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Next

REPORT ON NEW SOLUTIONS FOR PHARMACEUTICAL PACKAGING

IMPROVEMENTS TO PATIENT SAFETY – THE OPC BREAK SYSTEM OPENING TECHNIQUE

A CASE STUDY BY
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SCHOTT
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IMPROVEMENTS TO PATIENT SAFETY

How combining the OPC break-system with correct opening techniques decreases particle loss, significantly reducing patient health risks.

*A case study by Victoria de la Torre,
Profesional Product Manager Ampoules,
SCHOTT Pharma AG & CO KGaA*

Pharmaceutical companies working with ampoules have two main concerns: Not only do they need to guarantee the safety of health care professionals (HCPs) and patients at the point of use, they need to ensure the fill & finish process runs smoothly to make a rentable product.

The pharmaceutical industry places significant emphasis on the continuous reduction of injuries to healthcare professionals (HCPs), as well as minimizing the generation of glass particles during ampoule opening. This is essential due to the potential health risks from even the smallest particle entering the patient's circulatory system (Perez, M., Maiguy-Foinard, A., et al. (2016). Particulate Matter in Injectable Drugs: Evaluation of Risks to Patients. *Pharmaceutical Technology in Hospital Pharmacy*, 1(2), 91-103).

SCHOTT Pharma's main focus is to offer easy-to-use pharmaceutical containers for all applications. To achieve this goal, extensive research has been conducted in reducing the risk of glass particle contamination and eliminating the challenge of hard-to-open ampoules.

Our research shows that the amount of particles generated by opening an ampoule can be reduced by more than 60% if the break-system is "one point cut" (OPC) or "easyOPC", which also makes the opening process easier when combined with the correct opening technique.



