

bottelpack[®]

BFS AMPOULE TEST KIT

The Test Kit includes 200 sterile empty ampoules with 10 ml filling volume, produced on a bottelpack[®] aseptic BFS machine with new plastic granulate. The empty ampoules are filled with sterile air and closed hermetically with a twist-off sealing and long cannula. The aseptic filling of the empty container is done preferably with a syringe under laminar-flow either by piercing the cannula directly with the needle of the syringe or by cutting off the tip of the cannula beforehand. In both cases immediately after the filling process, the cannula has to be sealed hermetically by using a hot clamp.

STANDARD TEST KIT includes:

1. LDPE Purell 1840H (LyondellBasell)*
2. LDPE Purell 3020D (LyondellBasell)*
3. LDPE Purell 3420F (LyondellBasell)*
4. Your choice from the below list.

FURTHER AVAILABLE PLASTIC TYPES:

- ✓ LDPE Purell 3040D (LyondellBasell)*
- ✓ LDPE CoEx: Purell 3020D / EVOH / Purell 3020D (LyondellBasell)
- ✓ HDPE Purell GF4750 (LyondellBasell)
- ✓ LDPE Bormed LE6609PH (Borealis)
- ✓ PP Bormed SB815MO (Borealis)
- ✓ PP Flint Hills 23M2A (Flint Hills/ Huntsmann)
- ✓ PP Total PPM R021 (Total Petrochemicals)

*) It is possible to order the „Extractable Studies“ documentation for these plastic types separately. This documentation can be used for product specific “Leachable Studies”. On request this documentation can also be offered for other plastic types specified by the customer.

- ✓ Nominal filling volume 10 ml
- ✓ Aseptically produced under GMP conditions
- ✓ Assured sterility inside the ampoules
- ✓ Test ampoules are hermetically closed

SCOPE OF DELIVERY:

- ✓ 4 cardboard boxes with 5 x 10-block = 50 empty ampoules packed in reclosable bags. Those 4 boxes contain one plastic type each from above range as specified by the customer.
- ✓ One carrier plate to hold 3 empty ampoules during the filling and sealing process.
- ✓ 50 aluminum sachets 105 x 140mm to shrink-wrap the filled ampoules
- ✓ 50 aluminum sachets 135 x 190 mm to shrink-wrap the filled ampoules
- ✓ One documentation per type of plastic

THE DOCUMENTATION PER PLASTIC TYPE COVERS:

- ✓ Plastic specifications
- ✓ Safety data sheet
- ✓ Information on the outer packaging of aluminium sachets
- ✓ Description of the use of the BFS Ampoule Test Kit

NOTE:

These empty BFS ampoules are to be used exclusively for laboratory purposes and not for human and animal use.

