

Analysis Certificate N. 15/17/CQMI  
 Code : LM42506  
 Batch N. 89077  
 Preparation date: March 2015

**PRODUCT: Ginkgo Biloba ethanolic extract film-coated tablets (placebo)**

DETERMINATIONS	RESULTS	M. U.
<b>APPEARANCE</b> 9 mm diameter, white convex round shape film coated tablets	Complies	
<b>MEAN WEIGHT</b>	455.5	mg/tab.
<b>UNIFORMITY OF MASS</b> Eur. Pharm. (2.9.5)	Complies	
<b>DISINTEGRATION TEST</b> Eur. Pharm. (2.9.1)	< 30	min.
<b>HPLC IDENTIFICATION</b> of Terpenes	Negative	
<b>HPLC IDENTIFICATION</b> of Ginkgo flavonglucosides	Negative	
<b>As</b>	0.012	ppm
<b>Pb</b>	0.039	ppm
<b>Cd</b>	0.005	ppm
<b>Hg</b>	< 0.0005	ppm
<b>MICROBIOLOGICAL CONTROL</b> Eur. Pharm. (2.6.12, 2.6.13 and 2.6.31)		
- Total Aerobic Microbial Count	500	cfu/g
- Total Combined Yeast/Moulds Count	< 10	cfu/g
- Bile-Tolerant Gram-Negative Bacteria	absent	cfu/g
- Escherichia coli	absent	/g
- Salmonella	absent	/25g
- Staphylococcus aureus	absent	/g

Milan, March 31, 2015

Dr.ssa Viviana Cerutti  
 Head of Quality Control  
 INDENA S.p.A., Milan Plant

*Franco Santini*

INDENA S.p.A.  
 MILAN PLANT  
 TECHNICAL DIRECTOR  
 Dr. Franco Santini

*Viviana Cerutti*

Analysis Certificate N. 15/18/CQMI  
 Code : LM42502  
 Batch N. 89078  
 Preparation date: March 2015

**PRODUCT: Ginkgo Biloba ethanolic extract 120 mg film coated tablets**

DETERMINATIONS	RESULTS	M. U.
<b>APPEARANCE</b> 9 mm diameter, white convex round shape film coated tablets	Complies	
<b>MEAN WEIGHT</b>	414.6	mg/tab.
<b>UNIFORMITY OF MASS</b> Eur. Pharm. (2.9.5)	Complies	
<b>DISINTEGRATION TEST</b> Eur. Pharm. (2.9.1)	< 30	min.
<b>HPLC IDENTIFICATION</b> of Terpenes	Positive	
<b>HPLC IDENTIFICATION</b> of Ginkgoflavonglucosides	Positive	
<b>HPLC ASSAY</b> of Bilobalide	3.44	mg/tab.
<b>HPLC ASSAY</b> of Ginkgolides A, B, and C	3.98	mg/tab.
<b>HPLC ASSAY</b> of Ginkgoflavonglucosides	28.8	mg/tab.
<b>As</b>	0.104	ppm
<b>Pb</b>	0.134	ppm
<b>Cd</b>	0.011	ppm
<b>Hg</b>	0.001	ppm
<b>MICROBIOLOGICAL CONTROL</b> Eur. Pharm. (2.6.12, 2.6.13 and 2.6.31)		
- Total Aerobic Microbial Count	500	cfu/g
- Total Combined Yeast/Moulds Count	< 10	cfu/g
- Bile-Tolerant Gram-Negative Bacteria	absent	cfu/g
- Escherichia coli	absent	/g
- Salmonella	absent	/25g
- Staphylococcus aureus	absent	/g

Milan, March 31, 2015

  
**INDENA S.p.A.**  
 MILAN PLANT  
 TECHNICAL DIRECTOR  
 Dr. Franco Santini

 Dr.ssa Viviana Cerutti  
 Head of Quality Control  
 INDENA S.p.A., Milan Plant



**Manufacturer's Address:**  
**Formulation Development Laboratory**  
INDENA S.p.A. (Milan Plant)  
Viale Ortles, 12  
20139 Milan, Italy

**STATEMENT – N° 15/036-MI**

Object: **Allergens statement**

<i>Product:</i>	<b>Ginkgo biloba ethanolic extract coated tablets (placebo)</b>
<i>Indena Code:</i>	<b>LM42506</b>
<i>Batch Number:</i>	<b>89077</b>
<i>This confirmation form has been completed by:</i>	Name: Dr F. Santini Company: INDENA S.p.A. (Milan plant) Position in the company: Technical Director

We inform that milk and soy derivatives and ingredients containing gluten are included in products manufactured on the same equipment involved in the production of "Ginkgo biloba ethanolic extract coated tablets (placebo)".

Accurate cleaning operations, described in dedicated SOPs, are carried out on the involved equipment before the further manufacturing operations, but at present, on the finished product, no further analytical investigations have been carried out to check the absence of these aforesaid allergenic substances or of other food allergens listed in Annex II of the Regulation 1169/2011/EC.

Milan, April 21, 2015

*Franco Santini*  
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Technical Director