

A photograph of two scientists in white lab coats. The woman on the left is holding a clipboard and looking at it. The man on the right is wearing glasses and looking at the clipboard. They are in a laboratory setting with a microscope visible on the left.

# Forced Extraction Study Reports

Baseline data to support your  
validation investigations

The qualification and validation of production, harvest and containment supplies are integral parts of any Biopharmaceutical application process. Regulatory guidelines around the world recommend that the production, storage and packaging components be assessed for extractables or leachables that may interact with or impact the product being manufactured.

To help guide your product selection and support your determination of the appropriate product to validate, we now offer studies to help you identify and quantify the amount of compounds that may be extracted from key components under extreme conditions. The studies may assist you in determining what further leachable studies are warranted to meet any applicable regulatory requirements or expectations, and are made available pursuant to a Confidentiality Agreement. Forced Extraction Studies can be requested by contacting us at [rocregsupport@thermofisher.com](mailto:rocregsupport@thermofisher.com)\*

#### Studies were conducted on different Thermo Scientific Nalgene product systems:

- Thermo Scientific™ Nalgene™ PETG Square Media Bottles and Closures (natural and white HDPE)
- Thermo Scientific™ Nalgene™ PC Biotainer™ Bottles and Closures (silicone liner and PP closure)
- Thermo Scientific™ Nalgene™ PP Carboys and Closures (TPE Gasket and PP white closure)
- Thermo Scientific™ Nalgene™ PETG Biotainer and Closures (PP liner and HDPE closure)
- Thermo Scientific™ Nalgene™ HDPE Bottles and Carboys System (Sterile and Non-Sterile)
- Thermo Scientific™ Nunc™ Cell Factory™ System
- Thermo Scientific™ Nunc™ EasyFill™ Cell Factory™ System
- Thermo Scientific™ Nalgene™ PET Square Media Bottles and Closures (natural HDPE)

#### Three extraction solvents and one acid matrix (for metal detection) were used on each unit for the forced extraction process:

- Water
- Ethanol
- Hexanes
- 10% nitric acid or 5% nitric acid / 5% hydrochloric acid matrix

Note: To better simulate conditions of use, Nunc Cell Factory Systems were tested with two extraction solvents; (20% isopropyl alcohol and PBS) and these same solvents were used for the metal detection.

#### Each extracted solution was subsequently analyzed by:

- Headspace Gas Chromatography/Mass Spectrometry (Headspace GC/MS) for volatile organic compounds
- Gas Chromatography / Mass Spectrometry (GC/MS) for semi-volatile organic compounds
- Liquid Chromatography / Mass Spectrometry (LC/MS) for non-volatile organic compounds
- Inductively Coupled Plasma (ICP) for metals and elemental extractables using an acid digested solution

Major chemical components were identified using NIST98K, Wiley and other databases. The methods utilized provide a semi-quantitative estimation of analytes identified by these techniques.

## Ordering information

Cat. No.	Description
105-0001	Forced Extraction Study - Thermo Scientific Nalgene PETG Bottles and Closures (Irradiated at 19-28 kGy)
105-0010	Forced Extraction Study - Thermo Scientific Nalgene PETG Bottles and Closures (Irradiated at 20-45 kGy)
105-0004	Forced Extraction Study - Thermo Scientific Nalgene PETG Biotainer Bottles (System)
105-0002	Forced Extraction Study - Thermo Scientific Nalgene PC Biotainer Bottles (System, US Resin)
105-0003	Forced Extraction Study - Thermo Scientific Nalgene PP Carboys (System)
105-0007	Forced Extraction Study - Thermo Scientific Nalgene HDPE Bottles and Carboys System (Sterile and Non-Sterile)
105-0008	Forced Extraction Study - Thermo Scientific Nunc Cell Factory Systems (US Resin)
105-0009	Forced Extraction Study - Thermo Scientific Nunc EasyFill Cell Factory Systems (EU Resin)
105-0011	Forced Extraction Study - Thermo Scientific Nalgene PET Bottles and Closures (US Resin) (Irradiated at 19-28 kGy)
105-0012	Forced Extraction Study - Thermo Scientific Nalgene PET Bottles and Closures (US Resin) (Irradiated at 20-45 kGy)
105-0013	Forced Extraction Study - Thermo Scientific Nalgene PET Bottles and Closures (EU Resin) (Irradiated at 20-45 kGy)

\* Following your request submission, a Confidentiality Agreement will be forwarded to you for completion. Studies are non-GMP and provided for informational purposes only. The identify and quantity of extractables may vary with routine changes made to the manufacturing process. Product information contained within the Forced Extraction Studies are provided to the best of our knowledge and belief, but without obligation or liability. Forced Extraction Studies are not a product warranty statement or recommendation for product usage. Any information or advice provided by Thermo Fisher Scientific in a Forced Extraction Studies is for reference purposes only, and does not relieve customer or users of their responsibility for determining the suitability of our products for the customer's or user's intended use. Forced Extraction Studies are not a substitute for any part of the customer's or user's own internal validation, nor may any such studies or documents from Thermo Fisher Scientific be submitted to regulatory bodies.

Find out more at [thermoscientific.com/extractionreports](http://thermoscientific.com/extractionreports)

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