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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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Diclofenac Sodium Extended Release Tablets 100mg

| 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 | | | | |

| 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 % | | |

*Average ± SD

**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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