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INTAS PHARMACEUTICALS LTD.

Factory : Plot No. 457, 458, Sarkhej-Bavla Highway, Matoda-382 210. Gujarat, India.
Phone : + 91 - 02717 - 661111, 661298 Fax : + 91 - 02717 - 661106

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Brand Name : ZODOX-50 INJECTION 2MG/ML,25ML(1X1 VIAL)(E11)
Generic Name : DOXORUBICIN INJECTION BP 2mg/mL
Composition : Each mL contains :
Doxorubicin Hydrochloride Ph.Eur .... 2 mg
Water for Injection Ph.Eur.....q.s.

Analysis as per : BP Specification

Plant : INTAS PHARMA.LTD.,MATODA
Batch Size : 140.000 nos
Receipt Dt. : 03.02.2016
Halb Batch size : 4615.00 nos
Report Dt. : 03.02.2016

Batch No. : T00613
AR Number : OIE15/16629
Mfg. Dt. : 12/2015
Exp. Dt. : 11/2017
Spec. No. : DOR1204-01
Halb Batch No.: S16629
Page No. : 1 / 2

SR. NO.	TESTS	RESULTS	LIMITS
01	Description	A clear red solution filled in clear glass vial. When examined under suitable conditions of visibility it is free from particles.	A clear red solution filled in clear glass vial. When examined under Suitable conditions of visibility it should be free from particles.
02	Identification	A) By UV : The light absorption of the resulting solution, in the range of 220 to 550 nm exhibits two maxima, at 233.95 and 251.20 nm, and found four less clearly defined maxima at 287.80,474.85,494.95 and 532.00 nm.	A) By UV : The light absorption of the resulting solution, in the range of 220 to 550 nm should exhibit two maxima, at 234 and 252 nm, and found four less clearly defined maxima at 288,475, 495 and 530 nm.
		B) By HPLC : In the Assay, the chromatogram obtained with test preparation shows a peak with the same retention time as the principal peak in the chromatogram obtained with standard preparation in the test of assay.	B) By HPLC : In the Assay, the chromatogram obtained with test preparation should show a peak with the same retention time as the principal peak in the chromatogram obtained with standard preparation in the test of assay.
03	Acidity (pH)	3.1	Between 2.5 and 3.5
04	Extractable volume	26.0 mL	The volume should not be less than the nominal volume.
05	Particulate contamination Sub visible	567 particle/container	A) Equal to or greater than 10 µm : Maximum 6000/container
		01 particle/container	B) Equal to or greater than 25 µm : Maximum 600/container

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CERTIFICATE OF ANALYSIS

Brand Name : ZODOX-50 INJECTION 2MG/ML,25ML(1X1 VIAL)(E11)

Batch No. : T00613
AR Number : OIE15/16629
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Report Dt. : 03.02.2016
Page No. : 2 / 2

SR. NO.	TESTS	RESULTS	LIMITS
06	Bacterial endotoxins	Less than 4.4 I.U of Endotoxin Unit per mL of solution.	It should not contain more than 4.4 I.U of Endotoxin Unit per mL of solution.
07	Sterility	There is no evidence of microbial growth.	There should be no evidence of microbial growth.
08	Related substances	Below disregard limit	A) Doxorubicinone :Not more than 1.0%
		0.1 %	B) Impurity at about RRT 2.7 (Dimer) : Not more than 0.7%
		0.06%	C) Any other impurity : Not more than 0.2%
		0.2 %	D) Total impurities : Not more than 2.0%
09	Assay	99.6 %	97.0% to 105.0% of label claim.

Remarks : Conforms to BP Specification

Nomenclature of known impurity:

Doxorubicinone : (8S,10S)-6,8,10,11-tetrahydroxy-8-(hydroxyacetyl)-1-methoxy-7,8,9,10-tetrahydrotetracene-5,12-dione (doxorubicin aglycone)

Q.C.HEAD : 10/02/16

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
14 JUN 2016
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