



GERRESHEIMER

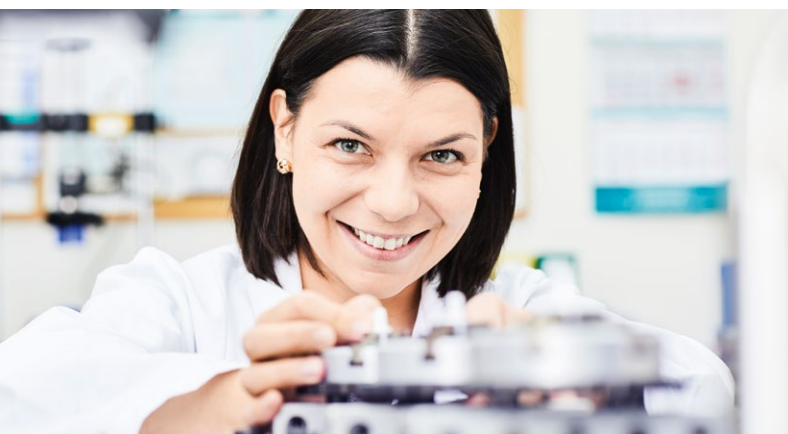
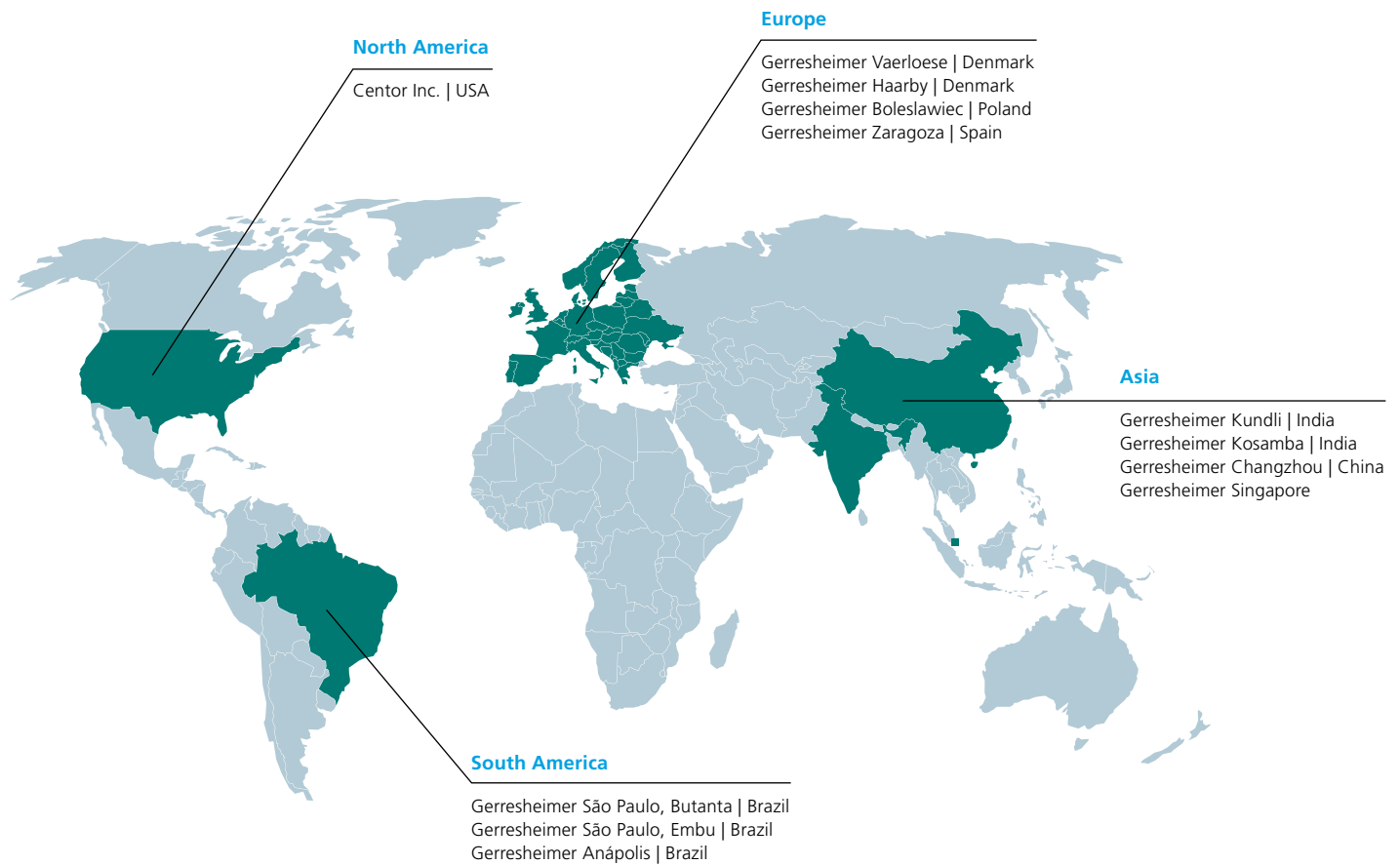
High-Quality Pharmaceutical Plastic Packaging and Systems

