

**GERRESHEIMER**

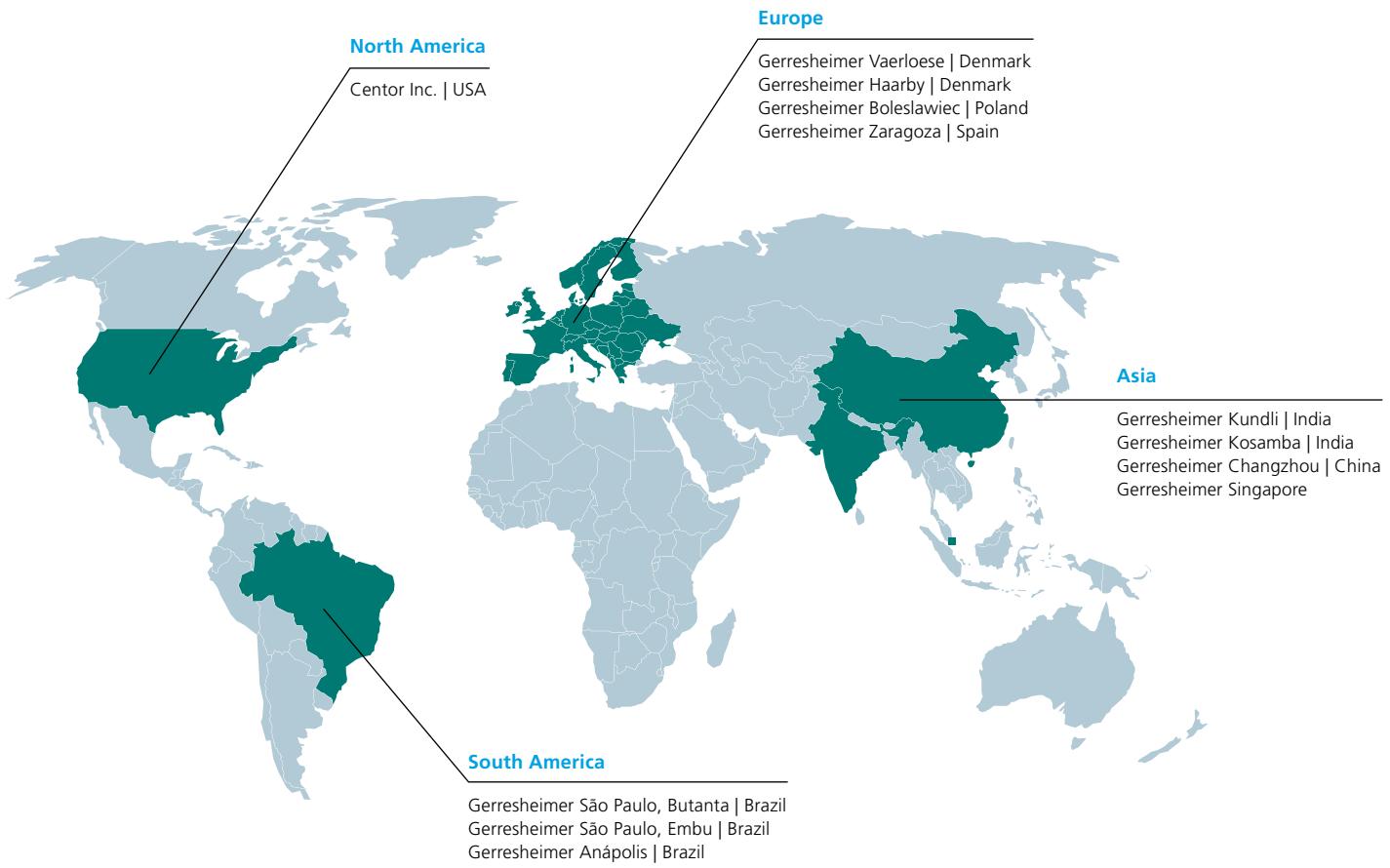


# High-Quality Pharmaceutical Plastic Packaging and Systems

for Ophthalmic, Nasal and  
Parenteral Applications



# Gerresheimer Plastic Packaging



## About Gerresheimer

Gerresheimer is a leading global partner to the pharma and health-care 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, prefilled 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 &amp; 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 pharmacopeia 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.

