## Chlordiazepoxide and Clinidium Bromide Tablets (5 mg/2.5 mg)

| Bill of Materials | | | |
|---|---|---|---|
| Scale (mg/tablet) | Item | Material Name | Quantity/1000 Tablets (g) |
| 2.50 | 1 | Clinidium bromide, 5% excess | 2.625 |
| 5.00 | 2 | Chlordiazepoxide, 5% excess | 5.25 |
| 131.02 | 3 | Lactose powder | 131.02 |
| 8.50 | 4 | Starch (maize) | 8.50 |
| 2.30 | 5 | Talc | 2.30 |
| 0.30 | 6 | Magnesium stearate | 0.30 |
| QS | 7 | Water, purified | QS |

### Manufacturing Directions

1. Prepare a paste with maize starch and water. Use this for separately granulating items 1 and 2. Use a 1:4 starch and water mixture, and heat to 50°C with continuous stirring.
2. Knead, granulate, dry, and sieve item 1 using step 1 paste. Mix a 1:5 ratio of items 1 to 3, and mix together for 5 minutes. Pass the mixture through an oscillating granulator using a 1-mm sieve. Add paste from step 1 and mix for 5 minutes. Add item 3 (part) and pass the wet mass through a 7-mm sieve. Dry at an humidity of 40% to 50%. Pass the dried granules through a 1.5-mm perforated sieve.
3. Knead, granulate, dry, and sieve item 2 using step 1 paste. Use a 1:3 ratio of item 2 to lactose, and mix for 5 minutes. Then pass the mixture through a 1-mm oscillating granulator. Pass the wet mass through a 7-mm sieve and dry at 60°C overnight in a relative humidity of granules that is 34% to 43%. Pass the dried granules through a 1.5-mm perforated sieve.
4. Mix the granules from steps 2 and 3, and tumble the mix for 1 hour at low rpm.
5. Premix items 5 and 6 for 5 minutes, and then blend this mixture with step 4. Tumble the mix for a half hour at low rpm.
6. Compress into 150-mg tablets, using 8-mm cylindrical biconvex punches at 4 to 5 tons of pressure.
7. Apply a sugar coating (see Appendix) to the final weight of 300 mg.

## Chlordiazepoxide Tablets (10 mg)

| Bill of Materials | | | |
|---|---|---|---|
| Scale (mg/tablet) | Item | Material Name | Quantity/1000 Tablets (g) |
| 10.00 | 1 | Chlordiazepoxide | 10.00 |
| 61.70 | 2 | Lactose | 61.70 |
| 6.17 | 3 | Starch (maize) | 6.17 |
| 0.60 | 3 | Talc | 0.60 |
| 0.30 | 4 | Magnesium stearate | 0.30 |
| QS | 5 | Water, purified | QS |

### Manufacturing Directions

1. Mix items 1 and 2 in a blender for 10 minutes at medium speed.
2. In a separate vessel, prepare a paste of item 3 with item 5, at 50°C, and maintain this temperature until fully gelatinized without lumps.
3. Transfer the hot paste to the blender in step 1, and mix for 30 minutes. Then pass it through a granulator with a 10-mm perforated screen.
4. Dry the granules overnight at 45°C.
5. Sift the dry granules in an oscillating granulator with a 1-mm sieve.
6. Add item 4, and mix in a tumbler for 10 minutes.
7. Compress into 80-mg tablets, using 6 × 3-mm cylindrical biconvex punches.
8. Sugarcoat the tablets. (See Appendix.)