Boehringer Ingelheim

Description and Composition of the Drug Product	
BEA 2180 BR Respimat® Solution for Inhalation Active Product and Matching Placebo	Internal Number ADD 774
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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.

2. 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.

Table 1 Composition of BEA 2180 BR Respimat® solution for inhalation (Mass per dose)

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

a 1 g of BEA 2180 corresponds to 1.211 g of BEA 2180 BR
b The declared amount of benzalkonium chloride refers to the anhydrous substance
c 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.
d One dose will be administered by 2 actuations of the inhalation device
e The placebo formulation used for clinical trials is identical to the active product formulation, except that it contains no active drug.
f Alternatively, Purified Water may be used.

Table 2 Composition of BEA 2180 BR Respimat® solution for inhalation (Percentage formula)

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

a 1 g of BEA 2180 corresponds to 1.211 g of BEA 2180 BR
b The declared amount of benzalkonium chloride refers to the anhydrous substance
c 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.
d One dose will be administered by 2 actuations of the inhalation device.
e The placebo formulation used for clinical trials is identical to the active product formulation, except that it contains no active drug.
f Alternatively, Purified Water may be used.