for Ophthalmic, Nasal and
Parenteral Applications



www.gerresheimer.com

Gerresheimer Plastic Packaging



About Gerresheimer

Gerresheimer is a leading global partner to the pharma and healthcare industry. With our specialty glass and plastic products, we contribute to health and well-being. We have worldwide operations and about 10,000 employees manufacture our products in local markets, close to our customers. With our plants in Europe, North America, South America and Asia, we generate revenues of approximately EUR 1.4 billion.

The comprehensive product portfolio includes pharmaceutical packaging and products for the safe, simple administration of medicines: Insulin pens, inhalers, micro pumps, prefillable syringes, injection vials, ampoules, bottles and containers for liquid and solid medicines with closure and safety systems as well as packaging for the cosmetics industry.

Gerresheimer Plastic Packaging Solutions

Intelligent products for diverse pharmaceutical applications



PET / Liquid & Solid



Solid Dosages



Ophthalmic, Nasal and Parenteral Applications

Gerresheimer Plastic Packaging specializes in the widely varied spectrum of pharmaceutical plastic packaging within solid, liquid and ophthalmic applications, plastic vials and plastic bottles for personal care. Our leading brands Duma®, Dudek™ and Triveni for solid dosage, edp-branded PET bottles for liquid dosage and our ophthalmic products form part of a comprehensive and innovative product range. Our monolayer plastic vials are based on COP and offer inert contact surface and deliver a unique packaging safety feature to manufacturers of toxic or high potency drug solutions.

Our standard range includes a wide choice of different types of containers and closures, PET bottles, eye droppers, nasal sprays as well as numerous customized developments.

Using our ideas and experience to produce intelligent, increasingly safe and user-friendly packaging solutions has enabled us to become an innovative partner to the global pharmaceutical industry.

We know, understand and reinforce our customers business.



Specialist and quality leader in primary plastic packaging

Our manufacturing operations use state-of-the-art technology and apply the most rigorous quality and hygiene standards. They cover all production technologies from injection moulding and injection blow moulding to blow moulding processes. The majority of our production operations are carried out in modern classified clean-rooms or in clean conditions. All plants apply the rules of Good Manufacturing Practice (GMP) and are certified in accordance with ISO standards.

- Solution providing
- Good Manufacturing Practice (GMP)
- ISO certifications (ISO 9001, ISO 15378, ISO 14001)
- Automated in-line controls
- Vision-based inspection system
- Class 7 (10,000) + class 8 (100,000) clean-rooms

Strong regulatory approach

We ensure full conformity of our products with the European pharmacopoeia, the United States pharmacopoeia and the requirements for FDA registration with a Drug Master File as the standard. Knowing the extensive requirements of our customers we focus on providing a high level of documentation with our products.

- High level of documentation and registration
- Standard product database
- FDA and world-wide registration of all products
- US and Canada Drug Master File
- Product registrations in Russia, China and the Ukraine
- Food approval

Strong quality culture

A strong quality culture supports our efforts to deliver excellent quality. The culture is defined by our shared beliefs, values and behaviour patterns.

- Quality attitude and team work
- Continuous improvements
- Systematic problem solving
- Quality by design
- Stable, robust, reliable and validated processes
- Risk-based approach

Feel safe with the most experienced company



Global presence

We have a global presence with uniform processes and machines. We are capable of maintaining our operation at any time.



Excellent quality

We have achieved superior USP test results on all our products.

We are pioneer and we are setting footprints in the market with a very high quality of our products.

We give you free access to our product database, that contains all information intended for your product registration.



Technical competence

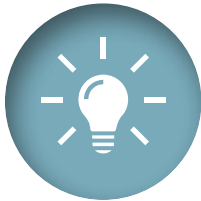
We are the company with the most extensive experience & know-how.

We offer full solution for irradiated products incl. validation. Radiation with VDmax = 17,5 kGr acc. to ISO 11137.



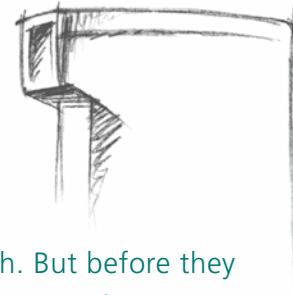
Innovation

Gerresheimer offers the markets broadest standard product range and we are happy to develop products for individual needs and requirements. Our machines give us maximum flexibility and allow us to adapt easily to any size of product series.



Constant innovation

Innovations are drivers for tomorrow's growth. But before they reach patients, pharmaceutical innovations must be fully developed, tested and validated. With our know-how and experienced R&D team we are capable of meeting your requirements.



Multi award-winning packaging during 5 decades.

We believe, that product innovations can be perceived as being:

- 1) a new product or
- 2) an extension of an existing product.

Both solutions can be solved by Gerresheimer.



Duma® Pocket CR Box



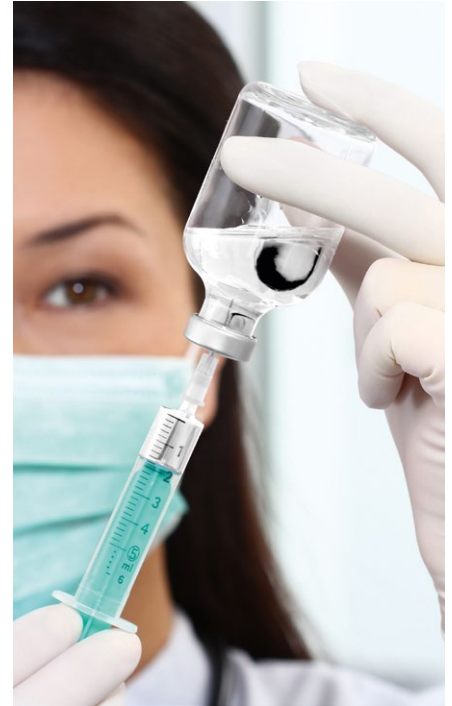
Cap with fixed TE-ring
Dropper bottles – System E

Sleeved cap
Dropper bottles – System F



Embrace circular economy with our sustainable packaging solutions. Recycled and biobased: Alternatives to conventional packaging materials.

Ophthalmic, nasal and parenteral applications



Our products for ophthalmic and nasal applications include bottles and droppers in LDPE and nasal sprays with pumps.

The monolayer plastic vials are based on COP for sensitive drug products.

Other materials, sizes and designs are available, as are closures with child-resistant or senior-friendly features.

- Dropper bottles
- Nasal sprays with pump
- Bottles in LDPE & HDPE
- Bottles in PP
- Droppers in LDPE
- Caps in HDPE & PP
- Large range of bottles & droppers
- Other materials, sizes and designs available
- Tamper-evident
- Child-resistant & senior-friendly closures
- Monolayer plastic vials (standard and RTS)
- FDA registered, DMF type III, DMF no. 22946, DMF no. 16117

Ophthalmic

- | | | | |
|--|---|---|--|
| <p>1</p>  | <p>Dropper bottles –
System A
Standard bottle</p> | <p>2</p>  | <p>Accessories System A
Caps with short droppers</p> |
| <p>3</p>  | <p>Dropper bottles –
System B
Special bottle design</p> | <p>4</p>  | <p>Accessories System B
Caps with long droppers</p> |
| <p>5</p>  | <p>Dropper bottles –
System D
Special bottle design</p> | <p>6</p>  | <p>Accessories System D
Caps with short droppers</p> |
| <p>7</p>  | <p>Dropper bottles –
System E/F
Standard US bottle</p> | <p>8</p>  | <p>Accessories System E/F
Cap with fixed TE-ring
Sleeved cap</p> |