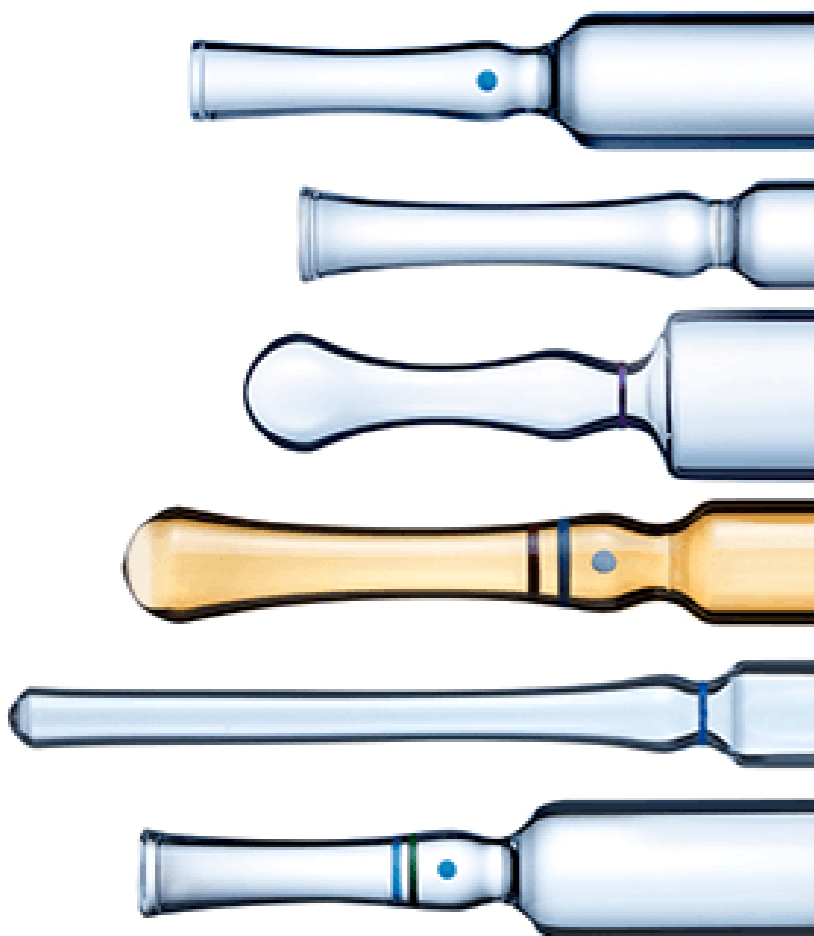
STILL THE MOST USED PHARMACEUTICAL CONTAINER IN THE 21ST CENTURY

Ampoules have been used to safely store pharmaceutical solutions since the middle of the 19th century. For more than 100 years, they have been the preferred container of the pharmaceutical industry, with more than 18 billion units now sold annually (IQVIA; 2021). Ampoules have a number of key benefits:

- Made of 100% glass, ampoules are tamper-safe; and since the drug is only in contact with glass, they offer an excellent extractable and leachable profile.
- Ampoules are hermetically sealed through melting, and so provide intrinsic container closure integrity.
- Ampoules are affordable, enabling easy access to basic health care.
- Ampoules offer the easiest and fastest access to medication, making them the preferred container in an emergency environment.

Ampoules support access to essential medicine and a range of applications including analgesics, sedatives, vascular drugs, emergency drugs, solutions to treat overdoses, anti-sickness, vitamins, and minerals.

SCHOTT produced its first batch of ampoules 100 years ago, and since then many things have changed. One of the key changes is the addition of a break-system to all ampoules, defined as the pre-applied break point or circumference, which allows the ampoule to open. In the past, ampoules did not have a break-system and HCPs would use small saws or knives to gain access to the drug inside. These opening methods delayed the time taken for an injection and increased the risk of injury to the HCP. In addition, the glass particle load while opening was very high, which is no longer acceptable.



There are four different ampoule break-systems on the market, all linked to the force required to open them. Each break-system also has its own opening technique.

One Point Cut (OPC): The latest and most popular break-system, which features a small cut on the constriction. A dot is printed above the cut as an indication for opening. The break-force (25-65N for 2 ml) fulfills ISO 9187-2, which is tighter than any other break-system ISO.

easyOPC: This SCHOTT Pharma innovation offers a significant improvement on the OPC. The easyOPC production process has been optimized to achieve a lower and more consistent break-force (see NEXT issue 09/2020: “Optimizing the break force range towards less complaints and reduced risk for injuries”). This offers a number of advantages to the pharmaceutical industry, such as easier opening and a reduced risk of HCP injury. SCHOTT Pharma’s easyOPC ampoule also offer a tighter break force specification (25-45N for 2 ml) than OPC (25-65N for 2 ml), fulfilling ISO 9187-2.

Scoring (SCO): This ingenious idea involves a cut applied all around the constriction of the ampoule, allowing the ampoule to open. However, as there’s no defined opening point, the break-force ranges between 30-80N for 2 ml. This fulfills ISO 9187-1.

Color break ring (CBR): Still in use in developing countries, CBR is the oldest break-system and consists of an enamel ring applied around the constriction of the ampoule. Since the enamel has a higher coefficient of thermal expansion than the glass, microcracks are introduced during the annealing process that allow the ampoule to open. A lower break-force range of 30-80N for 2 ml (ISO 9187-1) is a disadvantage when compared to other break-systems.

With higher break-force ranges than OPC and easyOPC, SCO and CBR are losing market share. An additional disadvantage for CBR is the prohibition of heavy metals in enamels due to health risks. Without the use of heavy metals, its break force varies between products of a single batch.

Ampoules market in 2022
Break-systems split

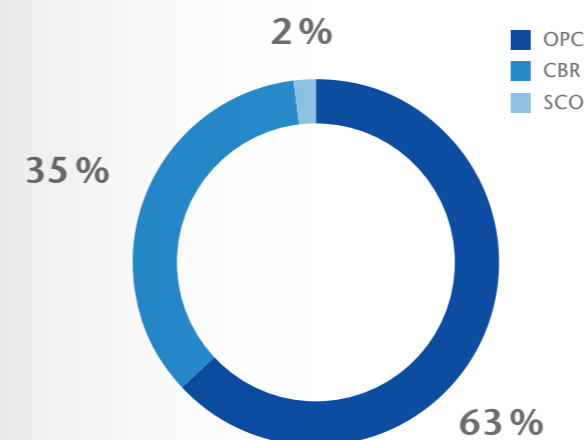


CHART 1:
Break-systems in %

OPC is the most adopted break-system with 63% global market share, followed by CBR with 35% and scoring with 2%.

