

Buspirone Fast-Melt Tablets

Formulations: Mix buspirone, 8%; sodium bicarbonate, 25%; citric acid anhydrous, 25%; avicel PH113, 12%; anhydrous lactose, 17%; xylitol, 11%; crodesta f160, 2%.

Manufacturing Directions

1. Dry all ingredients at 40°C to 60°C to significantly reduce the moisture content of each material.
2. Blend for 10 minutes and extrude in a hot melt extruder at 70°C to 100°C to soften and melt the thermal binders (sucrose stearate and xylitol) and to form granules containing the effervescent ingredients.
3. Mix BUS-EGF (20–80 mesh) 50%, microcrystalline cellulose (Avicel PH113) 31%, mannitol (Mannogen 3215) 10%,

AcDiSol 5%, aspartame 3%, redberry flavor 0.4%, magnesium stearate 0.5, and fumed silicon dioxide 0.1%.

4. Screen and blend for 5 minutes prior to compression.
5. Buspirone tablets are then compressed to a hardness of approximately 1–3 kPa and tablets disintegrate in water in approximately 15–35 seconds.

Buspirone Hydrochloride Tablets, BusPar

BuSpar is supplied for oral administration in 5-mg and 10-mg, white, ovoid-rectangular, scored tablets. BuSpar tablets, 5 mg and 10 mg, contain the following inactive ingredients: colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

Buspirone Hydrochloride Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
15.00	1	Buspirone hydrochloride	15.00
7.00	2	Polyvinylpyrrolidone	7.00
1.50	3	Silicon dioxide	1.50
150.00	4	Lactose	150.00
1.50	5	Glyceryl behenate	1.50
	6	Water qs	

Manufacturing Directions

1. Buspirone and lactose are placed in a fluidized bed apparatus.
2. An aqueous PVP solution (in 85 g of water) is sprayed to get granules.
3. The granules thus obtained are subsequently dried and passed through a sieve (1-mm mesh) and glyceryl behenate is weighed, added, and blended in a drum mixer.
4. The resulting mixture is pressed into 175-mg tablets.
5. These tablet cores are then coated with the following formulation: ethylcellulose 10.00, hydroxypropylcellulose 10.00, stearic acid 2.00, and alcohol 188.00 g.
6. Ethocel, povidone, and stearic acid are first dissolved in denatured alcohol (188 g). The coating solution is then sprayed onto the tablet cores in a coating pan.

Buspirone Hydrochloride Tablets, Controlled-Release (30 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
30.00	1	Buspirone hydrochloride	30.00
120.00	2	Polyvinyl chloride	120.00
11.00	3	Polyvinyl acetate C10-V7	11.00
1.60	4	Magnesium stearate	1.60
—	5	Alcohol	QS

Manufacturing Directions

1. Dry mix buspirone hydrochloride with polyvinyl chloride.
2. Granulate the powder mixture with a solution of polyvinyl acetate in ethanol.
3. Mill dried granules and compress into 7-mm round tablets (162.60 mg).