We have our customers in focus



## 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.



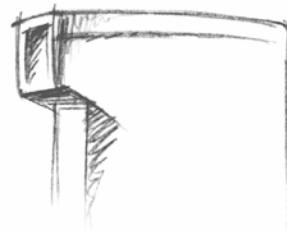
We offer full solution for irradiated products incl. validation. Radiation with  $VD_{max} = 17,5 \text{ kGr}$  acc. to ISO 11137.

# 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.

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

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

- 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



**1** Dropper bottles –  
System A  
**Standard bottle**



Accessories System A  
**Caps with short droppers**



**3** Dropper bottles –  
System B  
**Special bottle design**



Accessories System B  
**Caps with long droppers**



**5** Dropper bottles –  
System D  
**Special bottle design**



Accessories System D  
**Caps with short droppers**



**7** Dropper bottles –  
System E/F  
**Standard US bottle**



Accessories System E/F  
**Cap with fixed TE-ring  
Sleeved cap**

## Nasal



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

## Parenteral



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
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- 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

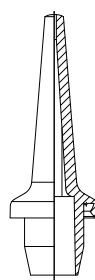
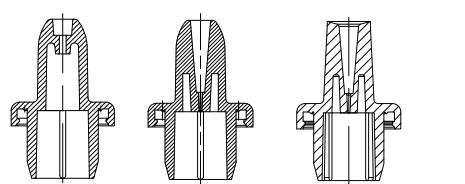
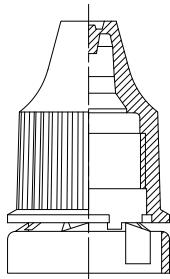
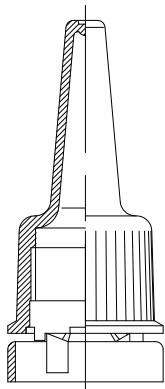
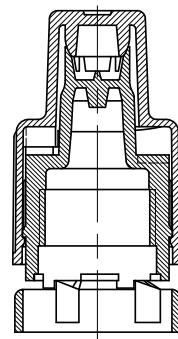
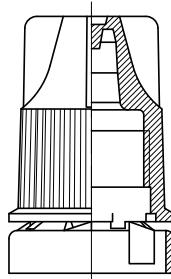


# Dropper bottles – System A Accessories



Dropper

Nozzle

Tamper-evident  
screw capTamper-evident  
wing screw capChild-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

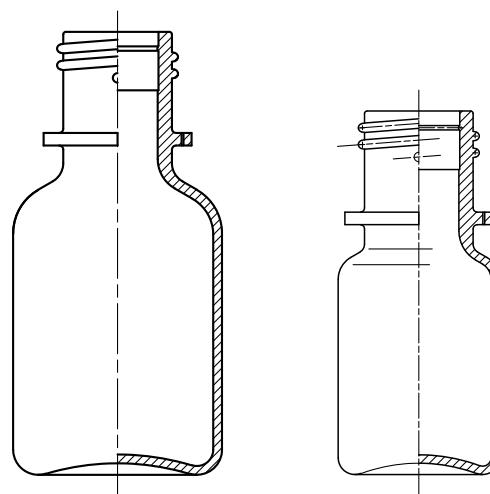
# Dropper bottles – System B



## SPECIFICATIONS



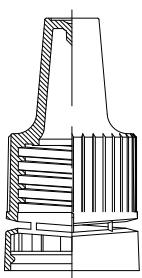
• Material: LDPE	38005	5	7,1	19	44	16 x 2
• Available in other materials, sizes and designs	38010	10	14,2	25	53	16 x 2



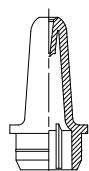
# Dropper bottles – System B Accessories



**Tamper-evident  
screw cap**



**Dropper**



ref

Drops/ml +/- 20%

Tamper-evident 15015 –

screw cap

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

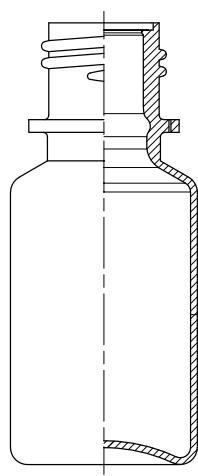


• Material: LDPE	35083	5	7,6	20	43,5	14,7
• Available in other materials, sizes and designs	35081	10	11,5	22	52,0	14,7

