





GlaxoSmithKline Manufacturing S.p.A.

GMS Verona Italy

Product Packaging Brief



GSK - Verona

Introduction

The GSK Verona site is situated on the edge of the historic city of Verona, approximately 150 km from Milan in northern Italy.

The site specialises in the manufacture of sterile Cephalosporin finished dose form products for global markets. It has modern facilities for the large-scale manufacture of vials from aseptic powder fill.

Key Capabilities	Key Regulatory Approvals
<ul style="list-style-type: none">• Sterile powder fill to vials• Sterile powder fill to monovials for global markets• Sterile powder fill to Add-Vantage vials for USA*• Flexible packaging lines for global supply <p>* (Add-Vantage is a registered trade mark of Abbott USA).</p>	<p>USA - FDA Europe Japan Australia Rest of World</p> <p>GSK Verona is a global supply site and thus maintains global regulatory approvals.</p>

Overview

The Verona site is a global centre of excellence for the sterile manufacture of powder fill Cephalosporin vials. The site has capabilities to aseptic powder fill to standard vials as well as Add-Vantage (subject to negotiation of the relevant 3rd Party IP technology) and Monovial devices.

It has an excellent quality record in this very challenging environment and considerable experience gained from working within GSK, as well as with contract manufacturing for third party customers.

The Verona Site also provides a high quality, secure and cost-competitive option for Cephalosporin finished dose supply. This brochure has been prepared to provide information on Verona Manufacturing site and its capabilities, both to undertake contract manufacturing work for third party customers and give a good knowledge of the site to GSK customers.

Product Presentations

Vial 17 ml

Verona is currently filling 17 ml vials with following dosages:

- 250 mg
- 500 mg
- 750 mg
- 1 g

17 ml can be packed with 3 ml ampoule

Types of packaging:

- x 1 (with or without ampoule)
- x 10 (without ampoule)
- x 25 (without ampoule)



Product Presentations

Vial

26 ml

Verona is currently filling 26 ml vials with following dosages:

- 1 g
- 1,5 g

26 ml can be packed with 10 ml ampoule

Types of packaging:

- x 1 (with or without ampoule)
- x 10 (without ampoule)
- x 25 (without ampoule)

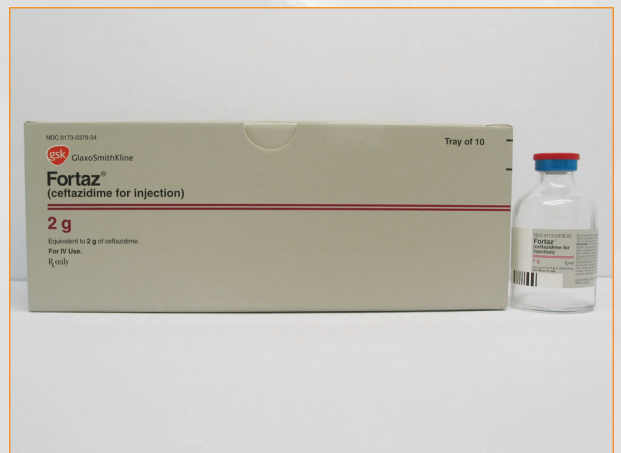


Product Presentations

Vial 60 / 77 / 127 ml

Types of packaging for big vial size:

- 60 ml x 1 & x 10
- 77 ml x 1
- 127 ml x 1; x 6; x 10



Product Presentations

Monovial

Vials can be pack with a special device used in hospitals called "Monovials"

The device is available for all markets

Monovial is filled in a 22 ml vial x 1

The presentation can also be packed with an infusion bag



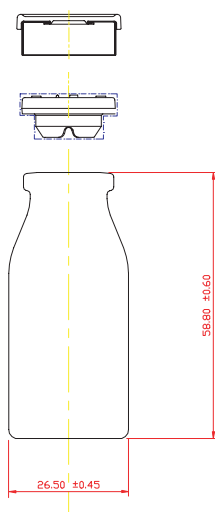
Primary Pack Standard Vial

Vials Components

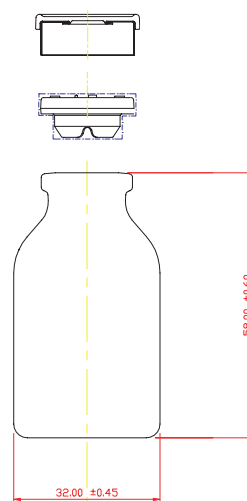
Vial - Verona uses moulded vial for infusion and injection products. As indicated in USP method or European Pharmacopeia glass is type 3 clear hydrolytic resistance.

Stopper - Verona uses no coated, bromo butyl gray rubber stopper for infusion products.

Closure - Vials are closed with snap-off closure. It is tamper evident closure composed by aluminium and plastic parts for vials stoppered with elastometric plugs.



