**Ibuprofen**

**WO 1994 010993 A1**

**Formula:**

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| **N°** | **Constituants** | **Quantity (% w/w)** |
| 1 | S –(+) – ibuprofen | 51% |
| 2 | Gelatin | 1% |
| 3 | Colloidal sillica | 0 .085% |
| 4 | Microcrystalline cellulose | 32.8% |
| 5 | Potato starch | 6% |
| 6 | Lactose | 6 .8% |
| 7 | Croscarmellose sodium | 2% |

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| **Component** | **Constituants** | **Quantity (% w/w)** | **Grade** | **Properties** |
| **I** | S –(+) – ibuprofen | 51% | In accordance with BP 1988 and BP Add.89. | * Crystal form: monoclinic * Space group: P2*1/c* . * Density: 1.098 g/cm3. |
| Potato starch | 6% | In accordance with Ph.Eur. , 2nd Ed. | * Density (bulk): between 0 .56 and 0.82 g/cm3. * Density (tapped): between 0 .8 and 0.9 g/cm3. * Moisture content : 18%. * Particle average size : 46 µm. |
| Lactose | 6 .8% |  | In accordance with Ph.Eur. , 2nd Ed. |
| Microcrystalline cellulose | 6.83% | AVICEL PH 101 | * Diluent. * Density (Bulk): 0 .32 g/cm3. * Density (tapped): 0 .45 g/cm3. * Density (true): between 1.512 and 1.668 g/cm3. * Specific surface area: 1.06 – 1.12 m²/g. * Particule size : 50µm. * Moisture content ≤5.0%. |
| Croscarmellose sodium | 1% | AC-Di-Sol | * Desintegrant. * Density (bulk): 0 .529 g/cm3. * Density (tapped) : 0 .819 g/cm3. * Density (true): 1.543 g/cm3. * Specific surface area: 0.81 – 0.83 m²/g. * Particle size distribution: no more than 2% retained on a 73.7 µm mesh and no more than 10% retained on a 44.5 µm mesh. |
| **I I** | Gelatin | 1% | In accordance with Ph.Eur. , 2nd Ed. | * Binder. * Moisture content : 9-11%. |
| **I I I** | Microcrystalline cellulose | 25.97% | AVICEL PH 102 | * Diluent. * Density (true): between 1.420 and 1.460 g/cm3. * Specific surface area: 1.21 – 1.30 m²/g. * Particule size : 100µm. * Moisture content ≤5.0%. |
| Croscarmellose sodium | 1% | AC-Di-Sol | * Disintegrant. * Density (bulk): 0 .529 g/cm3. * Density (tapped) : 0 .819 g/cm3. * Density (true): 1.543 g/cm3. * Specific surface area: 0.81 – 0.83 m²/g. * Particle size distribution: no more than 2% retained on a 73.7 µm mesh and no more than 10% retained on a 44.5 µm mesh. |
| Colloidal silica | 0 .085% | AEROSIL 200 | * Lubricant or glidant. * Specific surface area: 200 ±25 m2 /g. * Density (bulk): 0.029- 0.042 g/cm3. * Density (tapped):0.05 g/cm3. * Moisture content: ≤1.5%. |

**Film-coating solution:**

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| **Constituants** | **Quantity (% w/w)** | **Grade** | **Properties** |
| Hydroxypropyl-methylcellulose | 5% | Methocel E5 Premium LV | * Density (bulk): 0 .341 g/cm3. * Density (tapped) : 0 .557 g/cm3. * Density (true): 1.326 g/cm3. * Nominal viscosity: 5 mPa.s |
| Purified water | 95% | / | In accordance with the Pharmacopea. |

**Process:**

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| **Step** | **Description** | **Equipements** |
| 1 | Mixture of the constituents of:   * S -(+)- ibuprofen * Potato starch * Lactose * 6.83 % w/w Microcrystalline cellulose Avicel PH 101 * 1% w/w Croscarmellose sodium. | **C:\Users\fafa\Desktop\schémas procédé\high shear.png**  High shear granulator |
| 2 | Addition of the aqueous solution of “gelatin” to the mixture. |
| 3 | Granulation. |
| 4 | Sieving (sieve aperture size 1.6mm). |  |
| 5 | Drying |  |
| 6 | Addition of the constituents of:   * 25.97% w/w Microcrystalline cellulose Avicel PH 102 * 1% w/w Croscarmellose sodium * Colloidal silica.   With sieved and dried granules. |  |
| 7 | Sieving  (Sieve aperture size 1 mm). |  |
| 8 | Compression | **Tablet press** |
| 9 | Coating | **Coating pan** |