Savillex Technical Note

Non-Volatile Residue (NVR) Testing on Purillex® PETG Square Media Bottles

Introduction

Non-volatile residue (NVR) testing is used to evaluate the cleanliness and purity of plastic bottles, especially in industries such as pharmaceuticals, biopharmaceuticals, food and beverage, and medical device manufacturing. This test quantifies the amount of residue that remains after bottles are exposed to solvents and dried.

Purillex PETG Square Media Bottles

Any residual substances in plastic bottles can compromise the integrity, safety, and effectiveness of the products they contain. These residues may include plastic additives, manufacturing residues, or environmental contaminants. As regulatory requirements become more stringent, particularly in pharmaceutical applications, NVR testing helps manufacturers ensure that their packaging materials meet industry standards.

Savillex uses high-purity PETG (bottle) and HDPE (closure) resins in the manufacture of its Purillex® PETG Square Media Bottle assemblies. These resins are chosen specifically for their chemical purity, ensuring they meet stringent quality and regulatory requirements in pharma, biopharma, analytical sciences, and other industries. This selection of high-purity materials helps ensure the integrity and safety of products stored within these containers.

Samples Tested

Sample Description	Lot Number	Quantity
1000 mL Purillex PETG Square Media Bottle, Sterile	6-4-1L-S-00001	3

NVR Test Method

Savillex initiated NVR testing of sterile 1000 mL Purillex PETG Square Media Bottle assemblies via a third-party laboratory (Aspen Research, Maple Grove, MN, USA) to evaluate and characterize NVR levels after extraction in 50% ethanol at 40°C for 21 days.

Aspen ISO 17025, SOP STM 248 rev 1.1 “Gravimetric Analysis of Extracts for Non-Volatile Residue” was followed. The three Purillex PETG Bottles were filled with 1000 mL of 50% ethanol solution. The bottles were capped with their supplied closure, placed on their side in a Pyrex dish, and the whole system placed on a shaker box in

Tech Note

Savillex Technical Note

Non-Volatile Residue (NVR) Testing on Purillex® PETG Square Media Bottles

an oven set at 40°C. For the blank, 500 mL of the 50% ethanol solution was placed in a 32 oz Qorpak jar and capped with a Teflon-lined PP lid. The bottles and blank were extracted for 21 days with the platform oscillating at 20 rpm throughout the duration of the incubation period.

Results

NVR was determined following Aspen ISO 17025, SOP STM 248 rev 1.1 "Gravimetric Analysis of Extracts for Non-Volatile Residue". The blank appeared clear. No amount of residue was determined in the samples that exceeded the amount found in the blank (Table 1).

Table 1: NVR of Extracts and Blank Sample

Sample	Empty Bottle/Blank Pre-Weight (g)	Bottle/Blank and Residue Post-Weight (g)	Difference (g)	Difference (mg)	Residue in Bottle with Blank Correction (mg)
Blank	11.5013	11.5048	0.0035	3.5000	N/A
Bottle 1	11.4879	11.4896	0.0017	1.7000	0.0000
Bottle 2	11.5581	11.5598	0.0017	1.7000	0.0000
Bottle 3	11.5679	11.5698	0.0019	1.9000	0.0000

Conclusions

The Non-Volatile Residue (NVR) testing results indicate that no measurable weight of residue was detected in Savillex Purillex PETG Bottle extracts when compared to the blank. Each PETG Bottle sample showed zero difference in residue after blank correction:

- **PETG Bottle 1 and Bottle 2** each exhibited 1.7 mg of residue before blank correction and 0.0mg of residue after blank correction.
- **PETG Bottle 3** exhibited 1.9mg of residue before blank correction and 0.0mg after blank correction.

These findings confirm that Savillex Purillex PETG Bottles do not contribute any notable non-volatile residue, supporting their suitability for applications where cleanliness and low extractables are critical.

Click here to learn more about Purillex PETG Square Media Bottles and order complimentary samples today.

Savillex
10321 West 70th St. | Eden Prairie, MN 55344-3446 USA | Phone: 952.935.4100
Email: info@savillex.com | www.savillex.com