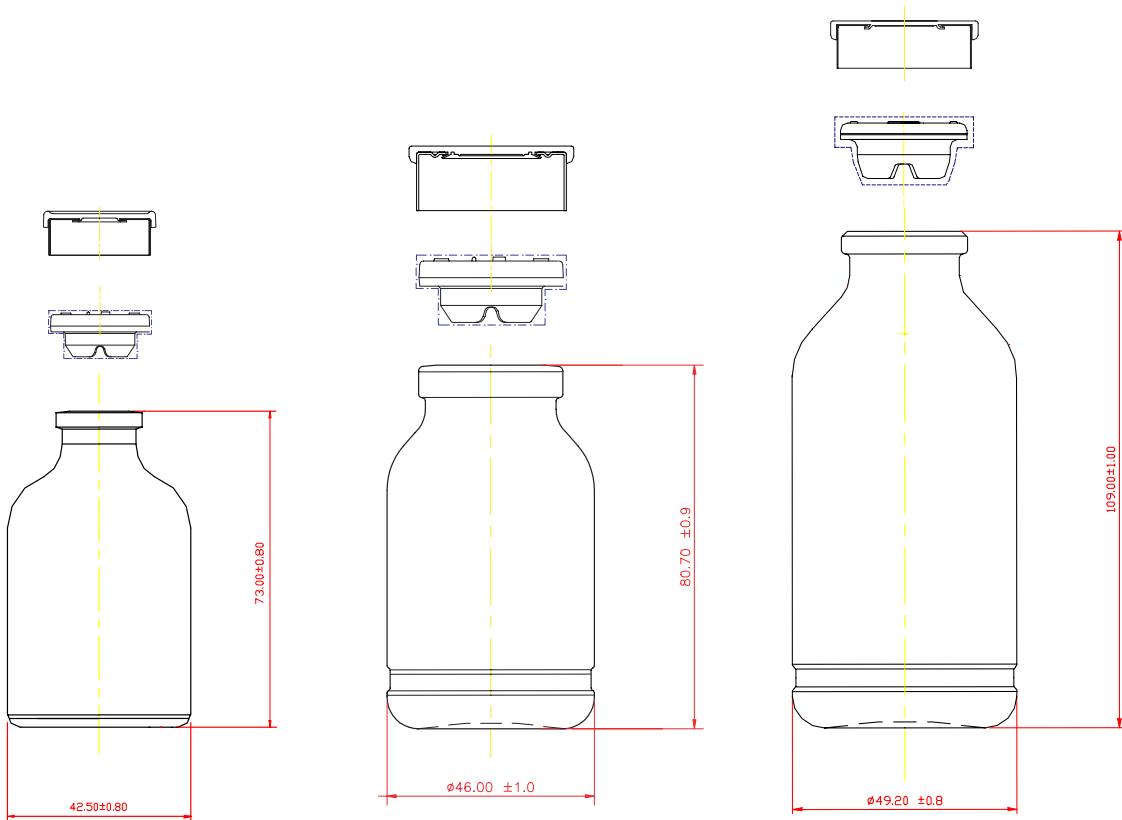
Vial 17 ml
ISO-DIN 8362
Stopper
Diameter 20 mm
Closure
Aluminium closure Ø
20 mm
with coloured flip-off



Vial 26 ml
ISO-DIN 8362
Stopper
Diameter 20 mm
Closure
Aluminium closure Ø
20 mm
with coloured flip-off

Primary Pack Standard Vial

Vials Components



Vial 60 ml
ISO-DIN 8362

Stopper
Diameter 20 mm

Closure
Aluminium closure Ø
20 mm
with coloured flip-off

Vial 77 ml
ISO-DIN 8536

Stopper
Diameter 32 mm

Closure
Aluminium closure Ø
32 mm
with coloured flip-off

Vial 127 ml
ISO-DIN 8536

Stopper
Diameter 28 mm

Closure
Aluminium closure Ø
28 mm
with coloured flip-off

Primary Pack Monovial

Device Components

Transfer set:

Capsule Needle Guard: transparent polymer resin Ektar MB DA003

Needle: stainless steel, anticoring treated

Sealing ring: bromo butyl rubber

Cup: low density translucent polyethylene resin Riblene FC20

Plunger stopper:

Bromo butyl rubber (ceftazidime)

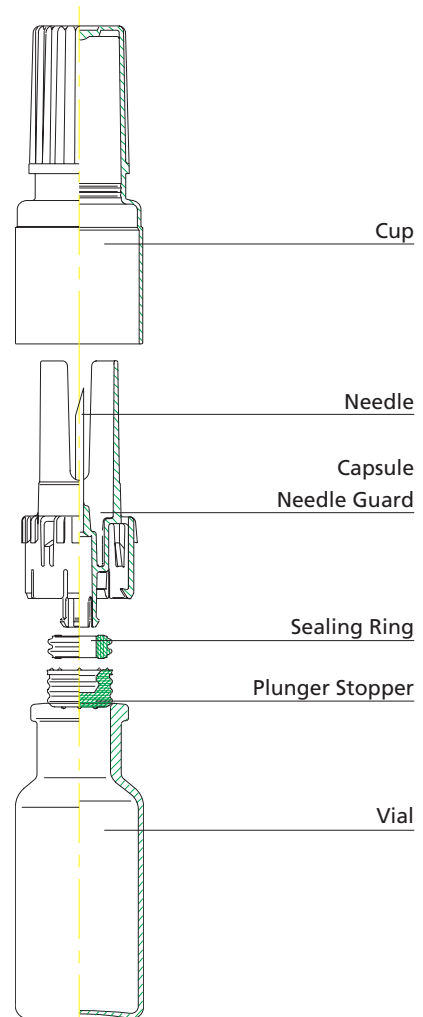
Coated or non coated bromo butyl rubber (cefuroxime)

Vial:

Glass clear type 1 as for USP XXII and

Ph European

Brimfull capacity 22ml





GlaxoSmithKline
Centro Ricerche

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