

# Certificate of Analysis

Capacity: 0250	Material Description: SIRUPFLASCHE 250 ML SAF HK	Colour: amber
Lot-No.: 20160908	Production date: 08.09.2016	Produced quantity: 50.160

Pallet No.: 000001 to 000029 à 1.680  
000030 to 000030 à 1.440

## 1. Material- / Article properties

	specification	result				
<b>1.1. Particles &amp; Germs</b>						
Particles	HG/01	complied				
Germs	Ph.Eur.	complied				
<b>1.2. Glass quality / Hydrolytic res.</b>						
Moulded Glass	YES					
Glass type per last issue Ph-Eur/USP/JP	Typ 3					
Arsen content Ph.-Eur.3.2.1	<0,1ppm	complied				
Ph.EU.3.2.1 SurfaceGlassTest (A)	complied					
Ph.EU.3.2.1 Spect.Transmiss. MAX	Req.: +10,00	Act: x 3,36	Act: min	Act: max	Unit %	

## 2. Material specification

### 2.1. Technical specification (drawing)

	Req.:	Act: x	Act: min	Act: max	Unit
Overall height	143,90 +-1,20	144,06	143,60	144,45	mm
Entry of mouth Ø (BoreØ)	20,00 +-0,30	19,97	19,89	20,10	mm
Core diameter Ø	24,90 +0,30 -0,35	25,02	24,90	25,19	mm
Thread Ø	27,10 +0,30 -0,35	27,05	26,88	27,22	mm
Diameter of crimp	27,70 +0,30 -0,35	27,60	27,39	27,82	mm
Finish height (Chamfer)	15,40 +-0,25	15,46	15,41	15,50	mm
Body	61,70 +-1,30	61,50	60,92	62,05	mm
Perpendicularity	+2,80	1,17	1,00	2,00	mm
Deviation from top surface	+0,60	0,15	0,10	0,25	mm

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Glass weight	152,00	155,63	154,40	156,70	g
Brimfull capacity	262,00 $\pm$ 4,80	261,92	261,20	262,70	ml

### 2.2. Surface treatment

Coating Hot End & Cold End	Hotend TC100/Coldend RP40LT				
	Req.:	Act: x	Act: min	Act: max	Unit
Coating thickness HG/02	12,50 $\pm$ 7,50	20,00	20,00	20,00	CTU
Angle of slip HG/03	15,00 $\pm$ 3,00	13,50	13,00	14,00	deg


### 2.3. Strength tests

### 2.4. Visual tests

Lot size N (pieces)	number of pallets (minimum number)	Numbers of shipping units to be opened (Min)	Number of individual pieces to be removed	Random sample size N
10.001 - 35.000	1	15	21	315
35.001 - 150.000	2	20	25	500
150.001 - 500.000	3	25	32	800
> 500.000	5	30	41-42	1250

Herewith we confirm that the quality of the containers mentioned above does comply with the valid testing standards in compliance with specifications and drawing detailed and the defect evaluation list for containers made from Moulded Glass, Vol. 14 (Editio Cantor Verlag, Aulendorf). The inspections have been carried out based on the current Pharm. Eur. USP and JP, the valid tolerances have not been exceeded.

Beriain, 7<sup>th</sup> April 2018

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