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

Client:	Iaf Network s.p.a.
Product:	Epadex
Batch number:	22D0222
Manufacture Date:	03/2022
Expire date:	03/2024
Batch Record number:	767/21

TESTS	SPECIFICATION	RESULTS
Appearance	Tablet with dots	Conform
Colour	Beige with brown-orange dots	Conform
Diameter	19 mm	Conform
Thickness	6,8-7,3 mm	7,1 mm
Hardness	20-25 kg	23,25 mm
Average weight (mg)	1000 mg ± 2%	1000,2 kg
Uniformity weight (mg)	1000 mg ± 3%	Conform
Friability	<1%	Conform

PACKAGING: PRIMARY ■   SECONDARY ■

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	Conform
Press not completely readable	<1%	Conform
Variable data not completely readable	<1%	Conform
Presence of broken boxes	<1%	Conform
Imperfect label on packaging material but readable	<1%	Conform

Note:

Approved   yes ■   No ☐

Date and Signature CQ Manager:

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.p.a.
Product:	Epadex
Appearance:	Tablets
Batch number:	22D0222
Manufacture date:	03/2022
Expire date:	03/2024
Batch Record Number:	767/21

TESTS	LABEL	SPECIFICATIONS	RESULTS
Total viable aerobic count	-----	$\leq 10^4$ Ufc/g	470 Ufc/g
Yeast and Moulds	-----	$\leq 10^2$ Ufc/g	<10 ufc/g
Escherichia Coli	-----	Absent/1g	Absent/1g
Enterobacteria	-----	≤ 100 Ufc/g	<10 ufc/g
Staphilococcus Aureus	-----	Absent/1g	Absent/1g
Salmonella SPP	-----	Absent/10g	Absent/10g
Gluten	-----	≤ 20 ppm	< 5 ppm*
Lactose	-----	-----	n.r.**

* 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: