



## Tramadol Hydrochloride Extended Release Tablets

The extended release tablet contains **Tramadol HCl 100 mg**. The formulation features use of **Carbopol\* 971P NF** and **Carbopol\* 71G NF polymers** as the extended release matrix ingredients.

Number	Ingredients	% w/w	mg/Tablet
	Intra-Granular Phase:		
1.	Tramadol hydrochloride	33.33	100.00
2.	Carbopol* 971P NF polymer	13.0	39.00
3.	Microcrystalline cellulose (Microcel® PH101)	22.17	66.51
	Extra-Granular Phase:		
4.	Carbopol* 71G NF polymer	16.00	48.00
5.	Microcrystalline cellulose (Microcel® PH102)	15.00	45.00
6.	Magnesium stearate	0.50	1.5
	TOTAL:	100.00	300.00

Lab batch size - 1000 g (Ethyl alcohol absolute used as binding liquid).

## **Process:**

- **1.** Pass tramadol hydrochloride, **Carbopol\* 971P NF polymer** and microcrystalline cellulose PH101 through 20 mesh screen. Add the ingredients to high shear mixer and blend for 10 minutes at 150 rpm.
- **2.** Granulate the blend with ethyl alcohol in high shear granulator, adding about 50-80g ethyl alcohol for 1 kg powder blend, adding the alcohol 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 obtain the Loss on Drying (LOD) of about 2%.
- **4.** Mill the granules through 20 mesh screen and blend them with Carbopol® 71G NF polymer and microcrystalline cellulose PH102 in a V-blender for 15 minutes at 25 rpm.
- 5. Weigh magnesium stearate and pass through a 30-mesh screen. Add to the V-blender and mix for 1 minute at 25 rpm.
- **6.** Compress the blend into tablets on a tablet press as follows:

• Punches: 9 mm standard concave round

• Target weight: 300.0 mg

• Mechanical strength: minimum 10 kP

• Friability (100 revolutions): NMT 1.0 % w/w





## Tramadol Hydrochloride Extended Release Tablets

Final Tablet Properties:		
Appearance: Biconvex, round tablets		
<b>Weight (mg)*:</b> 304 ± 2.8		
<b>Thickness (mm)*:</b> 4.01 ± 0.01		
Mechanical Strength (kP)*: 14.13 ± 0.97		
Friability (100 revolutions) (%): 0.05		

Dissolution**(% average of 6 tablets)		
Time (h)	Lubrizol	
1	27.40%	
2	41.30%	
4	65.10%	
6	71.60%	
9	81.90%	
10	84.40%	

<sup>\*\*</sup>Dissolution method USP Apparatus 1, 75 RPM, 900 ml 0.1 N HCl.

## \*Average ± SD **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.





9911 Brecksville Road Cleveland, OH 44141-3201 USA

Lubrizol.com/Health

The information contained herein is believed to be reliable, but no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end-product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the user. Lubrizol Advanced Materials, Inc., shall not be liable for and the customer assumes all risk and liability for any use or handling of any material beyond Lubrizol Advanced Materials, Inc.'s direct control. The SELLER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Nothing contained herein is to be considered as permission, recommendation nor as an inducement to practice any patented invention without permission of the patent owner. Lubrizol Advanced Materials, Inc., is a wholly owned subsidiary of The Lubrizol Corporation.