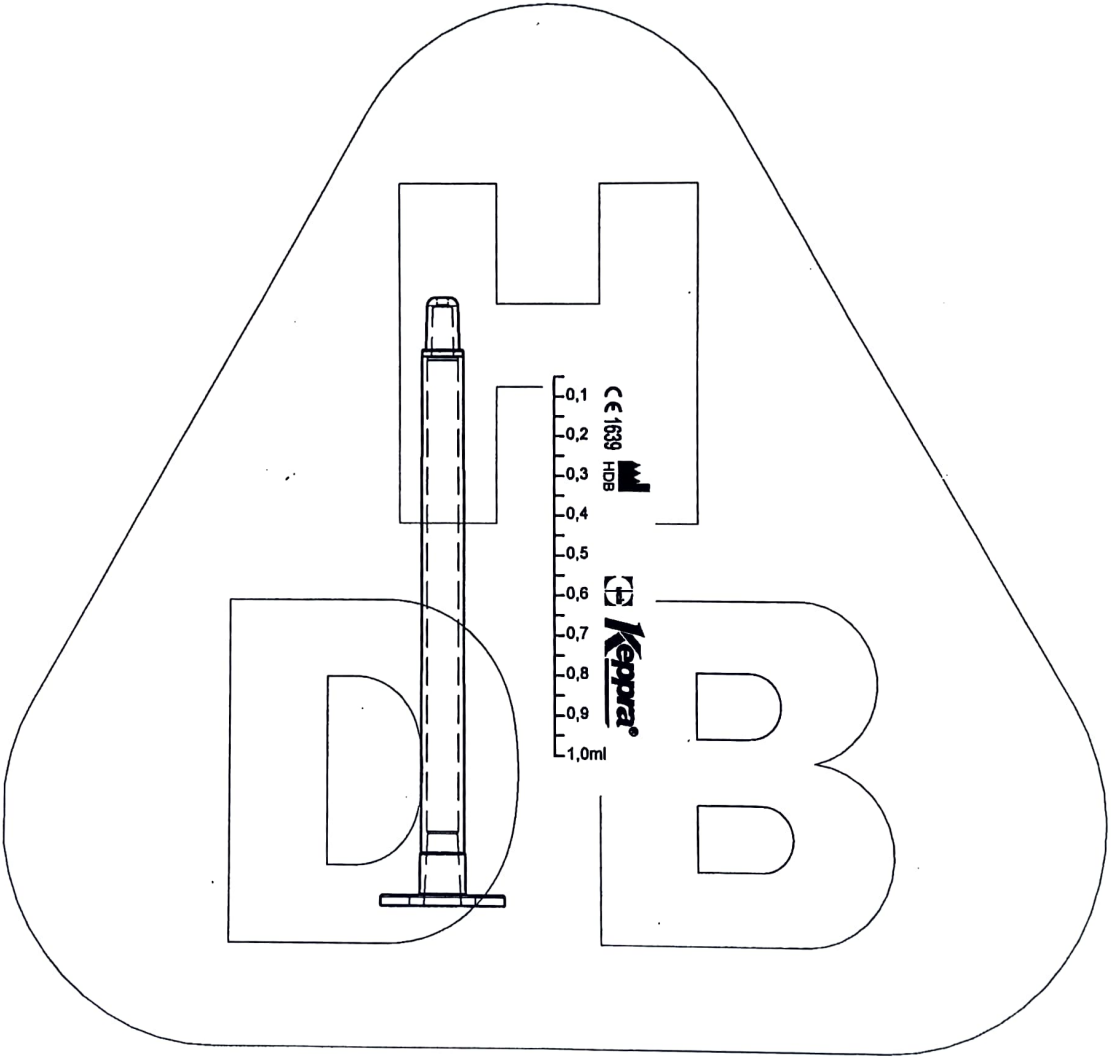




Modification:		Date:	Changed:	
<div></div>				
Notes: 1. The tolerance is only valid for the range going from the nominal capacity (1ml) up to and including 10% of the nominal capacity. The accuracy for graduation lines below 10% of the nominal capacity exceeds the defined tolerance, a dosing applicator should not be used to accurately dose less than 10% of its nominal capacity.				
Artwork approved by:		Artwork details:		
Customer:	UCB	Color:	PMS 180 C	
Name:	J.F. DECASTER	HDB-code:	459	
Date:	05-APR-2019			
Signature:		Name: MVD144	Date: 04/03/2019	Scale: 1/1
This drawing is copyrighted, all rights are reserved. This document may not be copied or reproduced without prior consent, in writing, from HDB.			Rev.: ①	HDB Norm: N1002/1
H.DE BACKER NV TEMSE BELGIUM		Title: Artwork Approval		Dwg N° K083
				Part N° T2023

