## **CERTIFICATE OF ANALYSIS**

Name of the Sample: Diclofenac Sodium Tablets

Quantity: 5,000,000 Tablets (500,000 Boxes)

Date of Mfg.: 03/2017

Standard: BP2003

Batch No.: 170301

Active ingredient: 50mg (Henan Lihua Ph.)

Date of Exp.: 03/2020

Report Date: 20th, Mar., 2016

Items	Specifications	Results
Description	Enteric-coated tablets, Orange	Conforms
Identification	Positive	Positive
Disintegration	1)In an acid medium(2 hours): Not a single tablet disintegrates in the middle	Conforms
	(2)In medium Buffer (1 hours):  Before 1 hour the tablets are completely disintegrated in buffer	Conforms
Average weight	± 7.5%, average weight	129.2mg
Uniformity of Dosage Units	Comply with requirements	Conforms
Dimensions	Diameter: 7.1 mm $\pm$ 0.3 mm Thickness: 3.0 mm $\pm$ 0.1 mm	7.0mm 3.0mm
Dissolution	(1)Acid phase: NMT 10% w/w of amount stated on the label, in 120 minutes.	0.20%
	(2)Buffer Phase: NLT 80% of the amount of diclofenac is released in 45 minutes.	101.1%
Related substances	(1)Any individual secondary peak: NMT 0.2%	0.06%
	(2)Sum of all secondary peaks: NMT 0.5%	0.06%
Microbial Limit	Comply with requirements	Conforms
AssayC <sub>14</sub> H <sub>10</sub> C <sub>12</sub> NNaO <sub>2</sub>	95.0%~105.0%	100.0%

The above results comply with the requirements of BP2003. Conclusion:

Q.C.DERICTOR: PAN XUEPING

NOC: 4784

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