LUBRIZOL LIFE SCIENCE

HEALTH

# Pentoxifylline Extended Release Tablets

The extended release tablet contains **Pentoxifylline 400 mg**. This formulation features use of **Carbopol® 71G NF** and **Carbopol® 971P NF polymer** as the extended release matrix ingredients. The formulation has high drug loading of 66.67% and meets the USP drug dissolution requirements (Test 1).

| Number | Ingredients | % w/w | mg / Tablet |
|---|---|---|---|
| | **Intra-Granular Phase:** | | |
| 1. | Pentoxifylline | 66.67 | 400.00 |
| 2. | **Carbopol® 971P NF polymer** | 5.00 | 30.00 |
| 3. | Silicon dioxide | 0.50 | 3.0 |
| | **Extra-Granular Phase:** | | |
| 4. | **Carbopol® 71G NF Polymer** | 15.00 | 90.00 |
| 5. | Microcrystalline cellulose (Microcel® PH102) | 11.83 | 71.00 |
| 6. | Glyceryl behenate (Compritol® 888 ATO) | 1.00 | 6.00 |
| | **TOTAL:** | **100.00** | **600.00** |

Lab batch size – 1000 g (Ethanol : water 1:1 mixture used as binding liquid).

**Process:**

**1.** Pass pentoxifylline, **Carbopol® 971P NF polymer** and silicon dioxide through 20 mesh screen. Add the ingredients to high shear mixer and blend for 10 minutes at 150 rpm.

**2.** Granulate the blend with 1:1 mixture of ethyl alcohol and water in high shear granulator, using about 50 g mixture for 1kg powder blend adding the mixture 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 45 °C) to loss on drying (LOD) of about 2%.

**4.** Pass the dry granules through 20 mesh screen and blend them with microcrystalline cellulose PH102, Carbopol® 71G NF polymer and Compritol 888 ATO in a V-blender for 15 minutes at 25 rpm.

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

- Punches: 18 x 7 mm standard convex caplet shape
- Target weight: 600 mg
- Mechanical strength: minimum 10 kP
- Friability: NMT 1.0 % w/w (100 revolutions)

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| Final Tablet Properties: |
|---|
| **Appearance:** Biconvex, caplet shaped tablets |
| **Weight (mg)*:** 606 ± 4.5 |
| **Thickness (mm)*:** 5.23 ± 0.04 |
| **Mechanical Strength (kP)*:** 22 ± 1.3 |
| **Friability (100 revolutions) (%):** 0.13 |

*Average ± SD

| Dissolution**(% average of 6 tablets) | | |
|---|---|---|
| **Time (h)** | **Lubrizol** | **USP Limits** |
| 1 | 9.91% | NMT 30% |
| 4 | 36.66% | 30-55% |
| 8 | 66.99% | NLT 60% |
| 12 | 91.33% | NLT 80% |

**Dissolution method per USP monograph of Pentoxifylline ER tablets (Test 1). USP Apparatus 2, 100 RPM, 900 ml water.


**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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