



# Analysis Certificate

Version:V03

**Project Number:** PARKER - 3029  
**Sample Details:** Nitrogen Gas Product

**Client:** Parker Hannifin Manufacturing Ltd  
**Subject:** Compliance testing of Nitrogen gas purity generated by NITROSource COMPACT range of generators

**Introduction:**

Analysis of product gas, Nitrogen (N<sub>2</sub>), produced by Parker NITROSOURCE COMPACT range of Nitrogen gas generators to demonstrate full compliance with food grade Nitrogen and "Food Additive – E941" purity criteria as detailed within:-

Commission Regulation (EU) N° 231/2012 of 09<sup>th</sup> March 2012 laying down specifications for food additives listed in Annexes II and III to regulation (EC) N° 1333/2008 of the European Parliament.

Additional references:

- EIGA Document 126/18 Minimum Specification for Food Gas Applications.
- EIGA Document 194/15 Safe Design and Operations of On-Site Nitrogen generators for food authority laying down procedures in matters of food safety. Regulation (EC) N°178/2002 of European Parliament of the Council of 28<sup>th</sup> January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety authority laying down procedures in matters of food safety.

COMPONENT IMPURITY	EC 231/2012 E941 N <sub>2</sub> SPECIFICATION	EUROPEAN PHARMACOPEIA
Assay (v/v)	≥99%	≥99.5%
Moisture	≤0.05%	≤67ppm
CO	≤10ppm	≤300ppm
CO <sub>2</sub>	Not Specified	<300ppm
NO/NO <sub>2</sub> (Combined)	≤10ppm	No Specified
Total Hydrocarbon inc Methane CH <sub>4</sub>	≤100ppm	Not Specified
Residual Gases (O <sub>2</sub> )	<1%	<50ppm

- EIGA Document 194/15:-

In the case where on-site generated Nitrogen is used as a food additive, such as in the Modified Atmosphere Packaging (MAP) application, Nitrogen should comply with the minimum purity criterial for E941 additive as described in EIGA Doc. 126/18.

Nitrogen\* ≥99% Vol

Oxygen ≤1% Vol

Water ≤0.05% Vol

\* 99% including other inert gases (Argon mainly)

Impurities:

Carbon Monoxide ≤10ppmV

Methane and other hydrocarbons (as Methane) ≤100ppmV

Nitrogen monoxide and Nitrogen dioxide ≤10ppmv

**Methods of Analysis:**

- EU 231/2012 of 09<sup>th</sup> March 2012
- EIGA Docs. 194/15 and 126/18
- European Pharmacopeia – Current Edition

**Certificate** W S Cullen 09<sup>th</sup> Jan 2020

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Melbec Microbiology Limited contract laboratory is considered to comply with the principles of Good Manufacturing Practice as detailed in Directive 2003/94/EC.

**CONTINUATION SHEET**

**Subject:** Compliance testing of Nitrogen gas purity generated by NITROSource COMPACT range of generators

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**Results:**

TEST	REGULATION & SPECIFICATION			RESULT	PASS / FAIL
	231/2012	EIGA 194/15	EUROPEAN PHARMACOPEIA		
<b>ASSAY</b> (Including trace inert gas, Argon Mainly)	≥99%	≥99%	>=99.5%	99.98%	<b>PASS</b>
<b>Moisture</b>	≤0.05%	≤0.05%	≤67ppm	0.0014% (14ppm)	<b>PASS</b>
<b>CO</b>	≤10ppm	≤10ppm	≤300ppm	<1ppm	<b>PASS</b>
<b>CO<sub>2</sub></b>	Not Specified	Not Specified	<300ppm	168ppm	<b>PASS</b>
<b>NO/NO<sub>2</sub> (Combined)</b>	≤10ppm	≤10ppm	No Specified	<0.2ppm	<b>PASS</b>
<b>Total Hydrocarbon including Methane</b>	≤100ppm	≤100ppm	Not Specified	7ppm	<b>PASS</b>
<b>Residual gases (O<sub>2</sub>)</b>	<1%	<1%	<50ppm	0.0046% (46ppm)	<b>PASS</b>

**Conclusion:**

The NITROSource COMPACT range of product's Nitrogen gas, as tested was found to meet the Assay and the Minimum Purity Specifications as laid out in EU 231/2012 of 09<sup>th</sup> March 2012 and EIGA Docs 194/15 and 126/18 and the current European Pharmacopeia.