ABCD

**Description and Composition of the Drug Product**

**BEA 2180 BR Respimat® Solution for Inhalation Active Product and Matching Placebo**

Internal Number

ADD 774

Document Number

U05-1314-01

Date

15 May 2007

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**Investigational Medicinal Product Documentation**

**BEA 2180 BR – Version 01 (trial 1205.14)**

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| **Product** |  |

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1. **DESCRIPTION OF THE DRUG PRODUCT**

BEA 2180 BR Respimat solution for inhalation consists of an aqueous solution of BEA 2180 BR filled into a cartridge, and a Respimat inhalation device. One cartridge is used per device.

Respimat is a hand held, pocket sized oral inhalation device that uses mechanical energy to generate a slow moving aerosol cloud of medication (“soft mist”) from a metered volume of drug solution.

Three dose strengths of BEA 2180 BR Respimat solution for inhalation, corresponding to 50, 100 and 200 µg and a placebo formulation will be used. One dose will be administered by 2 actuations of the inhalation device. In order to conform to international standards for declaration of active substances, the dose strengths refer to the cation, i.e. BEA 2180, as the active moiety of the molecule.

1. **COMPOSITION OF THE DRUG PRODUCT**

**2.1** **BEA 2180 BR RESPIMAT SOLUTION FOR INHALATION**

The BEA 2180 BR Respimat formulation is an aqueous solution containing BEA 2180 BR as active substance.

The compositions of BEA 2180 BR Respimat solution for inhalation corresponding to the dose strengths of 50, 100, and 200 µg as well as the placebo formulation are given in Table 1 and 2.

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| Table 1 | Composition of BEA 2180 BR Respimat solution for inhalation (Mass per dose) | | | | | | |  |  |
|  |  |  |  | |  |  |  |  |  |
|  | **Mass per dose d** | **Mass per dose d** | **Mass per dose d** | | **Mass per dose d** |  |  |  |  |
| **Name of** | **[mg]** | **[mg]** |  | **[mg]** | **[mg]** |  | **Function** | **Reference to** |  |
| **ingredient** | **dose strength** | **dose strength** | **dose strength** | | **placebo e** |  | **standards** |  |
|  |  |  |
|  | **50µg** | **100µg** |  | **200µg** |  |  |  |  |  |
|  |  |  |  | |  |  | |  |  |
| BEA 2180 a | 0.0500 | 0.1000 | 0.2000 | | - | Drug substance | | In house |  |
| Corresponding |  |  |  |  |  |  |  | standard |  |
| 0.0606 | 0.1211 | 0.2422 | | - |  |  |  |  |
| amount of |  |  |  |  |  |  |  |  |  |
| BEA 2180 BR a |  |  |  |  |  |  |  |  |  |
| Benzalkonium | 0.0023 | 0.0023 | 0.0023 | | 0.0023 |  | Preservative | Pharm. Eur. |  |
| chloride b, c |  |  |
| Edetate disodium | 0.0023 | 0.0023 | 0.0023 | | 0.0023 |  | Stabilizer | Pharm. Eur. |  |
|  |  |  |  |  |  |  |  |  |  |
| Citric acid, | 0.0007 | 0.0007 | 0.0007 | | 0.0007 |  | Acidifier | Pharm. Eur. |  |
| anhydrous |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| Water for | ad 22.4 | ad 22.4 |  | ad 23.7 | ad 22.9 |  | Solvent | Pharm. Eur. |  |
| injection f |  |  |  |
| Nitrogen | q. s. | q. s. |  | q. s. | q. s. | Gas for filtration | | Pharm. Eur. |  |
|  |  |  |  | |  |  |  |  |  |
| Total weight | 22.4 | 22.4 | 23.7 | | 22.9 |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

1. 1 g of BEA 2180 corresponds to 1.211 g of BEA 2180 BR
2. The declared amount of benzalkonium chloride refers to the anhydrous substance
3. Benzalkonium chloride may be used as a 50% aqueous solution or solid substance; both comply with the respective monographs of the Pharm. Eur. "Benzalkonium chloride solution" and "Benzalkonium chloride", respectively.
4. One dose will be administered by 2 actuations of the inhalation device
5. The placebo formulation used for clinical trials is identical to the active product formulation, except that it contains no active drug.
6. Alternatively, Purified Water may be used.

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| Table 2 | Composition of BEA 2180 BR Respimat | | | solution for inhalation (Percentage formula) | | | |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | **Percentage** | **Percentage** |  | **Percentage** | **Percentage** | |  |  |  |
|  | **Formula** | **Formula** |  | **Formula** |  | **Reference** |  |
| **Name of** |  | **Formula** | |  |  |
| **[g/100 ml]** | **[g/100 ml]** |  | **[g/100 ml]** | **Function** | **to** |  |
| **ingredient** |  | **[g/100 ml]** | |  |
| **dose strength** | **dose strength** |  | **dose strength** |  | **standards** |  |
|  |  | **placebo** | **d, e** |  |  |
|  | **50µg d** | **100µg d** |  | **200µg d** |  |  |  |  |
| BEA 2180 a | 0.223 | 0.446 |  | 0.844 | - |  | Drug substance | In house |  |
| Corresponding |  |  |  |  |  |  |  | standard |  |
| 0.270 | 0.541 |  | 1.022 | - |  |  |  |  |
| amount of |  |  |  |  |  |  |  |  |  |
| BEA 2180 BR a |  |  |  |  |  |  |  |  |  |
| Benzalkonium | 0.010 | 0.010 |  | 0.010 | 0.010 |  | Preservative | Pharm. Eur. |  |
| chloride b, c |  |  |  |
| Edetate disodium | 0.010 | 0.010 |  | 0.010 | 0.010 |  | Stabilizer | Pharm. Eur. |  |
|  |  |  |  |  |  |  |  |  |  |
| Citric acid, | 0.003 | 0.003 |  | 0.003 | 0.003 |  | Acidifier | Pharm. Eur. |  |
| anhydrous |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| Water for | ad 100.0 | ad 100.0 |  | ad 100.0 | ad 100.0 | | Solvent | Pharm. Eur. |  |
| injection f |  |  |
| Nitrogen | q. s. | q. s. |  | q. s. | q. s. |  | Gas for filtration | Pharm. Eur. |  |
|  |  |  |  |  |  |  |  |  |  |
| Total weight | 100.0 | 100.0 |  | 100.0 | 100.0 |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

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