Nasal

- 9
- 
- Spray and pump systems:
Snap-on bottles /
Crimp bottles

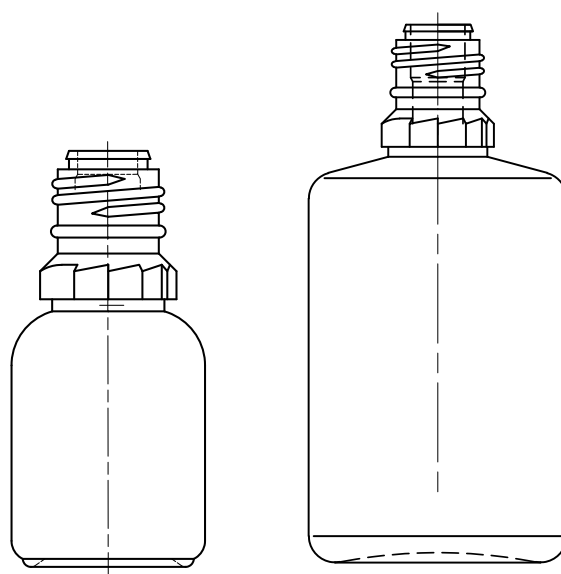
Parenteral

- 10
- 
- Monolayer
(standard and RTS)

Dropper bottles – System A (LDPE / HDPE / PET)



SPECIFICATIONS



Dropper bottles – System A (LDPE / HDPE / PET)



LDPE

35034	2	3	17	34,5	11 x 2
35036	5	7,5	21	42	14 x 2
35035	10	12,5	24	52	14 x 2
35048	10	12	24	52	14 x 2
35037	15	18,5	25	63	14 x 2
35030	25	28	31	65	14 x 2
35038	30	35	31	75	14 x 2
35080	50	60	39	81	14 x 2
32266	65	68	39	88	14 x 2
32293	115	124	45	107	14 x 2
32295	135	140	45	121	14 x 2
32271	280	314,5	60	148	14 x 2

HDPE

35073*	5	7,5	21	42	14 x 2
35047*	5	7,5	21	42	14 x 2
35046	5	7,5	21	42	14 x 2
35003	10	12,5	24	52	14 x 2
35032	15	18,5	25	63	14 x 2
35041	30	35	25	63	14 x 2
32333	60	62	39	81	14 x 2
32334	65	68	39	88	14 x 2
32331	115	124	45	107	14 x 2
32327	250	301	58	147,5	14 x 2
33067	360	387	58	181	14 x 2

* Material: PP – Limited availability (further information upon request)

PET

37010	10	13,7	24,1	51,8	14 x 2
-------	----	------	------	------	--------

- Available in other materials, sizes and designs
- Accessories see page 12 and 13
- Gerresheimer offers full solution for irradiated products incl. validation
- ETO sterilization on request

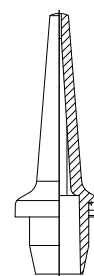
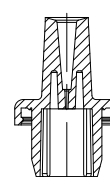
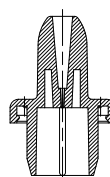
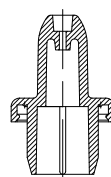
Dropper bottles – System A

Accessories



Dropper

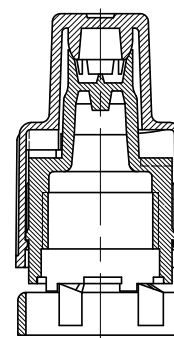
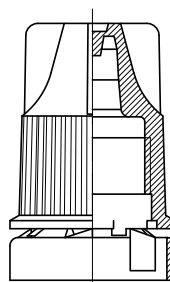
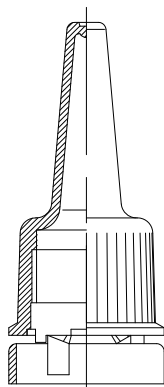
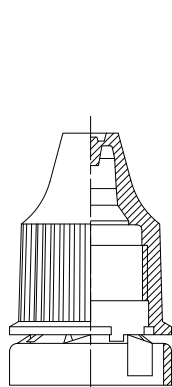
Nozzle