HOW TO SAFEGUARD PATIENT HEALTH

Ampoules are an important part of every professional's first aid kit, ambulance drug cabinet, and hospital infirmary. Pharmaceutical companies choose ampoules as their container of choice because of their simpler and faster opening process. However, a simpler and faster process doesn't mean it's not efficient, reliable, and safe.

	easyOPC	One Point Cut	Scoring & Color Break Ring
	Tighter than ISO 9187-2	ISO 9187-2	ISO 9187-1
1 ml	25-45	25-65	30-80
2 ml			
3 ml			
5 ml	30-60	30-70	
10 ml	30-65	30-80	30-90
20 ml			30-100
25 ml	-		
30 ml	-		

TABLE 1:
Breakforce comparison (measured in Newton) of different break-systems available

Efficient: Ampoules need to be opened with very little effort by the end user. The lower the break-force range, the less strength is required to open them. For this, OPC or easyOPC are recommended since they have lower break-force ranges than CBR or SCO.

Reliable: Ampoules must offer a consistent break-force, not only between ampoules in the same batch but also between different batches. To achieve this, break-systems with a score mark (cut) application on the ampoule (OPC or easy-OPC) are recommended.

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SAFE FOR HEALTH CARE PROFESSIONALS (HCPs)

Did you know that 82 million ampoules are opened around the world every day by 21.7 million HCPs?

In 2018, SCHOTT Pharma surveyed 700 European nurses and found that more than 85% face problems with handling ampoules, including unbreakable ampoules and bad breakage. From a health care perspective, opening an ampoule is the number one cause of injuries at hospitals.

After asking how many ampoules were unbreakable or unusable, SCHOTT Pharma found an average of 114 per nurse per year. Considering there are 21.7m HCPs in the world (World Health Organization), this figure equates to 10 million hospital nurses having problems with ampoule handling globally.

To minimize the issue of hard-to-open ampoules, SCHOTT Pharma developed easyOPC ampoules. By optimizing the converting process and break-system application, SCHOTT Pharma has achieved a narrower break-force range, as well as a tighter specification for cosmetic defect – reducing an AQL of 400ppm down to 50ppm in a product lot.

SAFE FOR PATIENTS

Putting patient safety first and protecting them from glass particles in their medication is one of SCHOTT Pharma's main goals, as we strive to reduce the amount generated during ampoule opening.

SCHOTT Pharma performed a study to compare the creation and loss of glass particles during ampoule opening with different break-systems. This involved testing small (2ml) and large ampoules (10ml) featuring OPC, SCO, and CBR break-systems, with 19-30 ampoules in each set. The mass of each ampoule was measured before and after opening, then after cleaning the stem and body of the ampoule with an air blast. Every weight measurement was repeated between three and five times.

COMPARISON BETWEEN SMALL OPC AND SCO AMPOULES (2 ML)

OPC ampoules have a lower break-force range than Scoring ampoules (25-65N vs. 30-80N). If less force and a smooth movement are applied to open an ampoule, the generation of particles will be lower.

Test results show that **particle loss can be reduced by 45%** if the OPC break-system is used.

COMPARISON BETWEEN LARGE OPC AND CBR AMPOULES (10 ML)

The first section mentioned that OPC ampoules not only have a lower break-force range than CBR (25-65N vs. 30-80N) but the break-force is more consistent. This means that a batch of OPC ampoules will contain less outliers and the break-force median will be more consistent.

As well as these benefits, the test results show us that **particle loss can be reduced by more than 18%** with the OPC break-system versus CBR.