Annex 3: Syringes and adaptor specification and drawing

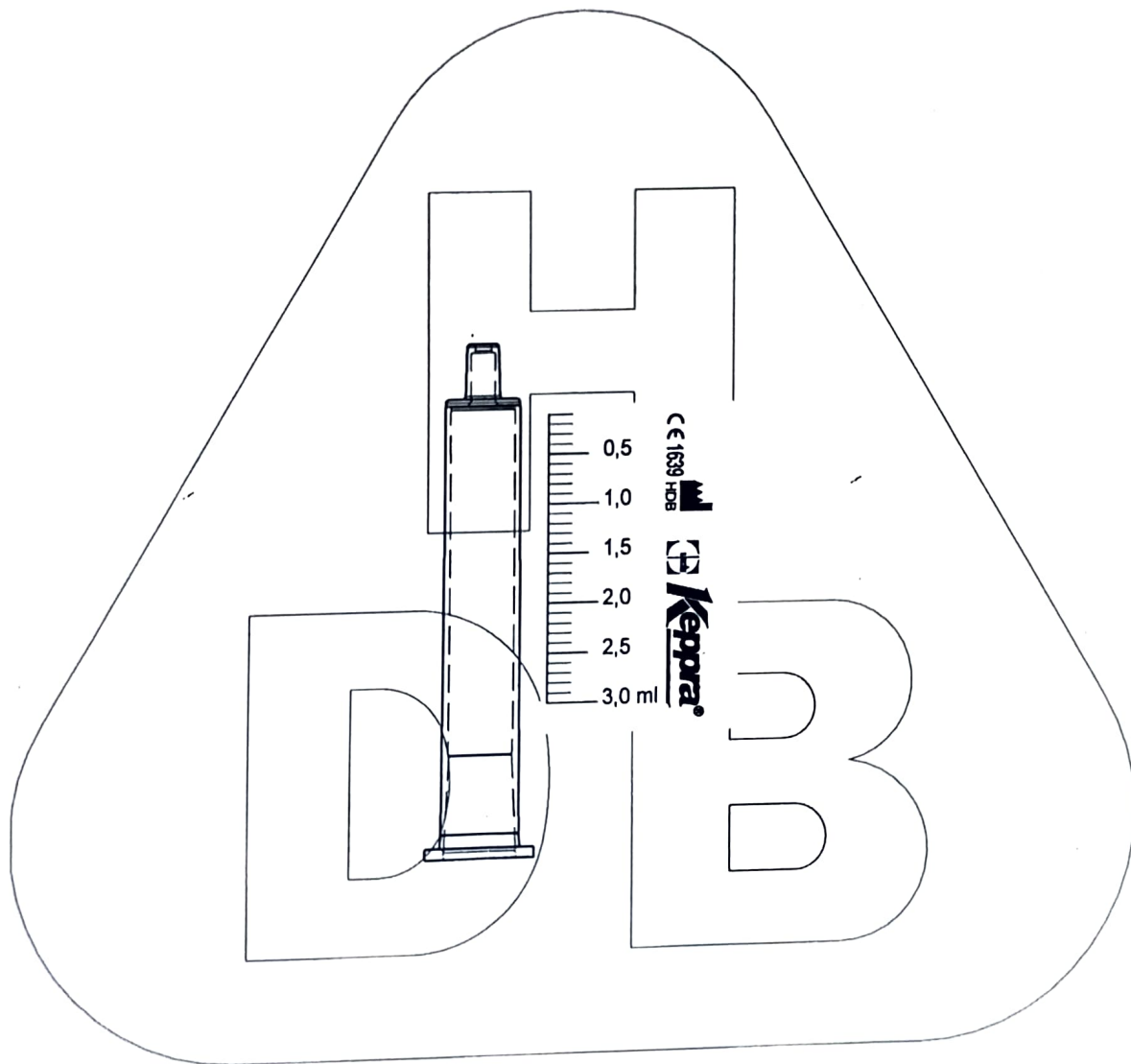
Annex 3.1: 1.0mL Syringe

<u>PARAMETERS</u>	<u>SPECIFICATIONS</u>	<u>METHOD</u>
Appearance	Translucent dosing pipette with white plunger and with black graduation in ml and CE mark (CE 0120) (See Figure 3, Figure 4 and Figure 5 for reference)	Visual inspection (n=10)
Identification (Barrel)	IR Absorption spectrophotometry (similar to spectrum in Figure 1)	Identify testing of the material by IR according to Ph.Eur. 2.2.24. (n=1)
Identification (Plunger)	IR Absorption spectrophotometry (similar to spectrum in Figure 2)	Identify testing of the material by IR according to Ph.Eur. 2.2.24. (n=1)
Dimensions (Barrel)	Length: 87.5 ± 1 mm Luer Bore Diameter: 4.65 ± 0.3 mm External diameter of the body at bottom (above pike): 6.4 ± 0.3 mm Inner diameter of the body at top: 5.7 ± 0.3 mm	Caliper (see drawing in Figure 3) (n=10)
Dimensions (Plunger)	Length: 97 ± 1 mm Diameter (lip): 11 ± 0.3 mm	Caliper (see drawing in Figure 4) (n=10)
Proper fit of plunger into the body	Plunger fits properly into body	Visual control (n=10)
Proper fit of dosing syringe into adaptor	Dosing syringe fits properly into adaptor (spec-000089)	Visual control (n=10)
Mass uniformity	Complies with Ph.Eur. 2.9.27.	CoA verification

Modification:

Date:

Changed:

**Notes:**

1. The tolerance is only valid for the range going from the nominal capacity (3ml) up to and including 10% of the nominal capacity. The accuracy for graduation lines below 10% of the nominal capacity exceeds the defined tolerance, a dosing applicator should not be used to accurately dose less than 10% of its nominal capacity.