**Tamper-evident
screw cap**


**Tamper-evident
wing screw cap**

**Child-resistant
tamper-evident
screw cap**





SPECIFICATIONS

	ref	 Drops/ml +/- 30%		ref	comments
Dropper	14110	21	Tamper-evident screw cap	15190	Available in white
	14166	23		15197	Fits ref 14214
	14182	23		15233	Available in colours (not white)
	14213	22		15255	Fits ref 14216
	14214	28	Tamper-evident screw cap for nozzle	15207	Fits ref 14180
	14216	22	Tamper-evident wing screw cap	15250	
	14219	13	Child-resistant tamper-evident screw cap	91176	
Nozzle	14180	–			

- Material: dropper LDPE, nozzle LDPE
- Available in other materials, sizes and designs
- Droppers and nozzles fit bottle sizes on page 10 and 11

- Material: tamper-evident screw cap HDPE, tamper-evident wing screw cap HDPE, child-resistant tamper-evident screw cap HDPE
- Available in other materials, sizes and designs
- Caps fit bottle sizes on page 10 and 11

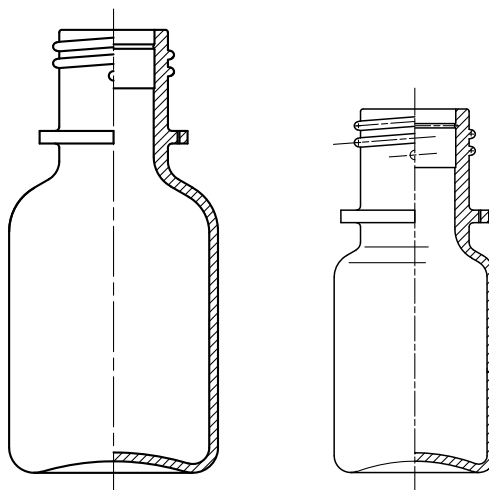
Dropper bottles – System B



SPECIFICATIONS

- Material: LDPE
- Available in other materials, sizes and designs
- Accessories: see page 15
- Gerresheimer offers full solution for irradiated products incl. validation
- ETO sterilization on request

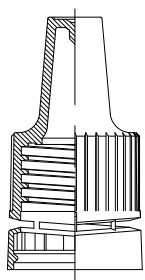
ref	ml	ml	mm	mm	mm
38005	5	7,1	19	44	16 x 2
38010	10	14,2	25	53	16 x 2



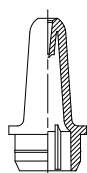
Dropper bottles – System B Accessories



**Tamper-evident
screw cap**



Dropper



Drops/ml +/- 20%

	ref	
Tamper-evident screw cap	15015	–
Dropper	14004	21

- Material: dropper LDPE, tamper-evident screw cap HDPE
- Available in other materials, sizes and designs
- Droppers and caps fit bottle sizes on page 14



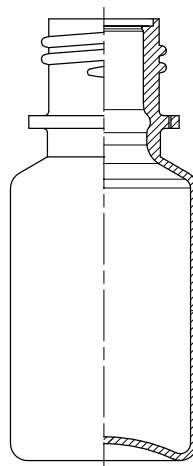
Dropper bottles – System D



SPECIFICATIONS

- Material: LDPE
- Available in other materials, sizes and designs
- Accessories: see page 17
- Gerresheimer offers full solution for irradiated products incl. validation
- ETO sterilization on request

ref	ml	ml	mm	mm	mm
35083	5	7,6	20	43,5	14,7
35081	10	11,5	22	52,0	14,7



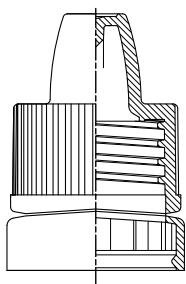
Dropper bottles – System D

Accessories

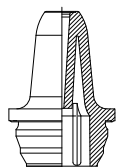


SPECIFICATIONS

**Tamper-evident
screw cap**



Dropper



ref

Drops/ml +/- 20%

Tamper-evident screw cap	15020	–
Dropper	14015	20

- Material: dropper LDPE, tamper-evident screw cap HDPE
- Available in other materials, sizes and designs
- Droppers and caps fit bottle sizes on page 16

