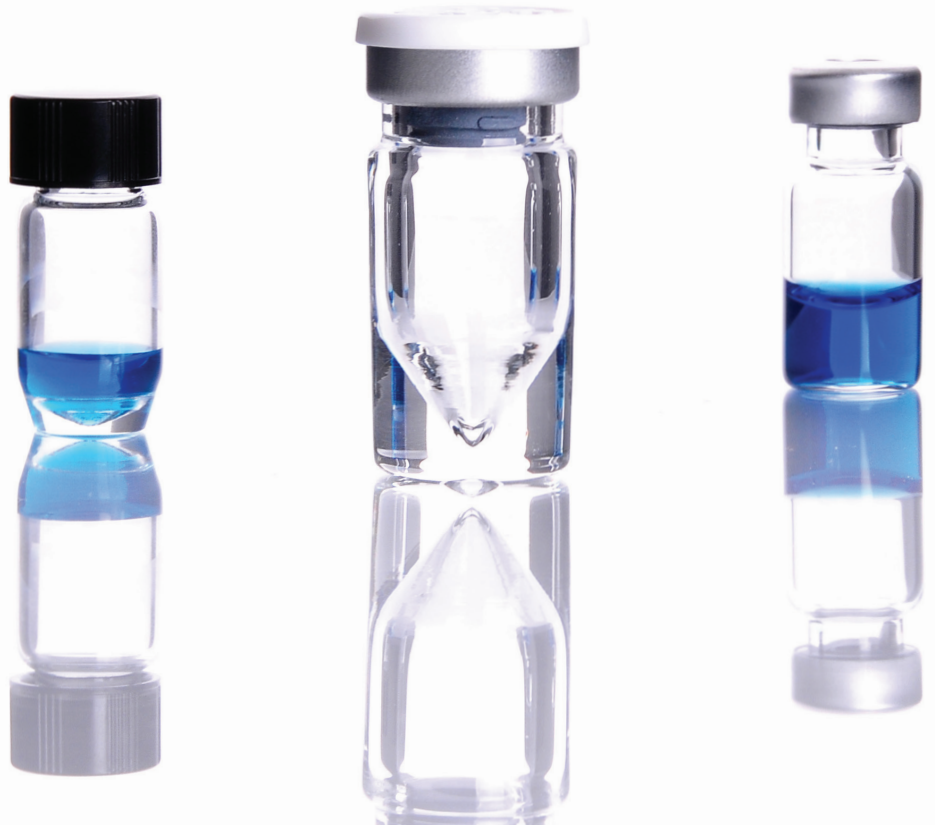


# WHEATON®

## High Recovery Vials Reduce Residual Product Waste by 99%

*A Cost-Effective Alternative for Pharmaceutical Product Packaging*



For primary packaging, particularly of high-value products including biologics and some vaccines, a high recovery vial such as the NextGen™ V-Vial® provides long-term savings for pharmaceutical manufacturers.

## INTRODUCTION

Pharmaceutical companies manufacturing billions of liquid doses each year risk significant product waste when using flat-bottom vials for end user packaging. According to the U.S. Pharmacopoeia (USP), “each container of an injection contains sufficient excess” of the labeled dose or size to allow withdrawal of the labeled quantity of drug.<sup>1</sup> High Recovery Vials (HRVs) that feature conical shaped bottoms significantly reduce residual waste by enabling maximum product retrieval without the need to overfill.

WHEATON®, a leading provider of laboratory glass and plastic consumables for life science and biopharmaceuticals, including HRVs, conducted a study that examined residual waste in HRVs and flat-bottom vials.

## STUDY PROCEDURE

WHEATON® compared a standard 2mL flat-bottom vial, a WHEATON 2mL E-Z Ex-Traction® Vial, and a WHEATON 2mL NextGen™ V-Vial®.

A balance was turned on with draft shields closed, allowed to equilibrate and tared to zero. The empty, dry vial was placed on the balance, and the mass was recorded ( $M_D$ ). The vial was removed from the balance, and 1.50mL of distilled water was added using a manual pipette. The filled vial was then returned to the balance where its mass was recorded ( $M_F$ ). The filled vial was removed from the balance and set on a flat surface. Using the manual pipette, as much distilled water as possible was retrieved from the vial. Finally, the mass of the emptied vial was measured and recorded ( $M_E$ ). Twenty-five individual vials were measured and recorded for each vial type.

From these collected data, both the volume of liquid in the vial, or filled volume ( $V_F$ ) and the residual volume ( $V_R$ ) of liquid left in the vial were calculated. Subsequently, the percent waste ( $P_W$ ) and percent decrease ( $P_D$ ) were determined.