FIGURE 1:
Comparison between 2 mL OPC and SCO

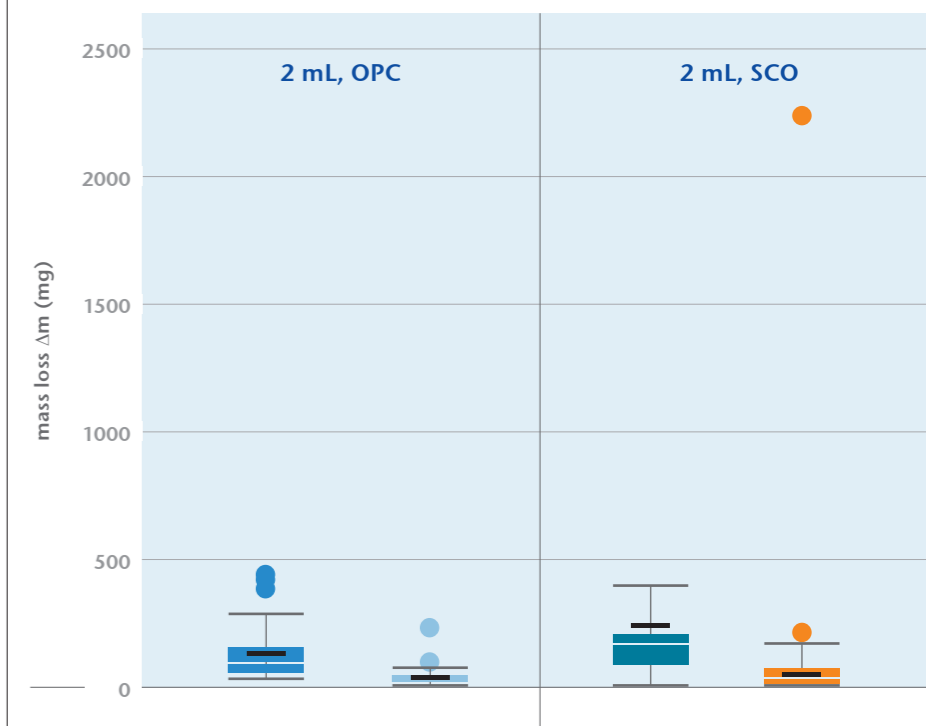
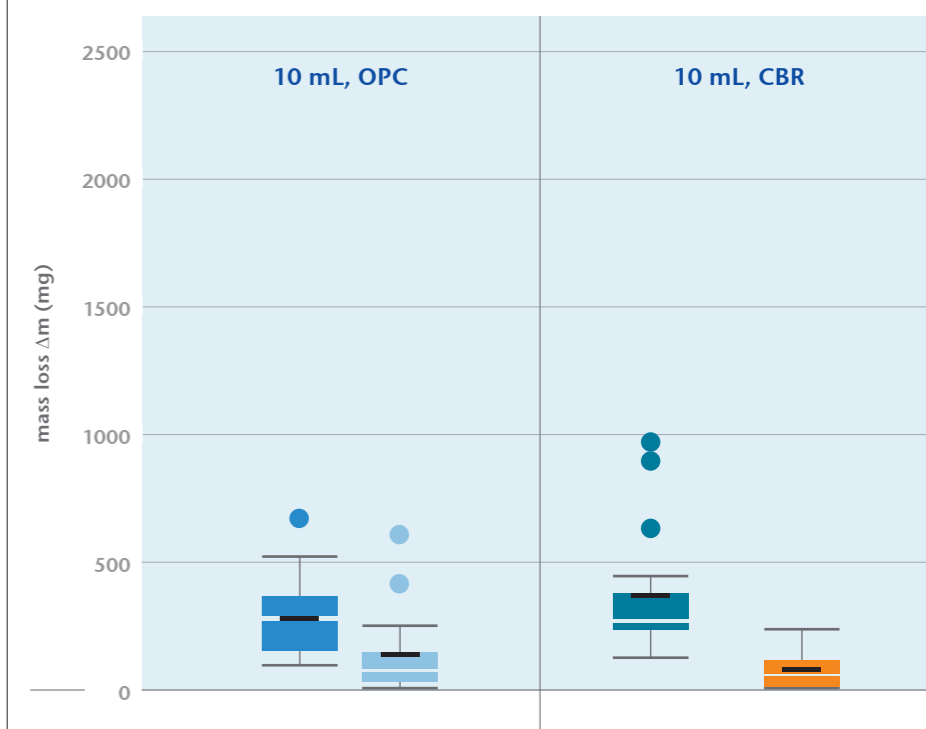