Artwork approved by:		Artwork details:	
Customer:	UCB	Color:	PMS 180 C
Name:	JF. DECASTER	HDB-code:	459
Date:	05-APR-2019	Name:	MVD144
Signature:		Date:	04/03/2019
This drawing is copyrighted, all rights are reserved. This document may not be copied or reproduced without prior consent, in writing, from HDB.		Rev.:	0
H.DE BACKER NV TEMSE BELGIUM		Dwg N°	K044
		Part N°	T2043
Title:		Artwork Approval	

Annex 3.2: 3.0mL Syringe

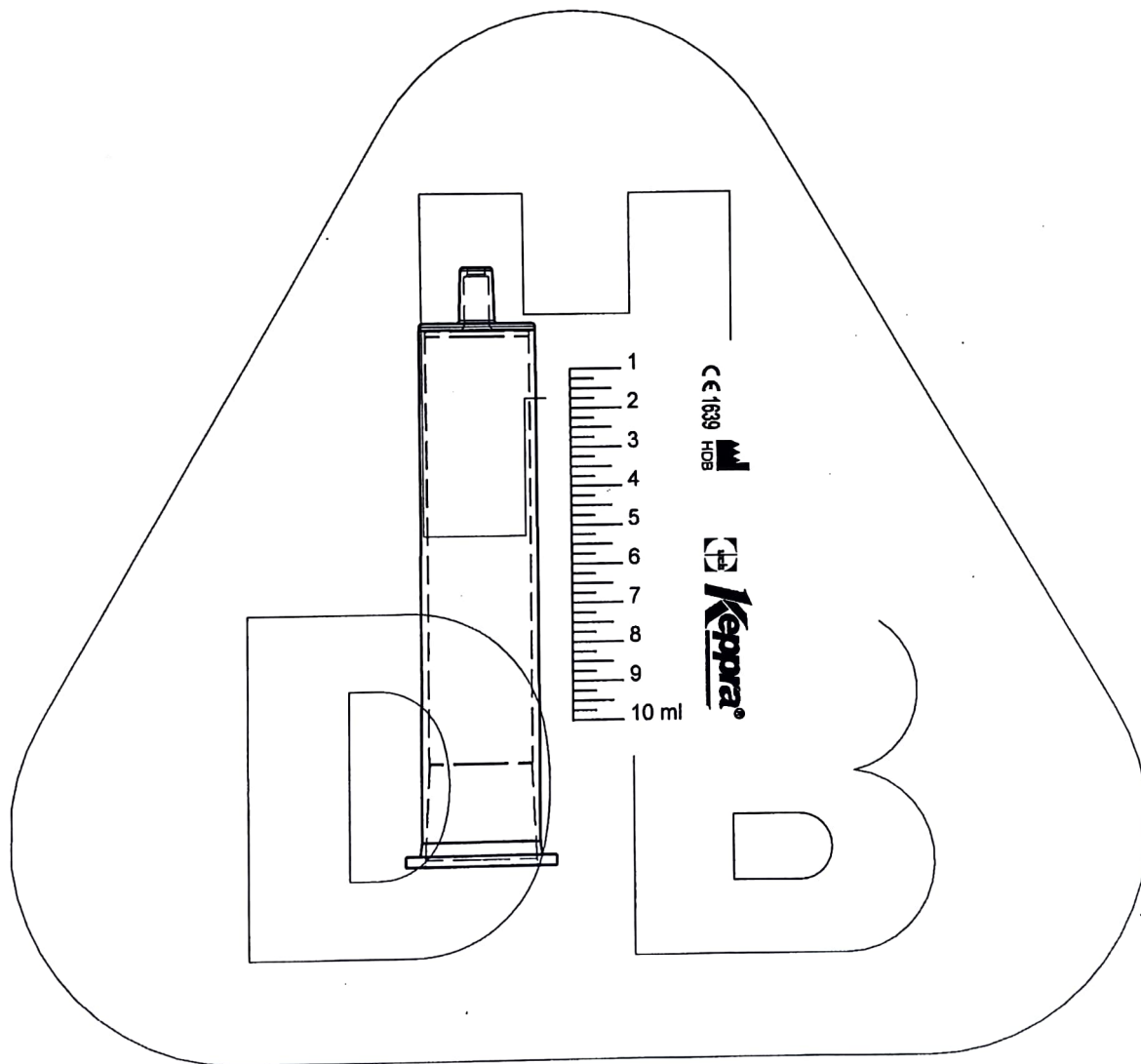
Syringe specification:

PARAMETERS	SPECIFICATIONS	METHOD
Appearance	Translucent dosing pipette with white plunger and with black graduation in ml and CE mark (CE 0120) (See Figure 3, Figure 4 and Figure 5 for reference)	Visual inspection (n=10)
Identification (Barrel)	IR Absorption spectrophotometry (similar to spectrum in Figure 1)	Identity testing of the material by IR according to Ph.Eur. 2.2.24. (n=1)
Identification (Plunger)	IR Absorption spectrophotometry (similar to spectrum in Figure 2)	Identity testing of the material by IR according to Ph.Eur. 2.2.24. (n=1)
Dimensions (Barrel)	Length: 74 ± 1 mm Luer Bore Diameter: 2.5 ± 0.3 mm External diameter of the body at bottom (above pike): 11 ± 0.3 mm Inner diameter of the body at top: 9.4 ± 0.3 mm	Caliper (see drawing in Figure 3) (n=10)
Dimensions (Plunger)	Length: 82 ± 1 mm Diameter (lip): 14 ± 0.3 mm	Caliper (see drawing in Figure 4) (n=10)
Proper fit of plunger into the body	Plunger fits properly into body	Visual control (n=10)
Proper fit of dosing syringe into adaptor	Dosing syringe fits properly into adaptor (spec-000089)	Visual control (n=10)
Mass uniformity	Complies with Ph. Eur. 2.9.27.	CoA verification.

Modification:

Date:

Changed:

**Notes:**

1. The tolerance is only valid for the range going from the nominal capacity (10ml) up to and including 10% of the nominal capacity. The accuracy for graduation lines below 10% of the nominal capacity exceeds the defined tolerance, a dosing applicator should not be used to accurately dose less than 10% of its nominal capacity.

Artwork approved by:		Artwork details:	
Customer:	ULB	Color:	PMS 180 C
Name:	J.F. DECOSTER	HDB-code:	459
Date:	05 - APR - 2019		
Signature:		Name: MVD144	Date: 04/03/2019
This drawing is copyrighted, all rights are reserved. This document may not be copied or reproduced without prior consent, in writing, from HDB.		Rev.: ①	HDB Norm: N1002/1
H.DE BACKER NV TEMSE BELGIUM		Title: Artwork Approval	Dwg N° K036 Part N° T2046

Annex 3.3: 10mL Syringe

PARAMETERS	SPECIFICATIONS	METHOD
Appearance	Translucent dosing pipette with white plunger and with black graduation in ml and CE mark (CE 0120) (See Figure 3, Figure 4 and Figure 5 for reference)	Visual inspection (n=10)
Identification (Barrel)	IR Absorption spectrophotometry (similar to spectrum in Figure 1)	Identity testing of the material by IR according to Ph. Eur. 2.2.24. (n=1)
Identification (Plunger)	IR Absorption spectrophotometry (similar to spectrum in Figure 2)	Identity testing of the material by IR according to Ph. Eur. 2.2.24. (n=1)
Dimensions (Barrel)	Length: 86 ± 1 mm Luer Bore Diameter: 2.5 ± 0.3 mm External diameter of the body at bottom (above pins): 17 ± 0.3 mm Inner diameter of the body at top: 15.05 ± 0.3 mm	Caliper (see drawing in Figure 3) (n=10)
Dimensions (Plunger)	Length: 94 ± 1 mm Diameter (lip): 20 ± 0.3 mm	Caliper (see drawing in Figure 4) (n=10)
Proper fit of plunger into the body	Plunger fits properly into body	Visual control (n=10)
Proper fit of dosing syringe into adaptor	Dosing syringe fits properly into adaptor (spec-000069)	Visual control (n=10)
Mass uniformity	Complies with Ph. Eur. 2.9.27.	CoA verification.

Modifications:		Date:	Changes:
1 Change end thickness		01/06/2018	1004
2 Add tolerance for end thickness of flange		01/06/2018	1004
3 Drawing changed according to production 01.07.2018 and 11.07.2018, dimension 2 1.00-1.00 mm added		01/06/2018	1004

Scale: 1:1

Author	Drawn	Checked	Released	Approved	Part Name	Part No.	Rev.	Rev. Description
M. DE BACKER NV					PLUG	01	T2060	

