

TAICANG PHARMACEUTICAL FACTORY

Address: Maoguantang Bridge , Xinmao, Chengxiang, Taicang

Tel:0086-512-53421166 Fax:0086-512-53421280

Batch Certificate

We, TAICANG PHARMACEUTICAL FACTORY as a manufacturer of INDOMETHACIN hereby certify that this batch has been manufactured by us in full compliance with GMP requirements of the local Regulatory Authority

GMP No.SUK0738 valid till 2/6/2014 issued by JIANGSU FOOD AND DRUG ADMINISTRATION OF CHINA on 3/6/2009 as per Chinese gmp rules was inspected

Transport and storage conditions: Store in well-closed container, protected from light

Product Name	INDOMETHACIN	Batch No.	T12-093
Quantity	500kg	Packing	25kg/fiber drum
Mfg.Date	May.19.2012	Anal.Date	May.25.2012
Exp.Date	May.18.2016	Specification	EP7
ITEMS	STANDARD	TEST RESULTS	
Characters	White or yellow, crystalline powder, Practically insoluble in water , Sparingly, soluble in alcohol.	Conforms	
Identification 1 Identification A and C 2 Identification A B D E	Test A: Melting Point 158-162℃ Test B: Absorption at 318(UV)170-190 Test C: IR spectra should be ad per ref standard Test D: reaction with ternc chlride Test E: reaction with dimethylaminovenzaldehyde	A: 158.5-160℃ B: 184.86 C: complies D: complies E: complies	
Related Substances(TLC)	<0.5%	complies	
Additional HPLC-Tests 4-chlorobenzoic acid 3,4dichloroindomethacin Methylester-indomethacin Ethylester-indomethacin Each unknown impurity Total impurity	≤0.5% ≤0.5% ≤0.5% ≤0.5% ≤0.1% ≤1.0%	0.02% 0.08% 0.01% 0.14% <0.1% 0.26%	
Loss on drying	≤0.5%	0.12%	
Sulphated Ash	≤0.1%	0.07%	
Heavy metals	≤20PPm	<20PPm	
Assay	98.5~100.5%	99.6%	
Residual solvent(ethanol)	≤0.5%(loss on drying)	0.12%	
Benzene	≤2ppm	complies	
Zn	≤6ppm	complies	
Conclusion	The Batch product conforms to EP7		

Director:

张莉娟

Checker:

黄瑞芳

Analyst:

何群