

CERTIFICATE OF ANALYSIS

Customer : -
 Your order :
 Quantity (kg) :

Batch No. : 0100470401
 Analysis No. : 414884

Code/Product: 380014 - HORSE CHESTNUT DRY EXTRACT
 EXTR. HIPPOCASTANI E SEM. SICCU

Register No.: 19_09763

19\$09763

Manufacturing date : September 2019
 Approval date : 7 October 2019
 Retesting date : 7 October 2022

PHYSICAL - CHEMICAL TESTS	SPECIFICATIONS	RESULTS	METHODS
IDENTIFICATION			
Appearance	Fine powder	Fine powder	SOP No. MG-279
Colour	Light brown	Light brown	SOP No. MG-279
Odour	Characteristic	Characteristic	SOP No. MG-279
Other characteristics	Hygroscopic	Hygroscopic	SOP No. MG-279
Identification by TLC	Corresponds to reference chromatogram	Corresponds to reference chromatogram	Ph. Eur., SOP No. TLC-095
TESTS			
Loss on drying	NMT_5.0 %	2.8 %	Ph. Eur., SOP No. MG-042
Total ash	NMT_20.0 %	5.2 %	Ph. Eur., SOP No. MG-039
Residual ethanol by GC (loq=0.62 mg/kg)	NMT_0.5 %	0.016 %	CPMP/ICH/283/95 (SOP No. GC-116)
Microbiological control			
Total aerobic count	NMT_1x10 ⁴ cfu/g	40.0 cfu/g	Ph. Eur.
Total combined yeasts/moulds count	NMT_1x10 ² cfu/g	<10.0 cfu/g	Ph. Eur.
Bile-tolerant gram-negative bacteria	NMT_100 cfu/g	>10-<100.0 cfu/g	Ph. Eur.
<i>Escherichia coli</i>	Absence /1g	Absence /1g	Ph. Eur.
<i>Salmonella</i>	Absence /25g	Absence /25g	Ph. Eur.
ASSAY			
Triterpeneglycosides, calculated as anhydrous escin	NLT_20 %	22.6 %	DAB, SOP No. DC-071

REMARKS:

PESTICIDE RESIDUES, HEAVY METALS, AFLATOXINS AND MICROBIOLOGICAL CONTAMINATION:

Tested on the herbal drug in accordance with Ph. Eur.

STORAGE: Store in a cool and dry area in well-closed containers.

The cited pharmacopoeia monograph corresponds to the respective valid version of the pharmacopoeia

Mollet del Vallés, 17 October 2019

RELEASED: Eulàlia Mas de Xaxars, Quality Control Manager