

CERTIFICATE OF CONFORMITY production and packaging

Allegato n. 4 SOP CQ009 (Redazione del certificato di conformità e certificato di analisi ed approvazione del lotto)

Client:	laf Network S.r.l.
Product:	Insulomin-R (jar)
Batch number:	21D0731
Manufacture Date:	09/2021
Expire date:	09/2023
Batch Record number:	261/21

TESTS	SPECIFICATION	RESULTS
Appearance	Tablet with dots, oval	Conform
Colour	Brown	Conform
Diameter	20 mm	20 mm
Thickness	8-8,55 mm	8,52 mm
Hardness	23-30 kg	26,15 kg
Average weight (mg)	1400 mg \pm 2%	1402,15 mg
Uniformity weight (mg)	1400 mg \pm 3%	Conform
Friability	< 1%	Conform

PACKAGING: PRIMARY <input checked="" type="checkbox"/>		SECONDARY <input type="checkbox"/>	
CONTROLLED POINTS	SPECIFICATIONS	RESULTS	
Material different from contract	absent	Conform	
Wrong data batch	absent	Conform	
Presence of different material	absent	Conform	
Primary seal packaging	Pass tests	n.a.	
Press not completely readable	<1%	Conform	
Variable data not completely readable	<1%	Conform	
Presence of broken boxes	<1%	Conform	
Average weight jar (beginning, half, end processing)	84 g	84 g	
Uniformity weight jar	Pass tests	Conform	
Imperfect label on packaging material but readable	<1%	Conform	

Note:

Approved yes No

Date and Signature CQ Manager: 18/10/2021

CERTIFICATE OF ANALYSIS

Allegato n. 8 SOP CQ009 (Redazione del certificato di conformità e certificato di analisi ed approvazione del lotto)

Client:	Iaf Network S.r.l.
Product:	Insulomin-R
Appearance:	Tablets
Batch number:	21D0731
Manufacture date:	09/2021
Expire date:	09/2023
Batch Record Number:	261/21

TESTS	LABEL	SPECIFICATIONS	RESULTS
Total viable aerobic count	-----	$\leq 10^4$ Ufc/g	<10 Ufc/g
Yeast and Moulds	-----	$\leq 10^2$ Ufc/g	<10 Ufc/g
Escherichia Coli	-----	Absent/1g	Absent/1g
Enterobacteriaceae	-----	≤ 100 Ufc/g	<10 Ufc/g
Staphiloccocus Aureus	-----	Absent/1g	Absent/1g
Salmonella SPP	-----	Absent/10g	Absent/10g
Gluten	-----	≤ 20 ppm	< 5 ppm*
Lactose	-----	-----	< 4,7 mg/kg**

* It is declared that the product is gluten free according to Regulation (EC) n. 828/2014.

** This value is the limit of quantification at below which the lactose present is not quantified.

Analytical data were performed by outside laboratory

Note:

Approved yes No

Date and Signature CQ Manager: 18/10/2021