

CLS-4209-B45: DURAN® GL45 Bromobutyl Rubber Stopper



- Stopper and material properties optimised to fit DURAN® GL 45 bottles
- Low permeability to air, gases and moisture (a perfect match with the low gas permeability properties of DURAN® glass)
- Manufactured from a high purity, bromobutyl rubber elastomer
- Elastic material for reliable self-sealing after needle piercing
- Upper surface with needle-piercing guides
- Wide usable temperature range: -50 to +121°C

FAQs

Q: What are the numbers 1 – 7 on the top of the DURAN® GL 45 stopper?

A: The numbers are a piercing guide. They are spaced to avoid re-piercing the same region.

Q: What is the chemical compatibility / resistance of the DURAN® GL 45 stoppers?

A: The stoppers are manufactured from an uncoated bromobutyl rubber. This synthetic material typically exhibits the following characteristics:

Good resistance:

Aqueous solutions, alkalis, acids, and oxygenated solvents (such as alcohols, glycol ethers, ketones, esters, and glycol ether esters)

Poor resistance:

Mineral oils, hydrocarbon solvents (aliphatic and aromatic hydrocarbons) and halogenated solvents (such as chlorinated hydrocarbons). Typically these chemicals will cause swelling.

Q: What size needles do you recommend for piercing?

A: We recommend only small-gauge needles (no larger than 20-gauge) be used. After the needle has been withdrawn from the stopper, the bromobutyl rubber provides outstanding resealing properties to protect the contents within from moisture and oxygen in the atmosphere. The stopper passes the Self-Sealing test specified in USP <381> The test specifies 10 punctures with a 21-gauge needle.

Larger bore needles (above 18-gauge) are more likely to produce corning particles, reducing the ability of the rubber to reseal. Corning particles were observed frequently after many punctures with 18-gauge needles, but infrequently with 20-gauge and rarely with 22-gauge needles.*

*Self-sealing capacity of vial stoppers after multiple needle punctures.

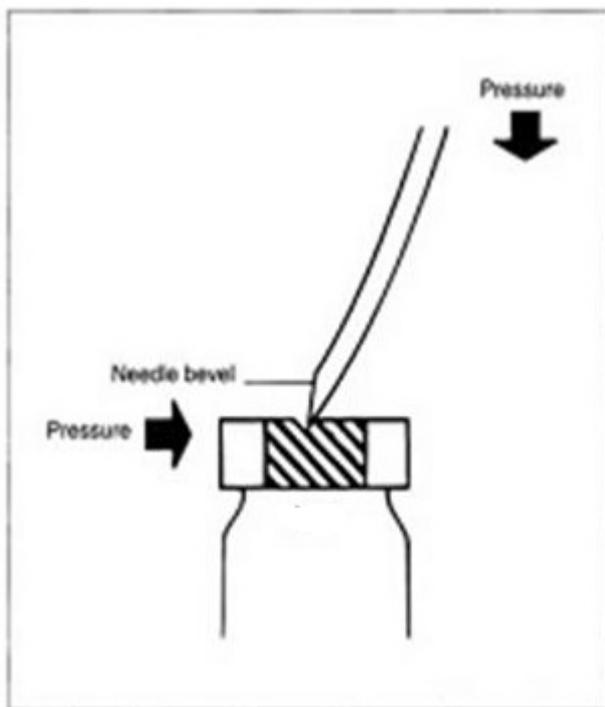
J Am Pharm Assoc (2003). 2013 Jan-Feb;53(1):58-60. doi: 10.1331/JAPhA.2013.12064.

Q: How can I ensure that the Bromobutyl rubber reseals after piercing?

A: Coring happens when a needle shears out cores from a rubber closure as it pierces the closure. If this occurs, the rubber is much less likely to fully reseal.

To prevent coring, insert the needle as shown:

Insert the bevel first, then press downwards and towards the bevel, so that the bevel tip and heel enter at the same point



Q: Can the DURAN® GL 45 stopper be sterilized?

A: Sterilization methods such as moist heat (i.e. steam at 121 °C) (commonly used for stoppers), or ionizing radiation (gamma or e-beam) (less commonly used for stoppers) may be used.

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Q: Are the DURAN® GL 45 stoppers supplied sterile or endotoxin free?

A: The stoppers are provided non-sterile, but have been washed with a final rinsing with purified water. However we currently cannot provide any certification regarding: endotoxin, bioburden, particles, extractables profiles, or silicone determination.

Q: Is it possible to obtain a Lot Certificate for the DURAN® GL 45 stopper?

A: Yes, the stoppers are lot controlled, and we can provide a lot certificate on request.

Q: Which International standards do the DURAN® GL 45 stoppers conform to?

A: On request, we can provide lot specific certification confirming compliance with requirements of a “Type 1” stopper as defined by the chemical tests in EP 3.2.9 / USP<381>. As the GL 45 stopper size and shape is “non-standard”, it does not conform to any ISO stopper shape, dimensions standards such as ISO 8536-2 or ISO 8362-6.

Q: Are the DURAN® GL 45 stoppers coated, such as with PTFE?

A: The stoppers are provided “uncoated”. However a small amount of lubricating silicone oil was applied to prevent the stoppers sticking together.

Q: What is the recommended shelf life of the DURAN® GL 45 stoppers?

A: We recommend 5-years. General guidance given by ISO 2230:2002 Rubber products -- Guidelines for storage indicates that bromobutyl rubber products should have a shelf life of 7 years from the date of manufacture.