



OS-CR KC-6

Diclofenac Sodium 100 mg Extended Release Tablets

This formulation features Diclofenac Sodium 100 mg tablets developed with Carbopol® 971P NF polymer and hypromellose as the extended release matrix ingredients.

	Ingredient Name	% w/w
A	1. Diclofenac Sodium	34.00
	2. Carbopol® 971P NF Polymer	6.80
	3. Hypromellose Substitution Type 2208 Metolose® 90 SH-4000 SR	5.10
	4. Dibasic Calcium Phosphate Dihydrate	22.10
	5. Water	q.s.
B	6. Sorbitol	26.19
	7. Anhydrous Silica	1.02
	8. Magnesium Stearate	1.36
	9. Talc	1.36
C	10. Conventional Film Coat	2.00

Tablet Properties

Appearance	Film coated, biconvex tablets
Weight (mg)	294 ± 2
Thickness (mm)	4.0 ± 0.2
Mechanical Strength (kP)	21 - 24
Friability %	0.50
Dissolution/Drug Release**	1 hour: 8 - 10%
	2 hour: 18 - 26%
	4 hour: 34 - 44%
	8 hour: 59 - 64%
	12 hour: 87 - 88%

** USP Apparatus 2, 100 rpm, 900 ml pH 6.8 buffer

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Procedure

1. Weigh diclofenac sodium, Carbopol® 971 P NF polymer, hypromellose and dibasic calcium phosphate and pass through a 40 mesh sieve. Add all the ingredients to a high shear granulator and mix for 2 minutes at slow speed (Impeller speed = 100 rpm; Chopper speed = 300 rpm).
2. Granulate with water (~ 40 ml for a 1,000 tablet batch) added gradually for 3 minutes while mixing the blend at medium speed (Impeller speed = 100 rpm; Chopper speed = 1000 rpm). Increase the chopper speed to 1500 rpm and continue adding water for 1 minute (~ 21 ml for a 1,000 tablet batch). Densify the granules by mixing for 9 minutes at an impeller speed= 100 rpm and chopper speed = 2880 rpm. Finally, mix for 1 minute (Impeller speed = 150 rpm; Chopper speed = 2880 rpm).
3. Pass the wet mass through a 12 mesh sieve and dry at 40°C to a moisture content of less than 2%.
4. Pass the dry granules through a 20 mesh screen and blend them with sorbitol (direct compression grade passed through a 30 mesh sieve) for 2 minutes. Add the magnesium stearate and talc (60 mesh sieve) and blend for 2 minutes.
5. Compress the blended granules as follows:
 - Punches: 9 mm standard concave
 - Target weight: 288 mg
 - Mechanical strength: 22 kP
 - Friability: NMT 0.5 % w/w (100 revolutions)

Note: The tablets can be coated with a non aqueous solution of hypromellose substitution type 2910 in isopropyl alcohol and methylene chloride to a weight gain of 6 mg/tablet.

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For more information or to request product samples, please visit www.pharma.lubrizol.com or contact your nearest Lubrizol Advanced Materials location.

North America 9911 Brecksville Road Cleveland, OH 44141-3247 TEL: 216.447.5000 TEL: 800.379-5389 FAX: 216.447.5740	North Latin America Montes Urales #215 Col. Lomas de Chapultepec Deleg. Miguel Hidalgo México, D.F. c.p. 11000 TEL: 52.55.3067.0860 FAX: 52.55.3067.0884	South Latin America Av. Fagundes Filho 134 - Cj. 101, 10 th Floor Edifício Victoria Office Center São Judas, São Paulo 04304-010 TEL: 55.11.4082.1330 FAX: 55.11.4082.1345	Europe, Middle East and Africa Chaussée de Wavere, 1945 B-1160 Brussels, Belgium TEL: 32.2.678.19.11 FAX: 32.2.678.19.90	Asia Pacific 1107-1110 Shui On Centre 6-8 Harbour Road Wanchai, Hong Kong TEL: 852.2508.1021 FAX: 852.2512.2241	South Asia 6 th and 7 th Floor Jaswanti Landmark Mehra Industrial Estate L.B.S. Marg, Vikhroli, (West) Mumbai 400079 India TEL: 91.22.6602.7800 FAX: 91.22.6602.7888
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