Citalopram Hydrobromide Tablets Celexa

Celexa is a film-coated, oval-scored tablet containing citalopram HBr in strengths equivalent to a 20- or 40-mg citalopram base. The inactive ingredients are copolyvidone, cornstarch, croscarmellose sodium, glycerin, lactose, monohydrate, magnesium stearate, hydroxypropyl methyl cellulose, microcrystalline cellulose, polyethylene glycol, titanium dioxide, and iron oxides are used as coloring agents in the pink 20-mg tablets.

Clarithromycin Tablets (250 mg/500 mg) Biaxin

Each yellow oval film-coated Biaxin tablet contains 250 or 500 mg of clarithromycin and the following inactive ingredients: cellulosic polymers, cros-carmellose sodium, D&C Yellow No. 10, FD&C Blue No. 1, magnesium stearate, povidone, propylene glycol, silicon dioxide, sorbic acid, sorbitan monooleate, stearic acid, talc, titanium dioxide, and vanillin. The 250-mg tablet also contains pregelatinized starch.

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
250.00	1	Clarithromycin[a]	256.00
80.90	2	Microcrystalline cellulose (Avicel PH 102)	80.90
8.00	3	Croscarmellose sodium (Ac-Di-Sol)	8.00
9.00	4	Povidone (PVP K-30)	9.00
1.10	5	Polysorbate 80 (Tween 80)	1.10
51.50	6	Microcrystalline cellulose (Avicel PH 102)	51.50
10.00	7	Croscarmellose sodium (Ac-Di-Sol)	10.00
22.00	8	Pregelatinized starch (starch 1500)	22.00
2.25	9	Magnesium stearate	2.25
4.50	10	Talc (fine powder)	4.50
3.00	11	Stearic acid	3.00
1.75	12	Colloidal silicon dioxide (Aerosil 200)	1.75
–	13	Alcohol (ethanol 95%)	88.00

[a]Clarithromycin 6.0 mg/tablet is added as an excess to compensate for the water content and assay of the material. The weight of clarithromycin is factored based on potency. The weight of microcrystalline cellulose (Avicel PH 101) is then adjusted to compensate for the factored potency of clarithromycin. Adjust the fill weight and formula for a 500-mg tablet.

Manufacturing Directions

Precautions: Avoid overmixing lubricants, otherwise hardness can be reduced. Process the products in an explosion-proof area, with relative humidity of not more than 50%, and a room temperature of not more than 27°C.

1. Screen, if necessary, through an approximately 710-µm screen, the following: clarithromycin, croscarmellose sodium, microcrystalline cellulose (Avicel PH 101), and silicon dioxide. Blend together in suitable massing equipment.
2. Dissolve povidone in approximately 240 mL of ethanol—a complete solution must be achieved.
3. While mixing the blended powders from step 1, add the povidone solution from step 2.
4. Continue mixing to ensure an even distribution of the solution, and then add extra ethanol until a characteristic granule mass is obtained.
5. If necessary, pass the wet mass through a 3- to 4-mm screen. Dry at approximately 50°C to 55°C until the LOD is not more than 3%.
6. Sift dried granule over a 1.4-mm (approximately) screen. Pass the oversized granules through a 1.7-mm (approximately) screen, using a suitable mill. Alternate screening and milling systems may be used to yield suitable sized granules.
7. Load a portion of the granule from step 6 into a suitable blender. Add microcrystalline cellulose (Avicel PH 102) and croscarmellose sodium, blend, add talc, purify, and blend until uniform.
8. Mix together stearic acid and magnesium stearate with a small portion of granule. If necessary, pass through a 0.5-mm (approximate) screen.
9. Add the steps above, mix, then add the balance of granule. Mix until uniform.
10. Compress tablets to the following parameters: tablet weight 8.5 g/10 tablets ± 3%.
11. Coat using an HPMC coating solution.