

SPECIFICATION

ALHYDROGEL 2 %

Test parameter	Acceptable range
Ash residue (Al ₂ O ₃)	Min. 1.90 % Max. 2.10 % w/w
Corresponding to Al(OH) ₃	Min. 2.91 % Max. 3.21 % w/w
Al	Min. 9.0 mg/ml Max. 11.0 mg/ml
N	Max. 0.005 % w/w
SO ₄ (free)	Max. 0.05 % w/w
SO ₄ (total)	Max. 0.1 % w/w
Fe (total)	Max. 15 ppm
pH (at the time of production)	Min. 6.0 Max 7.0
Sterility	No growth in test samples
Pyrogenicity in 3 rabbits	Max. 1.15 °C
(Pyrogenicity in 6 rabbits	Max. 2.80 °C)
Protein adsorption capacity	23 ± 5 mg HSA/ml

Brenntag Biosector

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Brenntag Biosector guarantees the specifications above under the liability specified in the company's "General Conditions of Sale and Delivery". However, individual customers may have internal specifications and/or acceptance limits or specifications which may include additional quality parameters reflecting their particular application of the product.

Brenntag Biosector does not accept to be held liable for any such additional parameter, nor guarantees any compliance with such, unless previously explicitly agreed in writing between the parties.

It is the sole responsibility of the customer to test the product for any such parameter that goes beyond the standard specifications of Brenntag Biosector before adding the adjuvant to their vaccine.