

D8-5

INTAS PHARMACEUTICALS LTD.

Factory : Plot No. 457, 458, Sarkhej-Bavla Highway, Matoda-382 210. Gujarat, India.
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INTAS

ONCOLOGY QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Name of working standard : DOCETAXEL (ANHYDROUS)

Evaluated with USP Lot No. : R002E0 Date of preparation : 30/06/2016

Raw material batch No. : CT0174 Valid up to : 30/06/2017

Working standard No. : S DOCE 161 Page No. : 1 of 2

Storage condition : Keep container tightly closed and store below 25°C in amber colour vials.

Reference : USP & Inhouse Specification

Sr. No.	Tests	Results	Limits
01	Description	White crystalline, hygroscopic powder.	White or almost white, crystalline, hygroscopic powder.
02	Identification	An infrared absorption spectrum of the substance being examined is concordant with reference spectrum of Docetaxel USP reference Standard.	An infrared absorption spectrum of the substance being examined should be concordant with reference spectrum of Docetaxel USP reference Standard.
03	Water content (By coulometric titration)	0.8%	Not more than 1.5%
04	Related substances (By HPLC)		
	A) Impurity A	Below disregard limit	Not more than 0.10%
	B) Impurity B	Below disregard limit	Not more than 0.10%
	C) Impurity C	0.10%	Not more than 0.15%
	D) Impurity D	Below disregard limit	Not more than 0.10%
	E) Impurity E	Below disregard limit	Not more than 0.10%
	F) Impurity F	Below disregard limit	Not more than 0.10%
	G) Impurity G	Below disregard limit	Not more than 0.10%
	H) 10-Tes-docetaxel	Below disregard limit	Not more than 0.10%
	I) Any unspecified Impurity	0.06%	Not more than 0.10%
	J) Total Impurities	0.20%	Not more than 0.5%
05	Residual solvents (By GC)		
	A) Methanol	72 ppm	Not more than 2000 ppm.
	B) Acetone	972 ppm	Not more than 5000 ppm.
	C) Acetonitrile	84 ppm	Not more than 410 ppm.
	D) Dichloromethane	126 ppm	Not more than 600 ppm.
	E) n-Hexane	2 ppm	Not more than 290 ppm.
	F) Ethyl acetate	Not detected	Not more than 2000 ppm.
	G) Tetrahydrofuran	16 ppm	Not more than 720 ppm.
	H) Cyclohexane	Not detected	Not more than 2000 ppm.
	I) n-Heptane	18 ppm	Not more than 2000 ppm.
	J) Pyridine	Not detected	Not more than 200 ppm.



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06	Assay (By HPLC)	99.6% 98.7% as such.	Not less than 98.0% and not more than 102.0%. (On anhydrous & solvent free basis) Record.

Remarks: The above material compared with USP reference standard for above tests and is suitable to use as a working standard.

Prepared by : *CH*
Date : 30/06/16

Reviewed by : *[Signature]*
Date : 30/06/16

Approved by : *[Signature]*
Date : 30/06/16