D. Decker

Erwin Veldman
18.07.2019

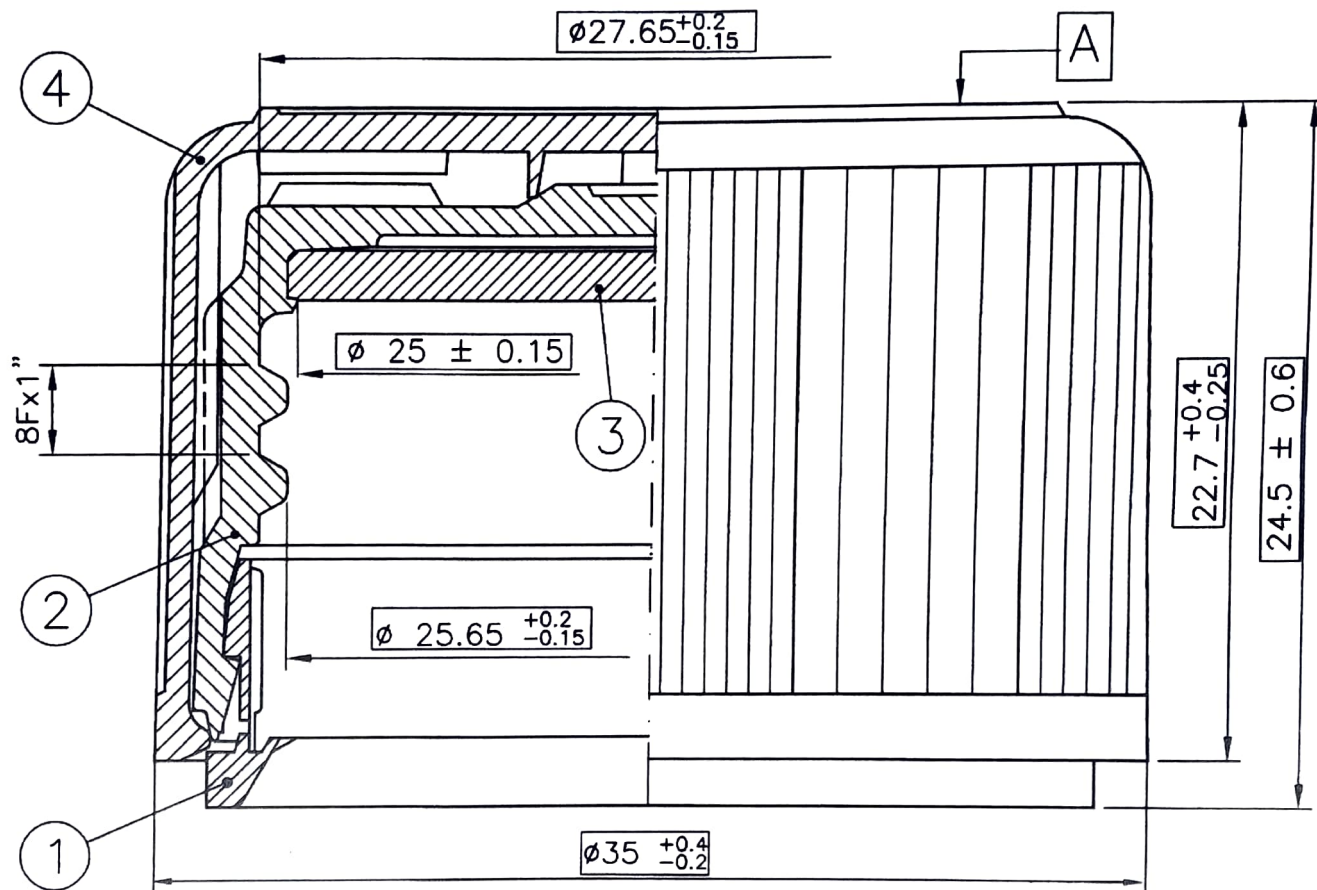
M. S. ASKAR

26.11.2019

V. J. K. K. K.
18.07.2019

Confidential

Rif./Ref	Data/Date	Descrizione modifica / Modification	Disegnatore / Designer
C	30/06/2017	INSERITO PESO, MATERIALE E DENOMINAZIONE LINER / Weight, material and denomination liner inserted	P.E.
D	20/03/2018	AGG. TOLLERANZE DIAMETRO FILETTO E FONDO FILETTO, CARTIGLIO, TABELLA Screw thread and screw thread diameter tolerance updated - Table updated	Z.M.
E	15/10/2018	INSERITO DIAMETRO LINER / Diameter liner inserted	Z.M.



VISTA DA A - View from A

Material Code: CS4001UC05
UCB Pharma A.Ş. adına Mesul Müdür
M. Serdar Aşkar

02.03.2020



INCISIONI COPRICAPSULA - Engraving outside cap
SCALA 1:1 - Scale 1:1

QUOTA FUNZIONALE
FUNCTIONAL DIMENSION

4	COPRICAPSULA CP28 / OUTSIDE CAP	PP	2.7 ± 0.2	1057	Disegno n° / Drawing n° A2265/D
3	GUARNIZIONE / LINER	--	0.4	YGR/1557	Diametro / Diameter Ø25.6 - Spessore / Thickness 1.75
2	CAPSULA CP28 / INSIDE CAP	PP	3.0 ± 0.3	IN 1055	Disegno n° / Drawing n° A1827/F
1	ANELLO T.E. 28 / T.E. RING	PE	0.6 ± 0.1	IN 1360	Disegno n° / Drawing n° A5226
Pos./Pos.	Particolare/Component	Mat./ Mat.	Peso(gr.)/Weight	Articolo/Ref.	Note/Notes

