



# XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD

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## Certificate of Analysis- Albendazole

**Batch Number: HNB160625**

**Batch Quantity:5000kg**

**Manufacturing Date:** June. 25<sup>th</sup> 2016

**Analysis Date:**June.27<sup>th</sup> 2016

**Certificate Date:** June.28<sup>th</sup> 2016

**Shelf life:** 2 Years from date of Manufacture stored in original container.

**Re-test Date when stored as directed:** June 24<sup>th</sup> 2018

Storage: store in a cool dry place in well closed/sealed containers. Protect from light.

Test	Specification	Results
Cas No.	54965-21-8	Conforms
Molecular formula	C <sub>12</sub> H <sub>15</sub> N <sub>3</sub> O <sub>2</sub> S	Conforms
Molecular weight	265.33	Conforms
Melting point	mp 223-226°C	Conforms
Appearance (visual test)	White to off-white powder	Conforms
Assay	≥99%	99.6%
Solubility-Visual tests 1)in water 2) in Methanol and ethanol	Insoluble in water, slightly soluble in acetone or chloroform	Conforms
<u>Residual Solvents-using Gas Chromatography</u> a)Methanol b) Ethanol; c) Acetone; d) Acetonitrile	≤100ppm ≤100ppm ≤100ppm ≤50ppm	10ppm 10ppm 10ppm 5ppm
Loss on Drying at 105 °C	≤2.5% w/w	0.16
Residue on Ignition	≤0.1%	0.01%

**This Product meets current European Pharmacopeia Requirements.**

### Additional Tests carried out in Addition to European Pharmacopeia requirements

Test	Specification	Results
<b><u>Heavy metals –by atomic absorption</u></b> 1)Total heavy metals 2) Arsenic (As) 3) Cadmium (Cd) 4) Lead (Pb) 5) Mercury (hg)	≤10ppm ≤0.5ppm ≤1ppm ≤2ppm ≤0.5ppm	0.12ppm 0.01ppm 0.03ppm 0.05ppm 0.03ppm
<b><u>Microbiological Tests</u></b> 1)Total Plate count 2) Total Yeast and Mould 3) E. Coli in 10g 4) Salmonella in 10g 5) Staphylococcus in 10g	≤100cfu/g ≤10cfu/g Absent Absent Absent	0.1cfu/g 0.1cfu/g Complies Complies Complies
<b><u>Other Impurities-using Gas Chromatography</u></b> 1)Sulphates 2) Organic Phosphates 3) Organic residues 4) DDT Pesticide residue-by GC 5) BHC Pesticide Residue-by GC	≤0.05ppm ≤0.05ppm ≤0.05ppm ≤0.05ppm ≤0.05ppm	0.001ppm 0.001ppm 0.001ppm 0.001ppm 0.001ppm



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