TAICANG PHARMACEUTICAL FACTORY

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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 ruels was inspected

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

Product Name	**INDOMETHACIN**	Batch No.	T13-130
Quantity	500kg	Packing	25kg/fiber drum
Mfg.Date	Nov.6.2013	Anal.Date	Nov.12.2013
Exp.Date	Nov.5.2017	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 chlcride Test E: reaction with dimethylaminovenzaldehyde	A:158. 5-160℃ B:187. 30 C: complies D: complies E: complies
Related Substances(TLC)	<0.5%	complies
Additional HPLC-Tests		
4-chlorobenzoic acid	≤0. 5%	0.02%
3,4dichloroindomethacin	≤0. 5%	0.07%
Methylester-indomethacin	≤0. 5%	0.02%
Ethylester-indomethacin	≤0. 5%	0.22%
Each unknown impurity	≤0. 1%	<0.1%
Total impurity	≤1. 0%	0.33%
Loss on drying	≤0.5%	0.12%
Sulphated Ash	≤0. 1%	0.07%
Heavy metals	≤20PPm	<20PPm
Residual solvent(ethanol)	≤0. 5%(loss on drying)	0.12%
Assay	98.5~100.5%	99.6%
Conclusion	The Batch product conforms to EP7	

Director: Checker: Analyst: