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INTAS PHARMACEUTICALS LTD.

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INTAS
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ONCOLOGY QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Name of Working Standard : DOXORUBICIN HYDROCHLORIDE			
Evaluated With EP Lot No. : 6	Date of Preparation : 14/07/2016		
Raw Material Batch No. : 0616136003	Valid up to : 14/07/2017		
Working Standard No. : S DOXO 161	Page No : 1 of 1		
Storage Condition : Keep container tightly closed and store below 25°C in amber colour vials.			
Reference: PH.EUR & INHOUSE specification.			
SR. NO.	TESTS	RESULT	LIMITS
01	Description	Orange red, crystalline powder, hygroscopic.	Orange red, crystalline powder, hygroscopic.
02	Identification	By IR : The infrared absorption spectrum of the substance being examined is concordant with the similar preparation of Doxorubicin hydrochloride EP reference standard.	By IR : The infrared absorption spectrum of the substance being examined should be concordant with the similar preparation of Doxorubicin hydrochloride EP reference standard.
03	Water	1.1%	Not more than 4.0%
04	Related substances		
	A) Doxorubicinone	A) Below disregard limit	A) Not more than 0.50%
	B) Any other impurity	B) Below disregard limit	B) Not more than 0.10%
	C) Total impurities	C) Below disregard limit	C) Not more than 1.0%
05	Residual solvents		
	A) Methanol	A) Not detected	A) Not more than 1000 ppm
	B) Acetone	B) 2041 ppm	B) Not more than 5000 ppm
	C) Ethyl acetate	C) 1291 ppm	C) Not more than 5000 ppm
	D) Chloroform	D) Not detected	D) Not more than 60 ppm
	E) 1,4-Dioxane	E) Not detected	E) Not more than 380 ppm
	F) Ethanol	F) 2077 ppm	F) Not more than 10000 ppm
	G) Total of Acetone and Alcohol	G) 0.4%	G) Not more than 1.0%
06	Assay	101.1% ≈ (100.0% For calculation purpose) 100.6% ≈ (100.0% For calculation purpose) on anhydrous basis 99.5% as such.	98.0% to 102.0% calculated on anhydrous and solvent-free basis. Record. Record.

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

Prepared by : *[Signature]*
Date : 14/07/16

Reviewed by : *[Signature]*
Date : 14/07/16

Approved by : *[Signature]*
Date : 14/07/16

