



JAYCO CHEMICAL INDUSTRIES

AN ISO 9001:2000 CERTIFIED COMPANY

MANUFACTURERS OF : API's and Intermediates

W.E. HIGHWAY, NEXT TO DODHIA PETROL PUMP, KASHI MIRA, POST MIRA, DIST. THANE - 401 104. MAHARASHTRA, INDIA

TEL : 0091-22-2845 5655 / 2845 8765 / 6595 9749 • FAX : 0091-22-2845 8739 / 2845 4948

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CERTIFICATE OF ANALYSIS

Lot: 081010

Name : ISOXSUPRINE HYDROCHLORIDE EP
 Batch No. : ISOX/121/10-11
 Mfg. Date : September - 2010
 Exp. Date : August - 2015
 Batch Size : 150.00Kg.

Date of Testing : 27-09-2010
 Test as per : EP
 AR. No. : ISOX/121/2010

Sr.No	TEST	RESULT	LIMIT
1	Description	White crystalline powder	White or almost white crystalline powder
2	Solubility	Sparingly soluble in water in alcohol practically insoluble in methylene chloride	Sparingly soluble in water in alcohol practically insoluble in methylene chloride
3	Melting point	Melts at 203°C with decomposition.	About 205°C with decomposition
4	Identification		
	A) UV	Specific Absorbance At 269 nm : 73.6 At 275 nm : 72.9	Specific Absorbance at max at 269 & 275 nm is 71 to 74 and 70 to 73 Respectively.
	B) IR	Complies	
	C) TLC test	Complies with reference Std.	Concordant with Std. Ref. IR
	D) Colour test	Test positive	Complies with reference Std.
	E) Chloride Test	Test positive	As per EP.
5	Appearance of solution	Clear & colorless solution	As per EP.
6	pH	5.04	Clear & colorless solution
7	Optical Rotation	0.0°	4.5 to 6.0 of 1% solution
8	Related substance by GC	Nil	- 0.05° to + 0.05°
9	Phenones	0.006	NMT 1.0 %
10	Heavy metals	Less than 20 ppm	Abs at 310 nm NMT 0.10
11	Loss on drying	0.17 % w/w	NMT 20 ppm
12	Sulphated Ash	0.029 % w/w	NMT 0.5 % w/w
13	Assay(on dry basis)	99.76 % w/w	NMT 0.1 % w/w
14	Residual Solvent	Methanol : 160 ppm Acetone : Nil	99.0% - 101.0 % w/w Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm

The above Mentioned product complies as per EP

Tested By <i>M. Saurant</i> 27/9/10	Checked by <i>B. Saurant</i> 27-9-10	Q. C. CHEMICAL MANAGER <i>Q. C. CHEMICAL</i> 27/9/10
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CERTIFICATE OF ANALYSIS

Name : ISOXSUPRINE HYDROCHLORIDE USP.
Batch No. : ISOX/121/10-11
Mfg. Date : September - 2010
Exp. Date : August - 2015
Batch Size : 150.00Kg.

Date of Testing : 27-09-2010
Test as per : USP
AR. No. : ISOX/121/2010

Sr. No	TEST	RESULT	LIMIT
1	Description	White, odorless crystalline powder having a bitter taste. Melt at 203°C with decomposition.	White, odorless crystalline powder having a bitter taste. Melt at about 200°C with decomposition.
2	Solubility	Slight soluble in water, sparingly soluble in alcohol	Slight soluble in water, sparingly soluble in alcohol
3	Identification		
	A) IR	Sample IR spectrum is concordant with Rf. Std IR of Isoxsuprine hydrochloride	Sample IR spectrum is concordant with Rf. Std IR of Isoxsuprine hydrochloride
	B) UV	Std. & spl. sol exhibits maxima at the same wavelength i.e at 269 & 275 nm	Std. & spl. sol exhibits maxima at the same wavelength
	C) Colour test	Complies	Chemical test as per USP
	D) Colour test	Complies	Chemical test as per USP
4	pH	5.04	Chemical test as per USP
5	Heavy metals	Less than 20 ppm.	4.5 to 6.0 of 1% solution
6	Residue on ignition	0.029 % w/w	NMT 20 ppm
7	Loss on drying	0.17 % w/w	NMT 0.20 % w/w
8	Related Compound	Nil	NMT 0.50 % w/w
9	Residual Solvent	Methanol : 160 ppm Acetone : Nil	NMT 1.0 % Methanol: NMT 3000 ppm Acetone : NMT 5000 ppm
10	Assay(on dry basis)	99.74 % w/w	97.0 % - 103.0 % w/w

The above Mentioned product complies as per USP

Tested By <i>meawar</i> 27/9/10	Checked by <i>Amourys</i> 27-9-10	Q. C. MANAGER <i>M. S. K.</i> THANE INDIA
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