

VERPACKUNGSZERTIFIKAT

Artikelbeschreibung

Datum: 17.05.2023

Chargen Nr.: 2314420
(10119517 + 10113032 + 10116572)

Artikelnummer: 027300

Artikelbezeichnung: Augentropfflasche 10 ml PE
natur + Verschluss + Tropfeinsatz;
sterilisiert

Verpackungsdaten

Menge pro VE: 250 Stück

Verpackt in:

Je 1 Stück pro Beutel, 10 Beutel in PE Folie,
25 x 10 Stück PE Beutel in einem PE Sack + Karton

keim- und partikelarm verpackt lt. DIN EN ISO 15378:2017

Bildein, 17.05.2023

Ort, Datum

Elpack Packaging GmbH Lager
Paracelsusweg 1
7521 Bildein

BESTRAHLUNGSZERTIFIKAT

Lieferscheinnr.: 20232832

Lieferdatum: 26.05.2023

Seite 1 von

PCN	PCN Datum	Produktnr.	Lot Nr.	Dnom [kGy]	Dmin [kGy]	Dmax [kGy]	Pakete Stk	
Kundenanlieferschein.: 23-0016								
202307367	26.05.2023	EL027300	2314420	25,0	50,0	30,8	38,6	24

Die Behandlung der Produkte erfolgte mittels E-Beam nach EN ISO 13485 sowie ISO 11137.

Die Dosiskontrolle wird durchgeführt. Die Kalibrierung der Dosimeter ist rückverfolgbar auf einen NPL-Standard.

26.05.2023



(Shift Coordinator)

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Gerresheimer Boleslawiec S.A.
ul. Bolesława Chrobrego 15
59-700 Bolesławiec



Customer GROTEX	Batch no. 10119517	Art. Nr. 210035
Gerresheimer SAP article no. 256350350176	Gerresheimer article description 35035 BOTTLE 10 ML NATURAL	
Gerresheimer drawing no./version LT.35035.001	Print drawing no./version 02 K	
Customer reference no.	Machine no. 223	
Customer Order no. 46	Cavity from - to 145-156	
Customer Sales Order no. 2550015107	Mold no. M35035J	
Quantity Customer samples -	Production date from - to 17.05.2022 - 24.05.2022	
Production Order Quantity 300.000	Produced Quantity 300.000	
Raw-material description PE LD PURELL 1810 E	Colorant	
Raw-material batch BB2445I03; BC2845I04	Colorant batch	

Visual defects

Failure Code	Defect Criteria	AQL	Inspect.qty	D*	Ac*	inspect. result
0001	Contamination inside	0.00	800	0	0	According to requirements
0002	Contamination outside	0.25	800	0	5	According to requirements
0003	Colour out of tolerance	0.25	800	0	5	According to requirements
0004	Colour blotchy, streaky	1.00	800	0	14	According to requirements
0005	Foreign bodies incorporated in material < 0,5 mm	4.00	315	0	21	According to requirements
0006	Foreign bodies incorporated in material > 0,5 mm	0.25	800	0	5	According to requirements
0007	Severe misshapening, deformation, poorly formed - processing not possible	0.25	800	0	5	According to requirements
0008	Slight misshapening, deformation, poorly formed - processing possible	4.00	315	0	21	According to requirements
0009	Production waste not removed (flashes) - function affected	0.25	800	0	5	According to requirements
0010	Holes, cracks, inadequately welded seams	0.00	800	0	0	According to requirements

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Customer GROTEX	Batch no. 10119517	Art. Nr. 210035
Gerresheimer SAP article no. 256350350176	Gerresheimer article description 35035 BOTTLE 10 ML NATURAL	

0011	Weakness at welded seam (thin part), seam disintegrates under slight stress - function affected	0.25	800	0	5	According to requirements
0012	Thread/ snapper ring incompletely formed - function affected	0.00	800	0	0	According to requirements
0013	Mouth / sealing area deformed and/or damaged uneven (e.g. grooves, burrs, flasches), leakages	0.00	800	0	0	According to requirements
0014	Identification weak, text not legible in context, misinformation	0.00	800	0	0	According to requirements
0015	Identification weak / uneven, still legible, no misinformation	4.00	315	0	21	According to requirements
0016	Starting material must correspond to the specification	0.00	800	0	0	According to requirements
0017	Colour does not conform to the specification	0.00	800	0	0	According to requirements

Dimentional/Function defects

Failure code	Defect criteria	AQL	Inspect.qty	D*	Ac*	Required values	Actual values	inspect.result
0001	Internal mouth diameter /ovality	0.00	80	0	0	8,00 -8,20 MM	8,10 -8,10MM	According to requirements
0002	Wall thickness (body)	0.00	80	0	0	0,30 -1,20 MM	0,73 -0,90MM	According to requirements
0003	Volume (completely filled up)	0.00	80	0	0	12,00 -13,00 ML	12,32 -12,37ML	According to requirements
0004	Overall height	0.00	80	0	0	51,40 -52,20 MM	51,49 -52,20MM	According to requirements
0005	Neck ring diameter	0.00	80	0	0	14,00 -14,60 MM	14,00 -14,15MM	According to requirements
0006	Snapping ring diameter	0.00	80	0	0	10,30 -10,70 MM	10,32 -10,53MM	According to requirements
0007	Tamper proof ring diameter	0.00	80	0	0	16,70 -17,30 MM	16,74 -17,07MM	According to requirements
0008	Test for leakage (reduced pressure)	0.00	80	0	0	0 ST	0 -0ST	According to requirements
0009	Weight	0.00	80	0	0	3,20 -3,60 G	3,37 -3,39G	According to requirements

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Customer GROTEX	Batch no. 10119517	Art. Nr. 210035
Gerresheimer SAP article no. 256350350176	Gerresheimer article description 35035 BOTTLE 10 ML NATURAL	

0010	External body diameter	0.00	80	0	0	23,80 -24,40 MM	23,82 -24,15MM	According to requirements
0011	Length of neck	0.00	80	0	0	20,00 -20,50 MM	20,17 -20,47MM	According to requirements
0012	Total height of the snap ring	0.00	80	0	0	2,00 -2,30 MM	2,06 -2,29MM	According to requirements
0013	External thread diameter	0.00	80	0	0	13,80 -14,20 MM	13,82 -13,97MM	According to requirements

Ac* = acceptance level
D* = quantity of defects

We hereby confirm that the batch mentioned above has been produced and inspected in accordance with the specifications agreed upon. The permissible limit values have not been exceeded.

Date, signature

2022 -05- 27	Specjalista ds. Jakości	2022 -05- 27	Manager ds. Jakości
Inspector QC		2022 -05- 27	
	Elzbieta Czubak		Marcin Ciotkowski

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Customer Tubilux Pharma S.P.A.	Batch no. 10116572	Art. Nr. 210002
Gerresheimer SAP article no. 256141660088	Gerresheimer article description 14166 DROPPER NATURAL	
Gerresheimer drawing no./version LT.14166.001	Print drawing no./version 02 K	
Customer reference no. 33064/1	Machine no. 314	
Customer Order no. STOCK	Cavity from - to 263-294	
Customer Sales Order no. 2550006161	Mold no. M14166N	
Quantity Customer samples 80	Production date from - to 26.10.2021 - 27.10.2021	
Production Order Quantity 280.000	Produced Quantity 280.000	
Raw-material description PE LD PURELL 1840 H	Colorant	
Raw-material batch AG0145H26	Colorant batch	

Visual defects

Failure Code	Defect Criteria	AQL	Inspect.qty	D*	Ac*	inspect. result
0001	Colour out of tolerance	0.00	800	0	0	According to requirements
0002	Holes or tears, incompletely formed, deformation	0.00	800	0	0	According to requirements
0003	Deformation - function impaired	0.10	800	0	2	According to requirements
0004	Folds, notches, scratches, rough surface, flash > 0,3mm	2.50	500	0	21	According to requirements
0005	Duct partially blocked-function impaired	0.10	800	0	2	According to requirements
0006	Duct blocked-dosage impossible	0.00	800	0	0	According to requirements
0007	Starting material must correspond to the specification	0.00	800	0	0	According to requirements
0008	Roughness in the area of the dropping rim and of the sealing areas - seal not possible	0.00	800	0	0	According to requirements
0009	If during examination an example of a different type that would not be detected through impairment of the processing procedure is found, then the delivery must be immediately quarantined and thoroughly sorted.	0.00	800	0	0	According to requirements
0010	Burn marks > 2 mm diameter	0.10	800	0	2	According to requirements

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Customer Tubilux Pharma S.P.A.	Batch no. 10116572	Art. Nr. 210002
Gerresheimer SAP article no. 256141660088	Gerresheimer article description 14166 DROPPER NATURAL	

0011	Burn dots 0,5 to 2 mm diameter	0.40	800	0	7	According to requirements
0012	Foreign bodies enclosed in material	0.40	800	0	7	According to requirements
0013	Over-injection, flash at the sealing points	0.10	800	0	2	According to requirements
0014	Injection point does not comply- lateral max 0,5 mm	0.10	800	0	2	According to requirements
0015	Contamination with foreign bodies or material residues or considerably soiled and/or dust- mixing up with the filling liquid	0.00	800	0	0	According to requirements

Dimentional/Function defects								
Failure code	Defect criteria	AQL	Inspect.qty	D*	Ac*	Required values	Actual values	inspect.result
0001	Overall height	0.00	80	0	0	18,50 -19,30 MM	18,69 -19,13MM	According to requirements
0002	Duct diameter	0.00	80	0	0	0,60 -1,00 MM	0,80 -0,80MM	According to requirements
0003	Body, lamellae or olive diameter	0.00	80	0	0	8,30 -8,55 MM	8,30 -8,43MM	According to requirements
0004	Sealing plate diameter	0.00	80	0	0	12,10 -12,40 MM	12,10 -12,31MM	According to requirements
0005	Air tube diameter, external	0.00	80	0	0	5,90 -6,10 MM	5,91 -6,00MM	According to requirements
0006	Test for leakage (reduced pressure)	0.00	80	0	0	0 ST	0 -0ST	According to requirements
0007	Sealing plate thickness	0.00	80	0	0	2,80 -3,00 MM	2,88 -2,98MM	According to requirements
0008	Length of dropper tube	0.00	80	0	0	7,70 -7,90 MM	7,70 -7,79MM	According to requirements

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D* = quantity of defects

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Customer Tubilux Pharma S.P.A.	Batch no. 10116572	Art. Nr. 210002
Gerresheimer SAP article no. 256141660088	Gerresheimer article description 14166 DROPPER NATURAL	

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Date, signature

2021 -11- 0 5 Specialista ds. Jakości	2021 -11- 0 5 Menadzer Kontrolny Jakości
Inspector QC	Manager QC

Elżbieta Czubak

Daniel Rutkowski

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Customer Elpack Packaging GmbH	Batch no. 10113032	Art. Nr. 210010
Gerresheimer SAP article no. 256151900147	Gerresheimer article description 15190 CAP TE WHITE GI	
Gerresheimer drawing no./version LT.15190.001	Print drawing no./version 03 K	
Customer reference no. 210010	Machine no. 411	
Customer Order no. 21-0103	Cavity from - to 202-217	
Customer Sales Order no.	Mold no. M15190N	
Quantity Customer samples -	Production date from - to 28.10.2020 - 05.11.2020	
Production Order Quantity 504.000	Produced Quantity 117.600	
Raw-material description PE HD PURELL GC 7260	Colorant White Euthylen 00-1905 concentrate	
Raw-material batch YF0142102; YG0542101	Colorant batch 0020302318; 0022684765	

Visual defects

Failure Code	Defect Criteria	AQL	Inspect.qty	D*	Ac*	inspect. result
0001	Tamper-proof ring missing	0.00	1.250	0	0	According to requirements
0002	Colour out of tolerance	0.00	1.250	0	0	According to requirements
0003	Holes or tears, incompletely formed, deformation	0.00	1.250	0	0	According to requirements
0004	Deformation - function impaired	0.10	1.250	0	3	According to requirements
0005	Folds, notches, scratches, rough surface, flash > 0,3mm	2.50	500	0	21	According to requirements
0006	Starting material must correspond to the specification	0.00	1.250	0	0	According to requirements
0007	Roughness in the area of the dropping rim and of the sealing areas - seal not possible	0.00	1.250	0	0	According to requirements
0008	If during examination an example of a different type that would not be detected through impairment of the processing procedure is found, then the delivery must be immediately quarantined and thoroughly sorted.	0.00	1.250	0	0	According to requirements
0009	Connecting strip torn off-numerically more than half of the studs	0.00	1.250	0	0	According to requirements
0010	Burn marks > 2 mm diameter	0.10	1.250	0	3	According to requirements

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Customer Elpack Packaging GmbH	Batch no. 10113032	Art. Nr. 210010
Gerresheimer SAP article no. 256151900147	Gerresheimer article description 15190 CAP TE WHITE GI	

0011	Burn dots 0,5 to 2 mm diameter	0.40	1.250	0	10	According to requirements
0012	Sealing cone/ring skew/ deformity	0.10	1.250	0	3	According to requirements
0013	Foreign bodies enclosed in material	0.40	1.250	0	10	According to requirements
0014	Over-injection, flash at the sealing points	0.10	1.250	0	3	According to requirements
0015	Injection point does not comply- central max 0,7 mm	0.10	1.250	0	3	According to requirements
0016	Contamination with foreign bodies or material residues or considerably soiled and/or dust- mixing up with the filling liquid	0.00	1.250	0	0	According to requirements

Dimentional/Function defects

Failure code	Defect criteria	AQL	Inspect.qty	D*	Ac*	Required values	Actual values	inspect.result
0001	Height to sealing pin	0.00	125	0	0	7,40 -7,60 MM	7,43 -7,58MM	According to requirements
0002	Rotational or snapping properties	0.00	125	0	0	15,00 -55,00 N	32,60 -48,80N	According to requirements
0003	Core diameter	0.00	125	0	0	13,00 -13,30 MM	13,00 -13,15MM	According to requirements
0004	Overall height	0.00	125	0	0	31,30 -32,50 MM	31,69 -32,18MM	According to requirements
0005	Top external diameter of fluting	0.00	125	0	0	17,20 -17,80 MM	17,22 -17,60MM	According to requirements
0006	Diameter above the collar	0.00	125	0	0	17,90 -18,50 MM	17,91 -18,12MM	According to requirements
0007	External diameter	0.00	125	0	0	20,20 -20,80 MM	20,22 -20,43MM	According to requirements
0008	Test for leakage (reduced pressure)	0.00	125	0	0	0 ST	0 -0ST	According to requirements

Ac* = acceptance level
D* = quantity of defects

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Customer Elpack Packaging GmbH	Batch no. 10113032	Art. Nr. 210010
Gerresheimer SAP article no. 256151900147	Gerresheimer article description 15190 CAP TE WHITE GI	

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Date, signature

Specialista ds. Jakości

Menedżer

Kontroli Jakości

2021 -04- 2 9	2021 -04- 2 9
Inspector <i>Margona Zacher</i>	Manager QC <i>Andrzej Rutkowski</i>