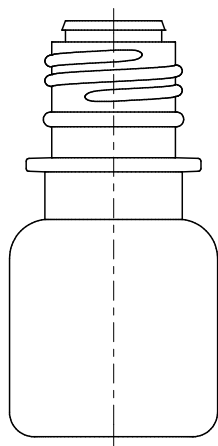
Dropper bottles – System E/F



SPECIFICATIONS

- Material: LDPE
- Gerresheimer offers full solution of irradiated products incl. validation
- ETO sterilization on request

ref	ml	ml	mm	mm	mm
35178	5	7,20	21,20	42,40	14,00
35179	10	12,40	24,10	51,80	14,00
35180	15	18,30	25,30	63,00	14,00
35181	30	34,00	30,75	75,00	14,00



Dropper bottles – System E/F

Accessories

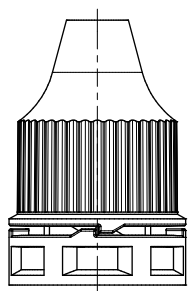


System E
Cap with fixed TE-ring

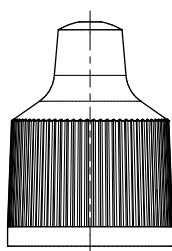


System F
Sleeved cap

SPECIFICATIONS




System E
Cap with fixed
TE-ring



System F
Sleeved cap

Caps System E

	ref	 Drops/ml +/- 20%
Tamper-evident screw cap white	15033	–
Tamper-evident screw cap colored	15035	–

Caps System F

Tamper-evident screw cap white	15009	–
Tamper-evident screw cap colored	15031	–

Droppers System E/F

	14166	23
	14182	23
	14110	21
	14213	22
	14219	13

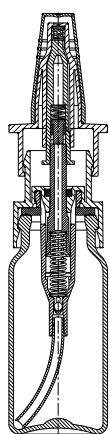
- Material: dropper LDPE, tamper-evident screw cap and sleeved cap HDPE



Spray and pump systems: Snap-on bottles / Crimp bottles



Snap-on bottles



ref	ml	ml	mm	mm	mm
35022	10	16,1	24	53	20
35023	15	18	24	58	20
35014	20	23	29	53	20
35176	20	27	31	50,7	20

- Material: bottle HDPE
- Available in other materials, sizes and designs
- Reference to spray / pump supplier on request

Crimp bottles

ref	ml	ml	mm	mm	mm
35175	15	20,5	25,5	54,4	20
35090	20	25	31	50,7	20

- Material: bottle HDPE
- Dedicated for crimp pumps

Monolayer vials (standard and RTS)



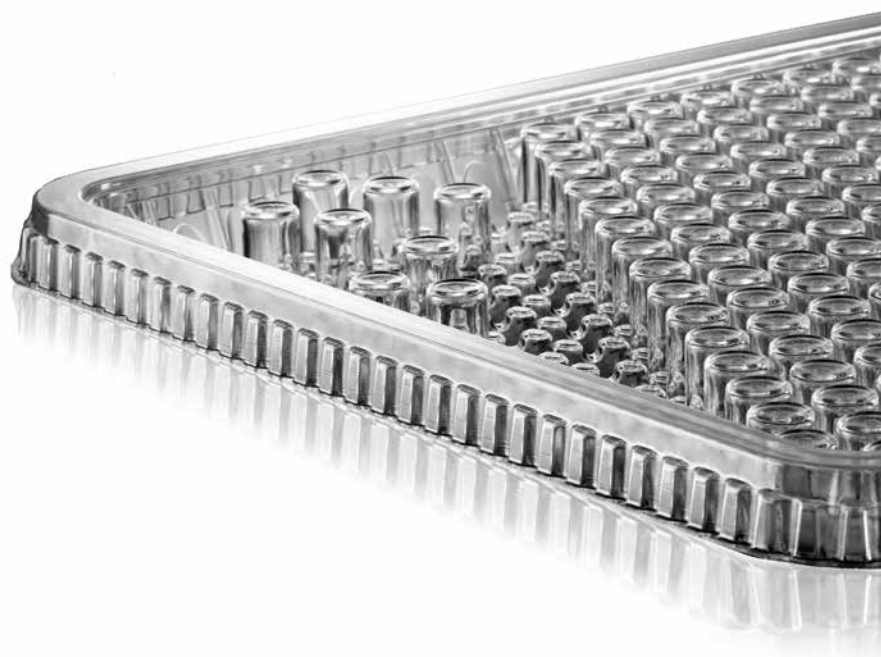
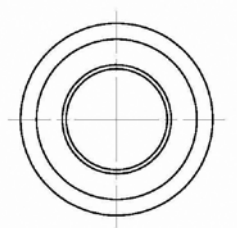
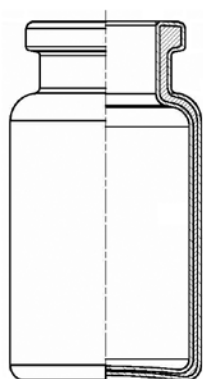
Product characteristics

