

PHARMA APPLICATION LEAFLET

#18/05/ 016

Diclofenac Sodium, Direct Compression

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Abstract

Diclofenac Sodium belong form (NSAID) Non-steroidal anti-inflammatory drug. It comes under (OTC) over the counter drugs. It is used as pain killer. Diclofenac Sodium tablet is available in the market with 25 mg, 50 mg 75 mg and 150 mg dose.

Ingredient composition

Sr.No.	Name of ingredients	mg/tablet	Contribution (%)
1.	Diclofenac Sodium	50.00	25
2.	HiCel™12 (Microcrystalline cellulose)	135	67.5
3.	Croscarmellose Sodium	10	5.0
4.	Purified Talc	05	2.5
Total		200.00	100

Procedure

HiCel™12 and croscarmellose sodium mixed for 5-10 mints and add Diclofenac Sodium (API), again mixed the mixture for 15-20 minutes. At last add lubricant purified talc and mix the mixture for 5 mints. The powder mixture was ready for direct compression.

Equipment

Sr.No.	Name of equipment	Application	Model/ make
1.	Tablet punching machine	Tablet Manufacturing	10 station, D tooling/ Proton mini press
2.	Weighing Balance	Weighing	MS204S/A01/ Mettler Toledo
3.	Tablet Hardness Tester	Hardness Test	TH 1050 M/ Labindia
4.	Tablet Friability Tester	Friability Test	FT1020 / Labindia
5.	Tablet Disintegration Tester	Disintegration Test	DT 1000 / Labindia
6.	Dissolution Apparatus	Percentage of drug release	DS 8000 / Labindia
7.	UV Spectrophotometer	Absorbance	1800/ Shimadzu

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Dissolution Test Detail

Dissolution Medium: 0.1N Hydrochloric Acid 900 ml. 37±2 °C temperature, at 50 rpm and using with USP dissolution type II apparatus.

Samples withdrawals at required time intervals .

Samples should be diluted if require and filtered. Check absorbance at $\lambda=276$ nm.

Tablet Characteristics

Sr.No.	Name of Parameter	Result
1.	Tablet description	Round, flat, white color.
2.	Tablet weight	200 mg
3.	Tablet Hardness	92.5 N
4.	Diameter	8.00 mm
5.	Disintegration time (n=6)	98 Sec
6.	Friability	<1%
7.	Dissolution Time (n=6)	45 min

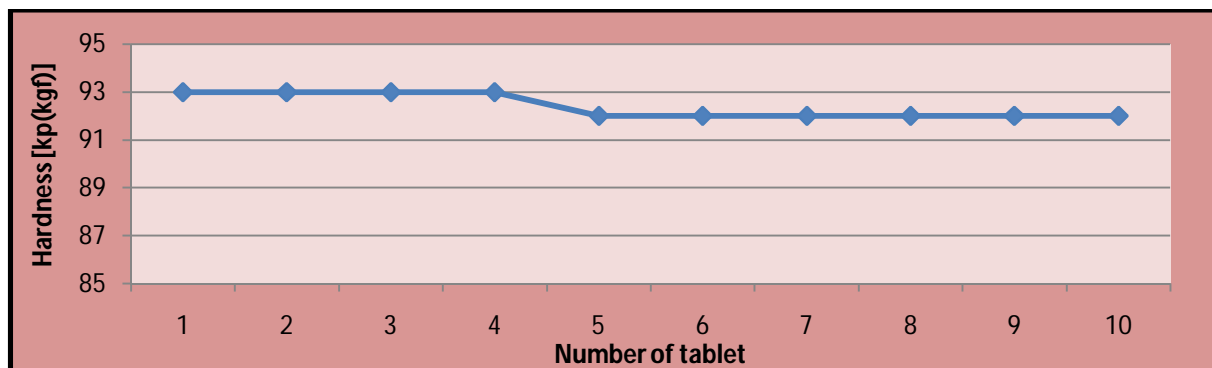


Fig.1. Hardness uniformity of Diclofenac Sodium Tablets

Summary

- HiCel™ 12 grade of MCC provides excellent tablet hardness.

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