LUBRIZOL LIFE SCIENCE

HEALTH

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

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

*Average ± SD

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%

**Dissolution method USP Apparatus 1, 75 RPM, 900 ml 0.1 N HCl.

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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