

29/11/2021

CERTIFICATE OF ANALYSIS

Customer : -
Your order :
Quantity (kg) :

Batch No. : 0100687501
Analysis No. : 422672

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

Register No.: 21_03455



Manufacturing date : July 2021
Approval date : 28 July 2021
Retesting date : 28 July 2024

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 %	2.6 %	Ph. Eur., SOP No. MG-042
Total ash	NMT_20.0 %	3.2 %	Ph. Eur., SOP No. MG-039
Residual ethanol by GC (loq=0.62 mg/kg)	NMT_0.5 %	n.d. **	CPMP/ICH/283/95 (SOP No. GC-116)
Microbiological control			
Total aerobic count	NMT_1x10 ⁴ cfu/g	<10.0 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-<1x10 ² 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 %	22.8 %	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

REMARKS ABOUT ANALYSIS:

** n.d. = not detected

Mollet del Vallés, 29 July 2021

RELEASED: Dr. Xavier Ragàs, Quality Control Manager