## CALCULATIONS

To measure residual waste, WHEATON® used these conversion factors and formulas:

### Conversion Factors:

$$1\text{g dH}_2\text{O} = 1\text{mL dH}_2\text{O} \text{ at STP}$$

### Variables:

$M_D$	in grams	Mass of dry vial
$M_F$	in grams	Mass of filled vial
$M_E$	in grams	Mass of emptied vial

### Formulas:

$$\text{Filled Volume } (V_F): \quad V_F = (M_F - M_D) \times \left( \frac{1\text{mL H}_2\text{O}}{1\text{g H}_2\text{O}} \right)$$

$$\text{Residual Volume } (V_R): \quad V_R = (M_E - M_D) \times \left( \frac{1\text{mL H}_2\text{O}}{1\text{g H}_2\text{O}} \right)$$

$$\text{Percent Waste } (P_W): \quad P_W = (V_R / V_F) \times 100$$

Percent Decrease ( $P_D$ ) in Liquid Remaining in EZ Ex-Traction (Z) or NextGen V-Vial (V) vs. Standard Flat-Bottom Vial (S):

$$P_D = \left( \frac{V_{RS} - V_{R[Z \text{ or } V]}}{V_{RS}} \right) \times 100$$



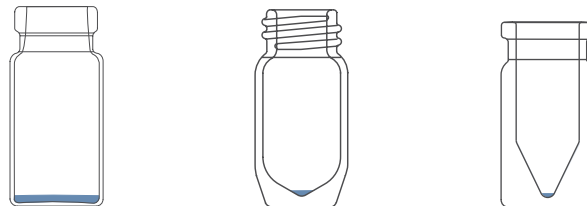
## STUDY RESULTS

The residual volume measured in each flat-bottom vial averaged 116.9µL. For the E-Z Ex-Traction, average residual volume was recorded as 2.7µL, while for the NextGen V-Vial, residual volume was 1.1µL, as shown in Table 1; n = 25 for all trials.

The E-Z Ex-Traction and NextGen V-Vials both significantly decrease product waste. The E-Z Ex-Traction Vial offers a 97.7% decrease in wasted residual product, while the NextGen V-Vial offers a reduction of 99.1%.

In addition, HRVs eliminate the possibility of end users “pooling” residual volumes from individual vials to create additional dosages.

Residual Volume  
(not to scale)



## STUDY IMPLICATIONS

Applying the sample data to a theoretical 50L batch size, the standard flat-bottom vials generated the most product waste with 7.8% of the product remaining in the vial. The E-Z Ex-Traction Vial produced a significant reduction in waste with only 0.2% of the residual product remaining and the NextGen V-Vial further reduced waste to 0.1%. This reduced waste results in 2350 more fills with the E-Z Ex-Traction Vial and 2383 more fills with the NextGen V-Vial compared to a flat-bottom vial.

For primary packaging, particularly of high-value products including biologics and some vaccines, a high recovery vial such as the NextGen V-Vial provides long-term savings for pharmaceutical manufacturers. Return on investment in HRVs stems from greater product recovery without the need to overfill for complete retrieval. The USP recommends that pharmaceutical manufacturers overfill vials as much as 24 percent “to permit withdrawal and administration of the labeled volumes.”<sup>2</sup> Using HRVs lets pharmaceutical manufacturers fill considerably more vials with the same batch volume, ultimately reducing manufacturing costs. In addition, HRVs eliminate the possibility of end users “pooling” residual volumes from individual vials to create additional dosages.

## THE WHEATON SOLUTION

WHEATON offers two High Recovery Vial options: The NextGen V-Vial and the E-Z Ex-Traction Vial. Heavy-walled NextGen V-Vials offer maximum protection of high value drug products and minimize product waste. For less expensive pharmaceutical compounds, the smaller, lighter E-Z Ex-Traction vials offer standard product protection and reduced product waste.

If a product outside the standard offering is required, WHEATON's Premium Services offers a range of services from cleaning and barcoding standard items to full product design.

	Standard Flat-Bottom Vial	E-Z Ex-Traction® Vial	NextGen™ V-Vials®
Description	Inverted Bottom, Thin-Walled	Concial Bottom, Thin-Walled	Steep Concial Bottom, Heavy-Walled
Fill Volume	1.5mL	1.5mL	1.5mL
Average Residual Volume (2mL vials)	116.9µL	2.7µL	1.1µL
% Waste	7.8%	0.2%	0.1%
Fills / Batch (50L)	30,923	33,273	33,308
Total Waste (with 50L Batch)	3614.9mL	89.84mL	36.64mL

Table 1: Summary of results showing theoretical savings using WHEATON HRVs.

The NextGen V-Vial features a steep conical well, offering exceptional downward drainage and enabling maximum product retrieval. Manufactured in the United States of USP Type I borosilicate glass, the V-Vial's heavy-walled design provides excellent chemical resistance and protection of high-value contents during packaging and transportation. With a choice of screw thread or crimp/serum finishes, the V-Vial is ideal for primary packaging of high-value biologics and diagnostic reagents.

The thinner-walled, E-Z Ex-Traction Vial is ideal for both chemical compound and biological sample storage. The conical well design and smooth transition from interior wall to conical well ensure increased sample recovery over standard flat-bottom vials. Manufactured in the United States of USP Type I borosilicate glass, each vial is quality engineered to tight tolerances for use with automated handling systems.

## REFERENCES

<sup>1</sup> USP <1> Injections

<sup>2</sup> USP <1151> Pharmaceutical Dosage Forms



# SciLabware

**SciLabware Limited** Unit 4, Riverside 2,  
Campbell Road, Stoke on Trent, ST4 4RJ, UK.  
**Tel:** +44 (0)1782 444406 **Fax:** +44 (0)1782 940436



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