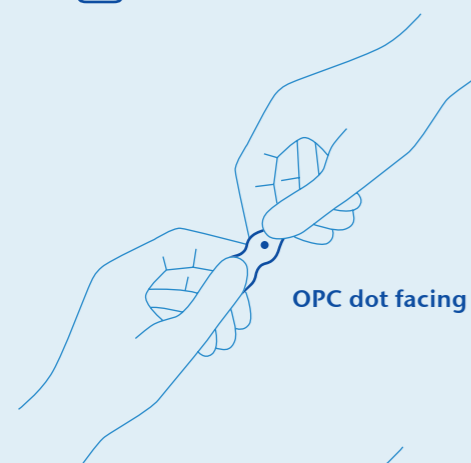
FIGURE 2:
Comparison between 10 mL OPC and CBR



1.

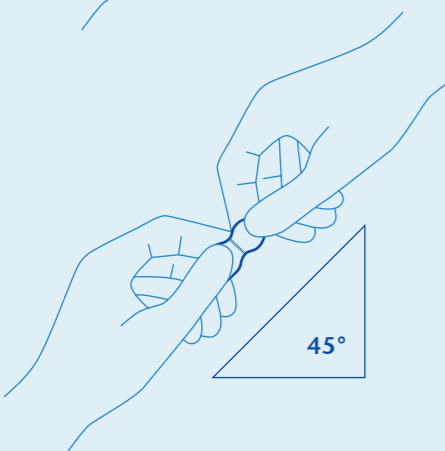


2.



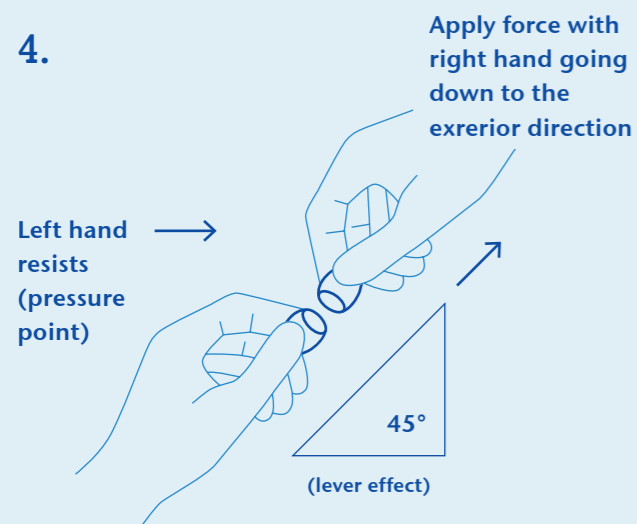
OPC dot facing

3.



45°

4.



Apply force with right hand going down to the exterior direction

Left hand resists (pressure point)

45°

(lever effect)

THE OPC BREAK-SYSTEM NEEDS TO BE COMBINED WITH THE CORRECT OPENING TECHNIQUE

OPC has proven to reduce the loss of particles during ampoule opening, minimizing the risk of particle contamination for patients. SCHOTT Pharma wanted to improve these outstanding results further, so developed a state-of-the-art opening technique which consists of four simple steps:

1. During ampoule preparation, make sure the liquid goes down by gently punching the head of the ampoule with your fingers.
2. Hold the ampoule between the thumb and bent index finger of the left hand (if you are right-handed), with both fingers positioned between the cylinder and shoulder of the ampoule, and **OPC dot facing the operator**.
3. Grip the bulb between the thumb and bent index finger of the right hand (if you are right-handed). **Your thumb must cover the OPC dot and ampoule holding position should remain at 45°.**
4. Apply force with the right thumb down to the exterior direction while resisting with the left index finger (pressure point). There should be no pulling or torsional effect on the ampoule. There should be no acceleration or disproportionate force – rather a **constant effort to achieve the breakage**.

