5%	0.04%
	6-Oxodocetaxel	N.M.T. 0.3%	0.02%
	4-Epidocetaxel	N.M.T. 0.3%	0.03%
	4-Epi-6-oxodocetaxel	N.M.T. 0.2%	Not detected
	Any unspecified Impurity (Max)	N.M.T. 0.10%	Not detected
	Total Impurities	N.M.T. 1.0%	0.09%



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Tests and Methods	Specifications	Results	
Residual solvents	Ethanol	N.M.T. 5000ppm	Not detected
	Acetone	N.M.T. 5000ppm	76ppm
	Acetonitrile	N.M.T. 410ppm	Not detected
	Dichloromethane	N.M.T. 600ppm	Not detected
	Ethyl acetate	N.M.T. 5000ppm	Not detected
	Hexane	N.M.T. 290ppm	Not detected
Assay	97.5%~102.0% (on the anhydrous and solvent-free basis)	100.52%	
Conclusion	Conforms to the requirement of USP 39 Organic Impurities, Procedure 1		

Rep. Date: Dec. 02, 2019



Check by: _____

Analyzed by: _____

Released by QA: _____