Denominazione: Description:		COMPLESSIVO CP28 X LINER	
Cliente: Customer:	STANDARD	Cap. Nom. ml Nom. capacity	--
Materiale: Material:	V. TABELLA	Cap. RB. ml Brimful capacity	-- ± --
Toll. Gen. ± General Tol.	0.3	Peso Gr. Weight	6.7 ± 0.6
Sostit. e Annulla Dis. N° Replace and delete Drw. N°	A4933/D	del issued	20/03/2018

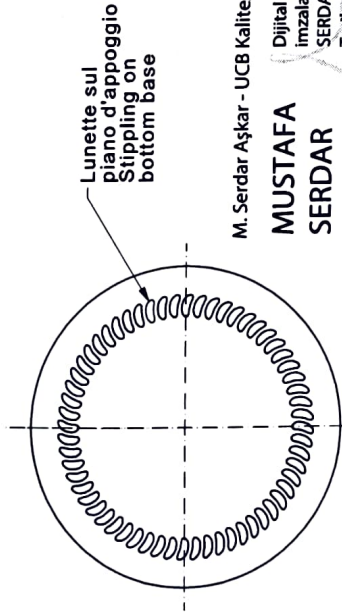


Bormioli Pharma

Dis. da / Designer M. PEDRONA	Data / Date 14/11/06	Scala / Scale 4:1	Nota: le quote funzionali devono essere tassativamente verificate
Appr. da / Approved by [Signature]	Data / Date 15/10/18	Dis. N° / Drw N° A4933/E	
Art. / Ref. N° CS4001			

- NB A NORMA DI LEGGE SI DIFFIDA DAL RIPRODURRE IL PRESENTE DISEGNO, O DI PASSARLO A TERZI -
- In according to the law it is forbidden to reproduce the drawing or to pass it to third parts -

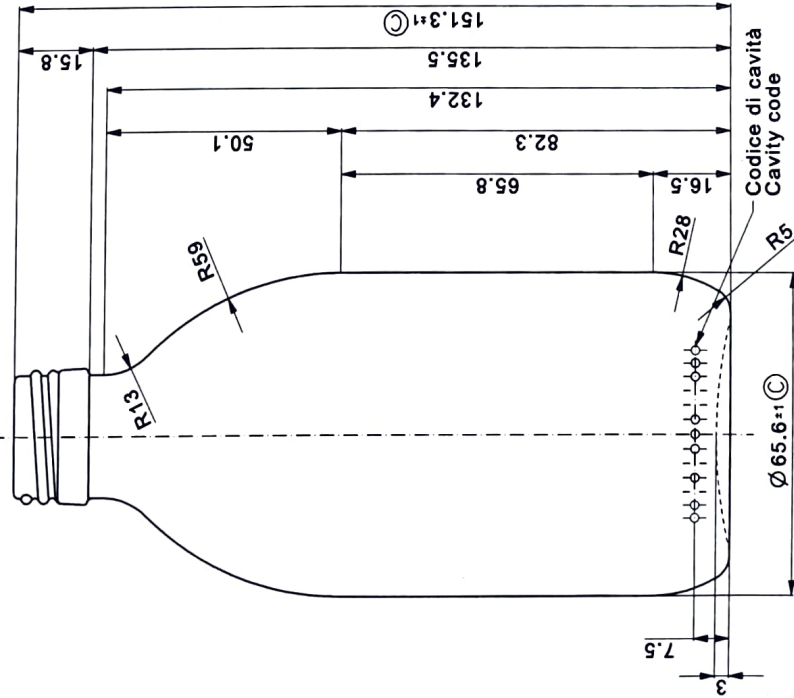
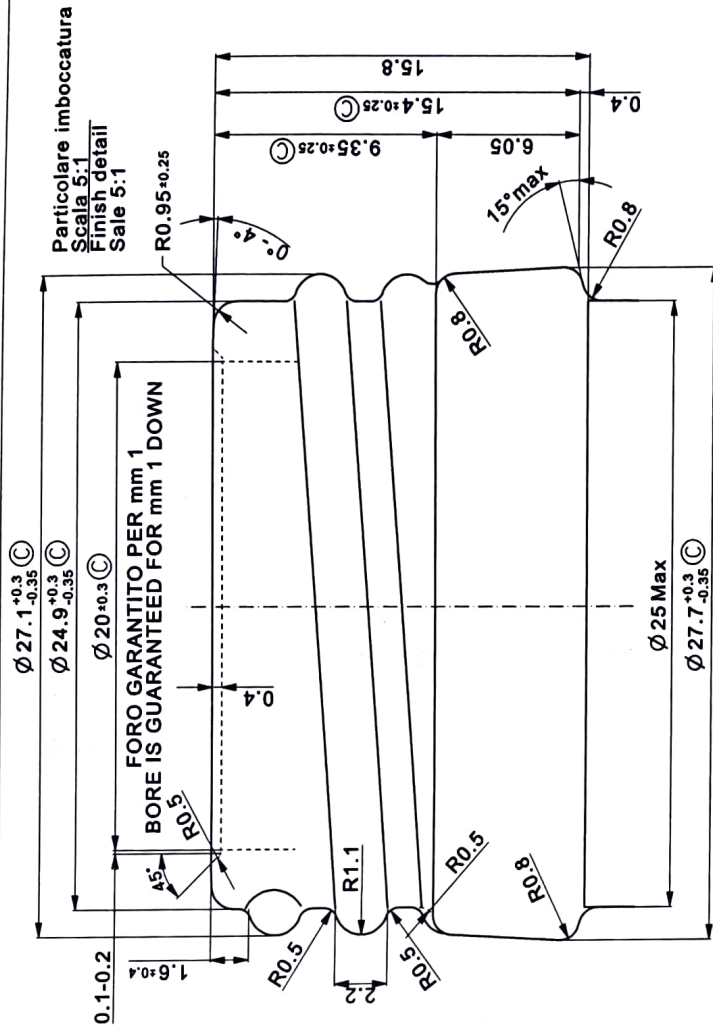
- QUOTE ESPRESSE IN mm -
- dimensions in mm -