SCHOTT Pharma commissioned further studies to substantiate these findings. These studies showed that, as well as the break-system, the opening technique has a major influence on particle loss, improving the break-system further.

To compare the generation of particles, a number of sets of OPC ampoules were opened using the opening technique recommended by SCHOTT Pharma (referred to as the “proper opening”). Another set of OPC ampoules was opened using a technique in which the dot was neither facing the operator or covered by the thumb (referred to as the “improper opening”).

The testing consisted of small (2ml) and large ampoules (20ml), all empty and fused, with 50 units analyzed for each format. The mass of each ampoule was measured before and after opening.



ADVANTAGE

Best break-system combined with state-of-the-art opening technique reduces mean load of particles by

60%

The results showed that for both ampoule formats, the mass loss was higher for the “improper opening system” set. The focal point is the high difference in particle generation using the different opening techniques. The generation of glass particles during ampoule opening was reduced by 60% when combining the OPC break-system with SCHOTT Pharma’s recommended opening technique.

FIGURE 3:
Results for small ampoules (2ml) – Comparison between proper and improper opening technique

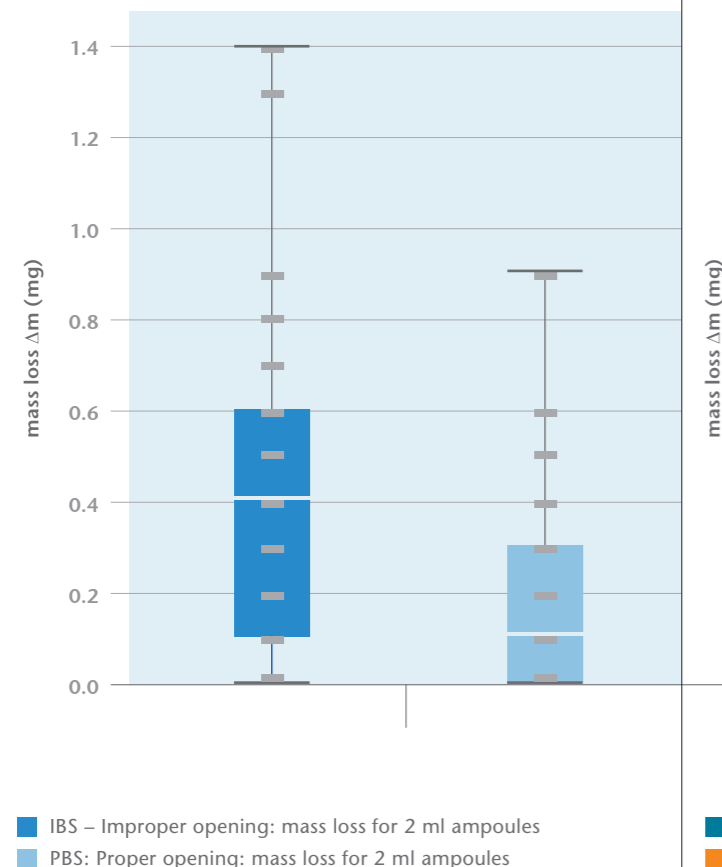
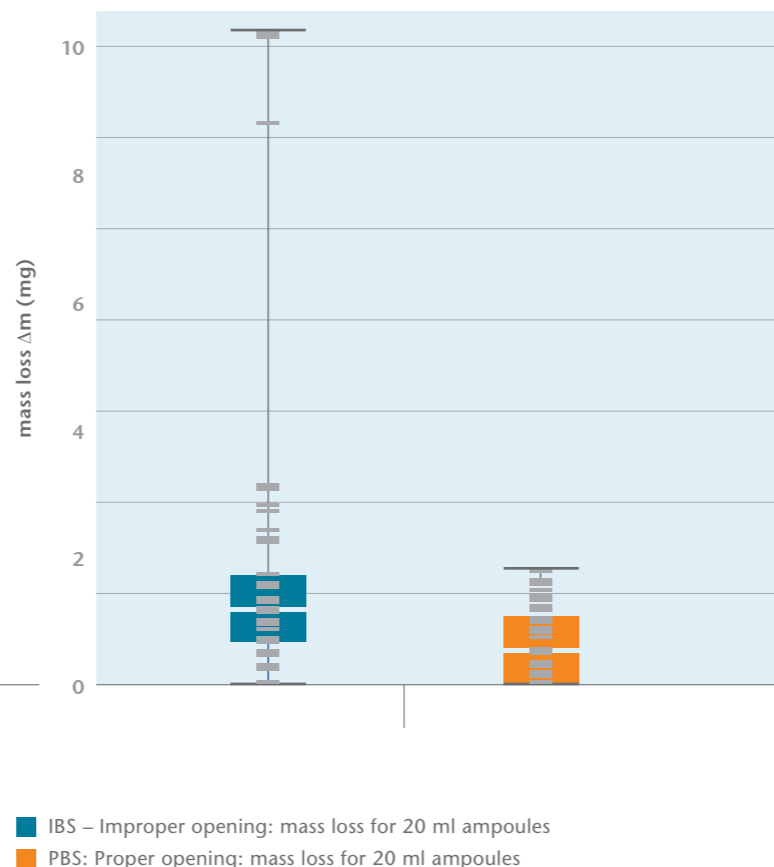


