

CERTIFICATE OF ANALYSIS

Name of the Sample: Diclofenac Sodium Tablets Batch No.: 170301
 Quantity: 5,000,000 Tablets (500,000 Boxes) Active ingredient: 50mg (Henan Lihua Ph.)
 Date of Mfg.: 03/2017 Date of Exp.: 03/2020
 Standard: BP2003 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 ± 0.3 mm Thickness: 3.0 mm ± 0.1 mm	7.0mm 3.0mm
Dissolution	(1)Acid phase: NMT 10% w/w of amount stated on the label, in 120 minutes. (2)Buffer Phase: NLT 80% of the amount of diclofenac is released in 45 minutes.	0.20% 101.1%
Related substances	(1)Any individual secondary peak: NMT 0.2% (2)Sum of all secondary peaks: NMT 0.5%	0.06% 0.06%
Microbial Limit	Comply with requirements	Conforms
AssayC ₁₄ H ₁₀ C ₁₂ NNaO ₂	95.0%~105.0%	100.0%

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

Q.C.DERICTOR: PAN XUEPING

ANALYST: XIA YUELI

NOC: 4784

