indena® S.A.S.
38,avenue G.Eiffel - BP 9528 37095 Tours Cedex 2
France
Tél.+33-2.47.49.52.00

PRODUCT : GINKGO BILOBA DRY PURIFIED ALCOHOLIC EXTRACT / GINKGOSELECT(R) PLUS PHYTOSOME(R) PHOSPHOLIPID.SF

CODE N. : 9100157
DESCRIPTION : GINKGO BILOBA HA PHOSPH.SF
BATCH N. : 19207
OLD CODE : 36GKP1090

ANALYSIS CERTIFICATE N. : 55092

MANUFACTURE DATE : 2019/04
RETESTING DATE : 2021/04

STARTING HERBAL MATERIAL

The starting herbal material has been identified against a crude drug standard or an authoritative literature source by botanical QC analyst.

Scientific Name:	Ginkgo biloba L.
English Common Name:	Ginkgo
Botanical Family:	Ginkgoaceae
Cultived/Wild:	Cultivated
Part of the Plant Utilized:	Leaf

PRODUCTION

Extraction Solvent:	Ethanol and Water
Excipients/Other Components:	Lecithin (origin Sunflower) Microcrystallin cellulose Silicon dioxide
Antioxydants/Preservatives:	None
Composition:	Ginkgo biloba dry extract: about 26% Lecithin (origin Sunflower): about 52% Microcrystallin cellulose: about 21% Silicon dioxide: 1%

DETERMINATION	RESULTS	SPECIFICATIONS	U.M.
HPLC CONTENTS Assay of Ginkgoflavonglucosides, with reference to the anhydrous and solvent-free substance	8.1	>= 7.0	%
HPLC CONTENTS Assay of Ginkgoterpenes, with reference to the anhydrous and solvent-free substance	2.4	>= 2.0	%

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DETERMINATION	RESULTS	SPECIFICATIONS	U.M.
HPLC CONTENTS Assay of Bilobalide, with referene to the anhydrous and solvent-free substance	0.8	>= 0.8	%
HPLC CONTENTS Assay of Ginkgolides, with reference to the anhydrous and solvent-free substance	1.6	>= 0.8	%
CHARACTERS/APPEARANCE	Complies	Light brown powder	
PARTICLE SIZE Pass 200 µm (#75 mesh)	93.5	For information only	%
PARTICLE SIZE Pass 100 µm (#150 mesh)	76.6	For information only	%
TAPPED DENSITY According to Eur. Ph. (2.9.34)	0.66	For information only	g/ml
TLC IDENTIFICATION Phospholipid (Lecithin)	Complies	Complies	
HPLC IDENTIFICATION Ginkgoflavonglucosides, after acidic hydrolysis	Complies	Complies	
HPLC IDENTIFICATION Ginkgoterpenes	Complies	Complies	
SULPHATED ASH According to Eur. Ph. (2.4.14)	6.2	<= 8.0	%
WATER (K. Fischer) According to Eur. Ph. (2.5.12)	1.2	<= 5.0	%
RESIDUAL ORGANIC SOLVENTS According to MDHRSD11			
Ethyl acetate	272	<= 5000	ppm
Ethanol	33	<= 5000	ppm
POTENTIAL IMPURITIES BY HPLC Total ginkgolic acids Determined on the native dried extract According to Eur. Ph. method	<1	<= 5	ppm
MYCOTOXINS DETERMINATION			
Sum of aflatoxins B1, B2, G1 and G2	< 2	<= 10	ppb
Aflatoxin B1	< 1	<= 5	ppb
Ochratoxin A	< 1	<= 80	ppb
HEAVY METALS			
Cadmium	< 0.1	<= 1.0	ppm
Mercury	< 0.1	<= 0.1	ppm
Lead	0.1	<= 3.0	ppm
PESTICIDES DETERMINATION According to EC 396/2005 and amendments	Complies	Complies	

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DETERMINATION	RESULTS	SPECIFICATIONS	U.M.
MICROBIOLOGICAL CONTROL Acc. harmonized EP, USP and JP regulation			
TOTAL AEROBIC MICROBIAL COUNT	< 10	<= 50 000	CFU/g
TOTAL COMBINED YEASTS/MOULDS COUNT	< 10	<= 500	CFU/g
BILE-TOLERANT GRAM-NEGATIVE BACTERIA	< 10	<= 100	CFU/g
ESCHERICHIA COLI	Complies	Absence	/g
SALMONELLA	Complies	Absence	/25g

TOURS, 1/14/2020

This is a computer print of the analysis certificate which has been undersigned on the original and is valid without signature

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