Lunette sul
piano d'appoggio
Stippling on
bottom base

M. Serdar Aşkar - UCB Kalite/Mesul Müdür
**MUSTAFA
SERDAR
AŞKAR**
Dijital olarak
imzalayan MUSTAFA
SERDAR AŞKAR
Tarih: 2021.05.07
15:05:11 +03'00'

Vista dal fondo
Bottom view



2	24-11-20	Aggiornato marchio di fabbrica Updated trademark	Descrizione modifica / Modification	Feintin
1	20-09-12	Aggiunto traduzioni in lingua inglese (Added english translations)	Feintin	
Rev.	Rit. / Ref.	Date / Date	Designator / Designer	
Denominazione: VETRERIA				
Descrizione: Flac. ALFA 2000				
Codice e tipo di vetro Code and glass type:				
3229 Vetro giallo III Amber glass III				
3100 Vetro bianco III Flint glass III				
Clienti: VETRERIA				
Customer: Flac. ALFA 2000				
Capacità R8 ml: 318 ± 5.8				
Bruttol capacity ml: 318 ± 5.8				
Capacità nominale ml: 300				
Nominal capacity ml: 300				
Imboccatura: UNI 6144 28 MEDIA				
Neck finish: HP 981/300				
Tipo e applicazione delle incisioni al fondo sono a discrezione della vetreria. Type and application of the engravings on the bottom, are left to glass supplier discretion.				
A norma di legge si diffida dal riprodurre o passare a terzi il presente disegno. According to law, it is forbidden to reproduce or spread this drawing to anyone.				

bormioli pharma

Disegnato da: Designer: Disegnato da: Designer:	Disegnato da: Designer: Disegnato da: Designer:	Disegnato da: Designer: Disegnato da: Designer:	Disegnato da: Designer: Disegnato da: Designer:
08-08-03	08-08-03	08-08-03	08-08-03
15-12-20	15-12-20	15-12-20	15-12-20
1:1	1:1	1:1	1:1
A6398-3	A6398-3	A6398-3	A6398-3
HP 981/300	HP 981/300	HP 981/300	HP 981/300
Disegnato da: Designer:	Disegnato da: Designer:	Disegnato da: Designer:	Disegnato da: Designer:
08-08-03	08-08-03	08-08-03	08-08-03
15-12-20	15-12-20	15-12-20	15-12-20
1:1	1:1	1:1	1:1
A6398-3	A6398-3	A6398-3	A6398-3
HP 981/300	HP 981/300	HP 981/300	HP 981/300
Disegnato da: Designer:	Disegnato da: Designer:	Disegnato da: Designer:	Disegnato da: Designer:
08-08-03	08-08-03	08-08-03	08-08-03
15-12-20	15-12-20	15-12-20	15-12-20
1:1	1:1	1:1	1:1
A6398-3	A6398-3	A6398-3	A6398-3
HP 981/300	HP 981/300	HP 981/300	HP 981/300

Solo le quote con indicazione di tolleranza sono impo-
guative.
Only the dimensions with tolerance indication are guaranteed.