- Accessories: see page 17

• Gerresheimer offers full solution for irradiated products incl. validation

• ETO sterilization on request

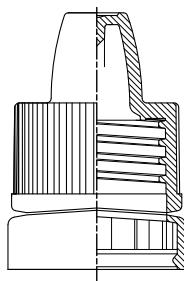


# Dropper bottles – System D Accessories

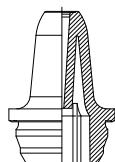


## SPECIFICATIONS

**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

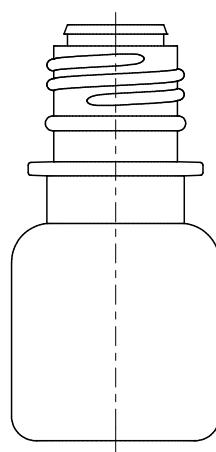
# Dropper bottles – System E/F



## 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

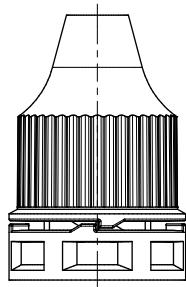


**System E**  
Cap with fixed TE-ring

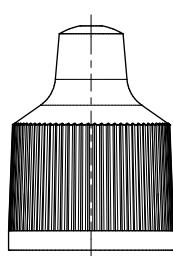


**System F**  
Sleeved cap

### SPECIFICATIONS



**System E**  
Cap with fixed  
TE-ring



**System F**  
Sleeved cap



Drops/ml +/- 20%

#### Caps System E

	ref	
Tamper-evident screw cap white	15033	–
Tamper-evident screw cap colored	15035	–

#### Caps System F

	ref	
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

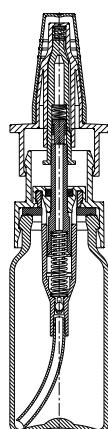
- Material: dropper LDPE, tamper-evident screw cap and sleeved cap HDPE



# 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



- Material: bottle HDPE
- Dedicated for crimp pumps

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

# Monolayer vials (standard and RTS)



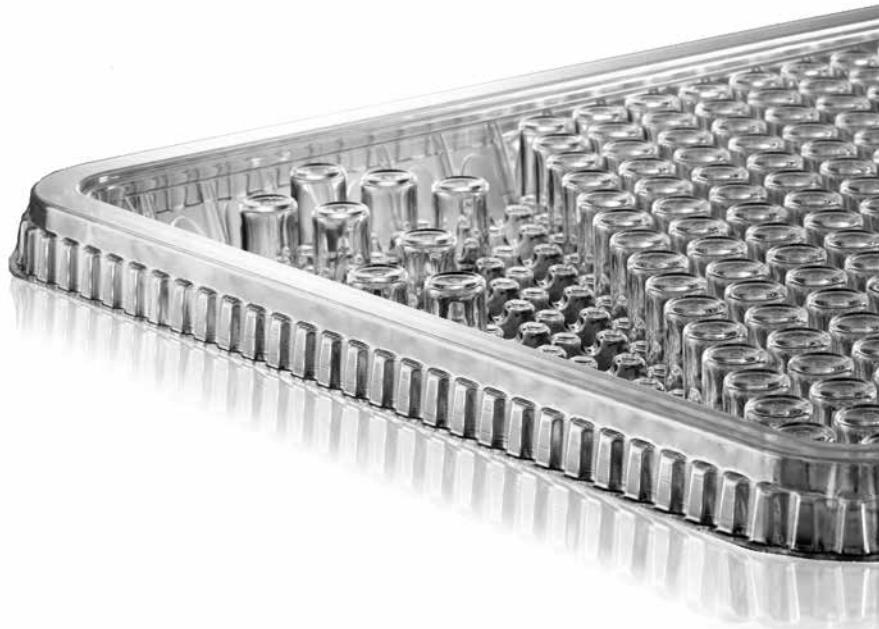
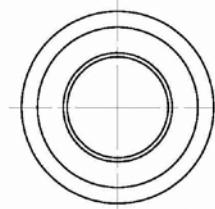
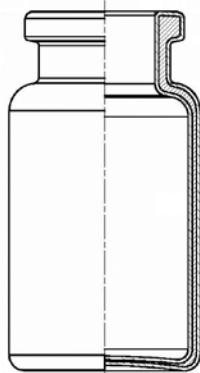
## Product characteristics

- 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	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			●

# GERRESHEIMER



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Pharmaceutical Plastic Packaging  
and Systems for South America is  
to be found in a separate catalogue