



Certificate No: **NZ/GMP/080/A/1/2018**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

The Ministry for Primary Industries, Agricultural Compounds and Veterinary Medicines (ACVM) Programmes Group, being the competent authority of New Zealand for agricultural compounds and veterinary medicines, confirms the following:

The company:

Alke Sağlık Ürünleri

covering the following site(s) of manufacture:

Merkez Organize Sanayi Bölgesi 2. Kısım10. Cadde No: 7 Tokat Turkey

has been inspected under the ACVM GMP Programme and the manufacturer's Operating Plan is authorised in accordance with Section 28 of the Agricultural Compounds and Veterinary Medicines Act 1997, and Regulations 2011.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted **7, 8, 9 and 10 March 2018** it is considered that the company complies with the ACVM Standard and Guideline for Good Manufacturing Practice.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified with the issuing authority, The Ministry for Primary Industries.



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Part 2

<input checked="" type="checkbox"/> Veterinary Medicines
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1	Manufacturing Operations - Sterile Products
1.1	<i>Aseptically prepared (complete processing operations for the following dosage forms unless otherwise stipulated)</i> 1.1.4 Small volume liquids <β-Lactam>
1.2	<i>Terminally sterilised (complete processing operations for the following dosage forms unless otherwise stipulated)</i> 1.2.6 Other terminally sterilised prepared products <β-Lactam pastes>
2	Manufacturing Operations - Non-sterile Products
2.1	<i>Non-sterile products (complete processing operations for the following dosage forms unless otherwise stipulated)</i> 2.1.11 Liquids for internal use
6	Quality Control Testing
6.1	<i>Microbiological: sterility</i>
6.2	<i>Microbiological: non-sterility</i>
6.3	<i>Chemical/Physical</i>

Any restrictions or clarifying remarks related to the scope of this certificate:

<Terminal sterilisation of the terminally sterilised β-Lactam pastes is not performed on the premises>