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 Anhydrous

Batch No.: 2001001

Manufacturing Date: Jan.19, 2020

Retest Date: Jan.18, 2023

Storage: Protected from light, in an airtight container.

Tests and Methods	Specifications		Results
Appearance	White or almost white, crystalline, hygroscopic powder		Conforms
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol, soluble in methylene chloride		Conforms
Identification			
A. Specific optical rotation	-41.5 ～ -38.5		Conforms
B. IR	IR spectrum is accordant with that of reference standard		Conforms
Appearance of solution	The solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution B_5		Conforms
Specific optical rotation	$[\alpha]_D^{20}$：-41.5 ～ -38.5		-40.0°
Related compounds	Impurity A	N.M.T. 0.2%	0.08%
	Impurity B	N.M.T. 0.3%	0.02%
	Impurity C	N.M.T. 0.15%	0.05%
	Impurity E	N.M.T. 0.15%	Not detected
	Unspecified impurities	N.M.T. 0.10%	0.05%
	Total Impurities	N.M.T. 0.8%	0.20%
Heavy metals	Not more than 20ppm		Conforms
Water	Not more than 1.5%		0.21%
Sulfated ash	Not more than 0.1%		0.04%
Bacterial endotoxins	Less than 0.3 IU/mg		Conforms
Residual solvents	Ethanol	N.M.T. 5000ppm	Not detected
	Acetone	N.M.T. 5000ppm	1508ppm
	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%（calculated on the anhydrous basis）		98.70%
Conclusion	Conforms to the requirement of EP9.2		

Rep. Date: Feb.28, 2020

Check by:

Analyzed by:

Released by QA:

BIOMAN PHARMA LIMITED 质检部 QC