



Rutland Biodynamics Ltd (Herbal Medicines)  
Town Park Farm, Brooke, Rutland, LE15 8DG, UK  
UK Dept of Health MHRA cGMP MIA number 28255  
www.rutlandbio.com

## Finished Product Certificate of Analysis

### Batch: 101230-2/1

#### PRODUCT INFORMATION

Product common name	<b>Milk Thistle, Silybum</b>
Product Latin name	<b><i>Carduus marianus</i></b>
Plant part	<b>Dried Seed</b>
Product code	<b>1423L</b>
Batch number	<b>101230-2/1</b>
Cultivation	<b>Conventional</b>
Herb : Liquid Ratio	<b>1:3</b>
Alcoholic Strength	<b>25%</b>

Extracts are prepared by suitable methods using ethanol or other suitable solvents according to the General Extracts monograph of the European Pharmacopoeia (Monograph 0765). Herbal drugs and organic solvents used for the preparation of extracts comply with any relevant monograph of the Pharmacopoeia.

Herbal drugs are obtained from cultivated or wild plants. Suitable collection, cultivation, harvesting, drying, fragmentation and storage conditions are essential to guarantee the quality of herbal drugs. Herbal drugs are, as far as possible, free from impurities such as soil, dust, dirt and other contaminants such as fungal, insect and other animal contaminations in accordance with European Pharmacopoeia Monograph 1433 (Herbal Drugs).

Extracts are manufactured and sold under a Duty Free Excise Licence for use as an ingredient for inclusion in medicines only. Any other use by the recipient attracts full liability for Spirits duty which will be payable by the recipient on demand by the authorities

#### ANALYTICAL RESULTS


Organolepsis <sup>1</sup>	
Appearance	<b>Conforms to specification</b>
Odour	<b>Conforms to specification</b>
Taste	<b>Conforms to specification</b>

1) All extracts comply with the requirements of the European Pharmacopoeia for Herbal Drug Preparations Monograph 1434. Determination according to Rutland Biodynamics SOP C22.



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Phytochemistry	
Thin Layer Chromatography <sup>2</sup>	
Total dissolved solids <sup>3</sup>	<b>Conforms to specification</b>
HPLC	<b>N/A</b>

Natural variations in the levels of constituents in different samples of a plant drug may lead to minor deviations from one chromatogram to another. The extent of deviation allowed before samples are considered unacceptable or contaminated with foreign material depends on experience and careful judgement. Samples are also evaluated in accordance with any relevant Pharmacopoeial monograph.

- 2) Determination according to Rutland Biodynamics SOP C51.
- 3) Determination according to Rutland Biodynamics SOP C72.

Microbiology <sup>4</sup>	
Total Aerobic Count (<10 <sup>4</sup> cfu/ml)	<b>Conforms to Ph. Eur.</b>
Yeast and Mould (<10 <sup>2</sup> cfu/ml)	<b>Conforms to Ph. Eur.</b>
Bile tolerant gram negative bacteria (<10 <sup>2</sup> cfu/ml)	<b>Conforms to Ph. Eur.</b>
Absence of <i>Escherichia coli</i>	<b>Conforms to Ph. Eur.</b>

4) All extracts comply with relevant aspects of the European Monograph for Microbiological quality of herbal medicinal products for oral use (Monograph 5.1.8.). Determination according to Rutland Biodynamics SOP C61.

I hereby certify that the above tests have been carried out under my authority, under the standard operational procedures of Rutland Biodynamics Ltd. and under Good Manufacturing Practice in conformance with the Company's current certificate of compliance with Good Manufacturing Practice (MIA 28255) laid down in Directive 2003/94/EC. This certificate and the results shown apply to the tested sample only. This report may not be used by third parties, including for promotional purposes, without the prior written permission of Rutland Biodynamics Ltd.

I certify that this batch has been declared fit for release.

Signed  Kate Stokes BSc MSc MRSC Qualified Person

Date 25/05/11