FIGURE 4:
Results for big ampoules (20ml) – Comparison between proper and improper opening technique



THE POWER OF CORRECT OPENING TECHNIQUES

An essential part of hospital infirmaries and ambulance kits, ampoules are used to store thousands of different drugs, many of which are lifesavers. Pharmaceutical companies have used this glass container for more than 100 years thanks to its simpler processability and effortless usability, in part due to the chosen break-system.

Thanks to SCHOTT Pharma’s decades of experience in producing ampoules alongside our close relationship with the pharmaceutical market, we understand the importance of the ampoule break-system. It not only allows easy access to a drug, but also helps to protect health care professionals and their patients.

OPC and easyOPC break-systems should be chosen for their lower break-force range and tighter consistency. Lower particle generation during ampoule opening is one of the most important advantages of the OPC break-system.

Even a small reduction in particle generation is beneficial since it decreases the risk of glass particles getting into a patient’s circulatory system and introducing health

threats. Our studies show that the amount of particle reduction is essential. Compared to CBR, the one point cut (OPC) break-system generates 18% less particles in large ampoules. When compared to SCO, particle generation is reduced by more than 45% for small ampoules.

Although positive, those results were not enough for SCHOTT Pharma. As part of our contribution to ensuring medications are safe to use around the world, we wanted to know if particle loss could be decreased further when using the best break-system available (OPC or easyOPC if a lower break-force is required).

Our main finding was that opening technique plays a highly significant role in reducing particle generation. If the ampoule is held at 45°, with the OPC dot facing the operator and the thumb of the dominant hand covering the dot, and the applied force is constant (without acceleration or effort), there could be up to 60% reduction in the amount of particle loss, protecting patients’ lives.



For more information, please visit:
www.schott-pharma.com



VICTORIA DE LA TORRE

Victoria de la Torre (Professional Product Manager Ampoules, SCHOTT Pharma AG & CO KGaA) started her career in the Product Management department of a medical device company as an Intern before joining SCHOTT Pharma 2020. In her role as Product Manager for bulk ampoules, she is responsible for the product strategy, including the product lifecycle and identification of new market opportunities.

Victoria holds an Argentinean and German Master's Degree in International Business (Hochschule Mainz from the University of Applied Sciences / Universidad de Ciencias Empresariales y Sociales (UCES)).

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