



# 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**<sup>\*</sup> 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:	Dissolution**(% average of 6 tablets)			
<b>Appearance:</b> Biconvex, caplet shaped tablets	Time (h)	Lubrizol	USP Limits	
<b>Weight (mg)*:</b> 606 ± 4.5	1	9.91%	NMT 30%	
<b>Thickness (mm)*:</b> 5.23 ± 0.04	4	36.66%	30-55%	
Mechanical Strength (kP)*: 22 ± 1.3	8	66.99%	NLT 60%	
Friability (100 revolutions) (%): 0.13	12	91.33%	NLT 80%	
Average ± SD **Dissolution method per USP monograph of Pentoxifylline ER tablets (Test 1). USP Apparatus 2, 100 RPM, 900 ml water.				

#### Summary:

Carbopol<sup>®</sup> 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

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