LUBRIZOL LIFE SCIENCE

HEALTH

Diclofenac Sodium Extended Release Tablets 100mg

The extended release tablet contains **Diclofenac Sodium 100 mg**. The formulation features use of **Carbopol® 971P NF polymer** as the extended release matrix ingredient. The formulation uses combination of Carbopol and Compritol providing synergy. The formulation meets the USP drug dissolution requirements (Test 2).

Number	Ingredients	% w/w	mg / Tablet
	Intra-Granular Phase:		
1.	Diclofenac sodium	40.00	240.0
2.	**Carbopol® 971P NF polymer**	8.50	21.25
3.	Lactose (200 mesh)	14.50	36.25
4.	Dibasic calcium phosphate dihydrate	26.00	65.00
	Extra-Granular Phase:		
5.	Compritol® 888 ATO	9.50	23.75
6.	Colloidal silicon dioxide	0.5	1.25
7.	Talc	0.5	1.25
8.	Magnesium stearate	0.5	1.25
	TOTAL:	**100.00**	**250.00**

Lab batch size – 1,000 g (water used as binding liquid).

Process:

1. Weigh diclofenac sodium, **Carbopol® 971P NF polymer**, lactose and dibasic calcium phosphate dihydrate and pass through 20 mesh screen. Add the ingredients to high shear mixer and blend for 10 minutes at 150 rpm.

2. Granulate the blend with water in high shear granulator, using about 200 g water for 1kg powder blend adding the water as a thin stream, as droplets using peristaltic pump or as a spray and impeller speed above 250 to 300 rpm during wet massing.

3. Dry the granules in fluid bed drier (inlet temperature at 60 °C) to loss on drying (LOD) of about 2%.

4. Mill the granules through 20 mesh screen.

5. Blend the milled granules with Compritol® 888 ATO in a V-blender for 15 minutes at 25 rpm.

6. Weigh colloidal silicon dioxide, talc and magnesium stearate and pass through 30 mesh screen. Add the ingredients into a V-blender and blend for 3 minutes at 25 rpm.

7. Compress the blend into tablets on a tablet press as follows:

- Punches: 9 mm standard concave round
- Target weight: 250 mg
- Mechanical strength: minimum 10 kP
- Friability: NMT 1.0 % w/w (100 revolutions)

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Final Tablet Properties:
Appearance: Biconvex, round tablets
Weight (mg)*: 254 ± 3.2
Thickness (mm)*: 3.7 ± 0.02
Mechanical Strength (kP)*: 8.87 ± 0.56
Friability (100 revolutions) (%): 0.11

*Average ± SD

Dissolution**(% average of 6 tablets)		
Time (h)	**Lubrizol**	**USP Limits**
1	11.10%	NMT 28 %
2	26.20%	20 – 40 %
4	51.20%	35 – 60 %
6	72.30%	50 – 80 %
10	97.90%	NLT 65 %

**Dissolution method as per USP monograph of Diclofenac ER Tablets (Test 2). USP Apparatus 2, 50 rpm, 900 ml 0.05 M phosphate buffer pH 7.5, wire sinkers.

Summary:

Carbopol® polymers have demonstrated to be useful and highly efficient as extended release matrix former making them a polymer of choice when formulating high drug load extended release tablets.

The Lubrizol Life Science Health website **www.lubrizol.com/Health** provides additional information:

- Bulletin 30 - Controlled Release Tablets and Capsules; Bulletin 31 - Formulating Controlled Release Tablets and Capsules with Carbopol; Bulletin 32 - Application of Carbopol 71G NF Polymer in Controlled Release Tablets
- Aqueous and non- aqueous granulation videos under video gallery
- Technical Papers, Technical Data Sheets, Test Procedures, Certificates, and other Formulations

Please contact your Lubrizol representative to get samples, quotations or further technical assistance.

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