

CERTIFICATE OF ANALYSIS

Name of the Sample: Diclofenac Sodium Tablets		Batch No.: 190728
Quantity: 2,000,000 Tablets (4,000Boxes)		Active ingredient: 50mg
Date of Mfg.: 07/2019		Date of Exp.: 07/2022
Standard: BP2003		Report Date: 11 th , Nov., 2019
Items	Specifications	Results
Description	Enteric-coated tablets, Orange	Conforms
Identification	Positive	Positive
Disintegration	1)In an acid medium(2 hours):	Conforms
	Not a single tablet disintegrates in the middle	
	(2)In medium Buffer (1 hours):	Conforms
	Before 1 hour the tablets are completely disintegrated in buffer	
Average weight	± 7.5%,average weight	133.20mg
Uniformity of Dosage Units	Comply with requirements	Conforms
Dimensions	Diameter: 7.1 mm ± 0.3 mm	7.0mm
	Thickness:3.0 mm ± 0.1 mm	3.0mm
Dissolution	(1)Acid phase: NMT 10% w/w of amount stated on the label, in 120 minutes.	1.0%
	(2)Buffer Phase: NLT 80% of the amount of diclofenac is released in 45 minutes.	99.6%
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 ₁₄ H ₁₀ C ₁₂ NNaO ₂	95.0%~105.0%	99.8%

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

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