[illegible]

Ergin Akdoğan

✓ Tüek Yüman

16 Kees 2018

16.11.15

M. Jorda ASKAR

26.11.2018

THE NON TOLERANCED MEASUREMENTS ARE GIVEN ONLY FOR INFORMATION

Dimensions: 181.3 H, 50.1, 45.8, 10.3, 5.4, 10.25

Labels: R13, R26, R29ENV, 300, 300, 300

Engraving at the bottom or the contour

CODE CORRESPONDING TO MOULD NUMBER MAXIMUM 9 POINTS

FACTORY LABEL

MOULD N° DIAMETRICALLY OPPOSITE SERIE OF POINTS

F	28.07.02	ENGRAVING NOTIFICATION	52454	01
E	21.11.91	NORM ACCORDING TO CEE EC 21	52454	01
D	23.06.90	REPLACEMENT OF BURLS BY SMALL DOTS, MOULD NUMBER ON THE BODY	52454	01
C	21.05.84		52454	01
B	27.03.84	INCREASE OF THE BRIMFUL CAPACITY (500 ML) AND TOTAL HEIGHT OF 150 MM	52454	99
REF	DATE	NOTE	MODIFICATIONS	
NECK FINISH: PILFERPROOF N° 28		APPROX WEIGHT: 170	Bromes	
Ø Opening: 20 ± 0.3 on max depth		BRIMFUL CAPACITY: 315		ml, ± 5.0 ml.
Ø 1 diameter: 16				
MOULD			52454	
DATE: 07.03.87			P.F. 68600	

STAMP: SAINT-GOBAIN DESJONQUIERES

SYRUP ALPHA 300 ML

Annex 2.2: Drawing for Keppra oral solution 300 ml glass bottle

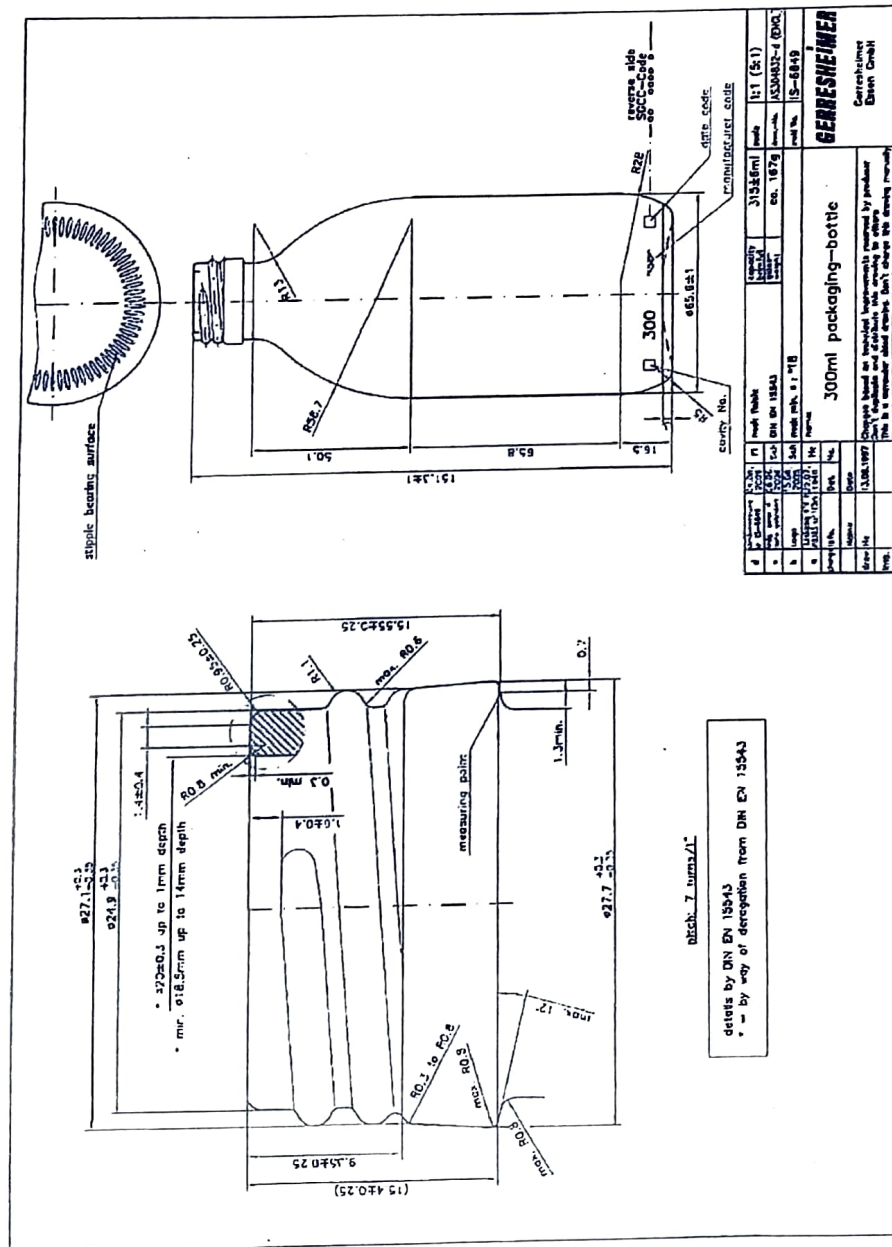
M. Sendar ASKAR

26.11.2018

07 Kasım 2018

1.7022 4/12/72

14.11.2018



Equity

V zweckmäßig

14 كذا 2018

100

UCB Property - Drug Product Process Documentation - Technology Transfer File
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Page 34 of 63

26-11-2018

07 Kasım 2018