

EXPERIMENTAL: MANUFACTURE OF 200 mg IBUPROFEN TABLETS

Ibuprofen, 2-(4isobutylphenyl)-propionic, acid is a widely used non-steroid anti-inflammatory agent. It is slightly soluble in water and has poor flow and compaction characteristic owing to its needle like crystalline structure. Ibuprofen is prescribed in high doses (200-800 mg), which normally precludes its direct-compression manufacture into suitable sized tablets. Recently a number of pre-granulated formulations have appeared on the market containing from 65 to 90% Ibuprofen.

Ibuprofen tablets are required to be film coated to mask the intense bitterness. The tablets produced in this class will not be coated.

Experimentation

The formulation and the manufacture of Ibuprofen tablets will require two working groups, one group to prepare tablets by Direct Compression, the other to prepare tablets by Wet Granulation. Both groups, however, are to participate in all demonstrations and to be aware of and to present the methods, operations and results for both manufacturing procedures. Tablets from each method of manufacture will be compared regarding weight variation, hardness, friability, and disintegration characteristics.

DIRECT COMPRESSION

IBUPROFEN 200 mg TABLETS

THEORETICAL YIELD: 500 TABLETS

Components	Uses and comments	Amount per tablet	Amount 500 tablets	Per	Amount actually weighed
Ibuprofen granules (contains 3% PVP*)		206 mg			
Lactose D.C. (direct compression)		220 mg			
Starch		24 mg			
Ac-di-sol*		6 mg			
Avicel 102		50 mg			
Magnesium stearate BP		6 mg			
Total weight					

* PVP (Polyvinylpyrrolidone); * Ac-di-sol (Cross-linked sodium carboxymethyl cellulose)

Manufacturing directions

Calculate the quantities of each of the materials required to produce 500 tablets, weighing each of the materials individually in small plastic containers (use only granulated ibuprofen and direct compression lactose).

Combine all the materials (except the magnesium stearate) by passing each through a 1000 µm mesh sieve and transfer the contents to the mixing container.

Mix in the Turbula mixer for 12 minutes, stop the mixer, add the magnesium stearate and continue mixing for a further 3 minutes. (The optimum mixing time of 15 minutes has been predetermined).

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S Ben Porath



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