

**SPECIFICATION****ALHYDROGEL<sup>®</sup> 2%****Tested for Ph.Eur. compliance**

Aluminium Hydroxide Gel Adjuvant

<b>Test parameter</b>	<b>Acceptable range</b>
Aluminium content	9.0 – 11.0 mg/ml
pH (at the time of production)	pH 5.5 - 8.5
Adsorption power	No detectable BSA in solution
Sedimentation	Less than 5 ml clear supernatant
Chlorides	Max. 0.33 % w/w
Nitrates	Max. 100 ppm
Sulphates	Max. 0.5 % w/w
Ammonium	Max. 50 ppm
Arsenic	Max. 1 ppm
Fe	Max. 15 ppm
Heavy metals (as Pb)	Max. 20 ppm
Pyrogenicity in 3 rabbits <sup>(1)</sup>	Max. 1.15°C
(Pyrogenicity in 6 rabbits)	Max. 2.80°C
Sterility	No growth in test samples

Note 1: The bacterial endotoxin test 2.6.14 prescribed in EP monography 1664 is problematic with Alhydrogel, since the phosphate residues of LPS (used as positive control and standard curve) bind unspecifically to Alhydrogel. This opinion is shared by the Danish Medicines Agency. We carry out the pyrogenicity test on the liquid phase of the product according to the EP 2.6.8 instead of the bacterial endotoxin test.

<b>Expiry date:</b>	26 months from production month
<b>Reference:</b>	European Pharmacopoeia Monograph 1664 current edition

**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.