- Break resistance
- Inert against high and low pH value (no delamination)
- Low absorption (protein derived active ingredients)
- Excellent drainability
- No heavy metal ions release
- Available in 2, 5, 10, 50 and 100 ml

Product offering

- Monolayer plastic vials based on COP – standard and ready-to-sterilize (includes certified Bioburden, Endotoxin and Particle level)





SPECIFICATIONS

ref		ml	ml	mm	mm	mm	mm	mm	g
39001	EN ISO 8362-1	2	3,5	16	35	3,6	13	7	2,7
39002	EN ISO 8362-1	5	9,1	22	40	3,6	20	12,6	4,9
39003	EN ISO 8362-1	10	12,5	24	45	3,6	20	12,6	6,1
39005	EN ISO 8362-4	50	67	42,5	73	3,8	20	12,6	16
39006	EN ISO 8362-4	100	132,2	51,6	94,5	3,8	20	12,6	26,5

PRODUCT PACKAGING AND FINISH DESCRIPTION

	Specification	Standard	RTS	Irradiated
Production environment	ISO 7	●	●	●
Packaging processing	Fully automated	●	●	●
Packaging environment	ISO 7	●	●	●
Packaging materials in direct contact with vials	Produced in ISO 7	●	●	●
Dimensions	Accord. to standard specification	●	●	●
Defects	Accord. to standard specification	●	●	●
Cleanliness	Accord. to standard specification	●	●	●
Endotoxin	Certified per batch; limit: EU		●	
Particles	Certified per batch; limit:		●	●
Bioburden	Certified per batch; limit: cfu		●	●
Gamma radiation	Validated sterilisation dose			●
Sterilisation	Certified per batch / parametric release			●
Endotoxin test post sterilisation	Certified per batch			●



Europe

Gerresheimer Vaerloese A/S

Walgerholm 2-8
3500 Vaerloese (Denmark)
Strandgade 87
5683 Haarby (Denmark)
Tel. +45 4477 7888

Gerresheimer Bolesławiec S.A.

ul. Bolesława Chrobrego 15
59-700 Bolesławiec (Poland)
Tel. +48 75 735 04 00

Gerresheimer Zaragoza, S.A.

P.I. Valdemuel
Camino del Sabinar, s/n
50290 Epila, Zaragoza (Spain)
Tel. +34 976 817 408

South America

Gerresheimer Plásticos São Paulo Ltda

Rua da Congregação 56
06816-902 Embu, São Paulo (Brazil)
Tel. +55 11 2133 1212

Gerresheimer Plásticos São Paulo Ltda

Rua Mario Regalo Pereira, Nr. 160 and 170
05550-060 Butantã, São Paulo (Brazil)
Tel. +55 11 3783 83 50

Gerresheimer Plásticos São Paulo Ltda

VP 3 E S/N. Qd 06 A Módulo 02
Barreiro do Meio – Distrito Agroindustrial
75132-100 Anápolis (Brazil)
Tel. +55 62 3142-2555

North America

Centor Inc.

5091 County Road 120
44610 Berlin, OH (USA)
Tel. +1 404 376 8157

Asia

Triveni Polymers Pvt. Ltd.

Kundli Plant, Haryana
G.T. Road, Piao Maniyari
Kundli-131028 Distr. Sonapat
Haryana (India)
Tel. +91 130 2219070

Triveni Polymers Pvt. Ltd.

Village Kunwarda, Taluka Mangrol
Kosamba (R.S.), Distr. Surat
394120 Gujarat (India)
Tel. +91 264 6270664

Gerresheimer Singapore Pte. Ltd.

1 Paya Lebar Link, Paya Lebar Quarter 1
#04-01 Singapore 408533
Tel. +65 6955 8639

Gerresheimer Plastic Packaging (Changzhou) Co., Ltd.

No. 280, Fumin Road, Lucheng Street
Changzhou City, Jiangsu Province (China)
Tel. +86 139 0182 8508