

Description		Document Code	Version	Edition
VIAL EZ-FILL VB 3mL 16x1x35 ISO 8362-1-A-2R, NE100		MS11151	A	00
Article Code	Customer	Customer Article Code	Language	
02B2080.0560	WEST PHARMACEUTICAL	100012717	EN	

Verified by:	Gianluca Crico	Approved by:	Flavia Batista	Customer approved by:	
Date:	09/05/2023 19:03	Date:	14/05/2023 13:14	Date:	

1 SPECIFICATIONS LIST

STEVANATO GROUP REFERENCES					
Code	Description	Version	Edition	Language	Notes
QS01045	QUALITY SPECIFICATION_DL0009	A	00	EN	
0560	ITEM DRAWING	A	04-02	EN	
SC04146	TUB CONFIGURATION	A	00	EN	
PA04028	SECONDARY PACKAGING SCHEME	A	01	EN	
LB00115	LABEL AND ID LABEL	A	06	EN	

2 ITEM GENERAL DATA

2.1	Dimensions (mm):	see item drawing	2.2	ISO Format:	2R
2.3	Weight (g):	4.5	2.4	Nominal capacity (mL):	3
2.5	Shoulder capacity (mL):	3.4	2.6	Brimful capacity (mL):	4±0.5
2.7	Hydrolytic surface resistance:	Reference: EP			
		Method: titration	Limit: EP		
		Reference: -			
		Method: -	Limit: -		
2.8	Glass color:	clear	2.9	Quality level:	FINA
2.10	Printing:	No			

2.11	Sterilization:	Yes	2.12	Sterilization Type:	ETO
2.13	Siliconization:	No			

2.14	Primary packaging type:	NEST and TUB	2.15	Pieces per unit:	100
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2.16	Additional requirements:	-			
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3 ITEM SPECIFICATION

3.1	Glass:	Glass type: borosilicate type I Glass expansion coeff: ref. 51E-07 K ⁻¹ Glass supplier: No prescription Additional notes: -	Glass color: clear
3.2	Glass Treatments:	Treatment type: - Process: -	Material: - Substance ID: -
3.3	Bulk Glass Siliconizaton	Treatment: - Process: -	Substance: -
3.4	Printing:	Printing ID: - Color: - Supplier: -	Material: - Pantone ref.: - Supplier code: -

4 PACKAGING SPECIFICATION

4.1	Nest	Composition: Polypropylene (PP) Color: Transparent	PCS per unit: 100
4.2	Tub	Composition: Polystyrene (PS) Color: White	Particularity: -
4.3	Nest cover	Composition: PE-HD fibers (Tyvek®) Particularity: Single Supplier: No prescription	
4.4	Tub Lid	Composition: PE-HD fibers and thermosetting adhesive (Tyvek®) Particularity: - Supplier: No prescription	
4.5	Steribag	Composition: PE-HD fibers (Tyvek®) / HDPE Bag composition: Double Sealing: No prescription Supplier: No prescription	Tyvek® Format: Complete interface
4.6	Box	Material: Alveolar PP	Pallet type: Wooden

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5 EZ-FILL PROCESS

5.1	Treatments:	Washing with WFI and depyrogenation		
5.2	Sterilization:	Type:	ETO	
		Sterilization test	Sterilization according to ISO 11135 current edition	
5.3	Note:	-		
5.4	Siliconization	Substance	-	Quantity (mg) -
		Concentration	-	
		Process	-	
		Grade:	-	

6 PACKAGING DATA

6.1 PRIMARY PACKAGING

6.1.1	Pieces per unit:	(#)	100
6.1.2	Unit net weight:	(Kg)	0.45
6.1.3	Unit gross weight:	(Kg)	0.72
6.1.4	Unit per layer:	(#)	3
6.1.5	Layer per box:	(#)	5
6.1.6	Unit per box:	(#)	15
6.1.7	Pieces per box:	(#)	1500
6.1.8	Box net weight:	(Kg)	6.8
6.1.9	Box gross weight:	(Kg)	12.6

6.2 SECONDARY PACKAGING

6.2.1	Boxes per layer:	(#)	4
6.2.2	Layers per pallet:	(#)	3
6.2.3	Boxes per pallet:	(#)	12
6.2.4	Pieces per pallet:	(#)	18000
6.2.5	Pallet net weight:	(kg)	81
6.2.6	Pallet gross weight:	(kg)	200
6.2.7	Tot dimensions	(mm)	800x1200x1880
6.2.8	Customer max height:	(mm)	-
6.2.9	Customer max weight:	(kg)	-

6.3 PACKAGING NOTES

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7 LABEL AND STERILIZED INDICATOR

7.1 LABEL DATA

7.1.1	Label type:	adhesive paper
7.1.2	Label description:	VIAL EZ-FILL VB 3ml 16x1x35 ISO8362-1-A-2R, NE100

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7.2 LABEL OF STERILIZATION

7.2.1	Type of Stamp:	Sterilized indicator
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8 SOPS

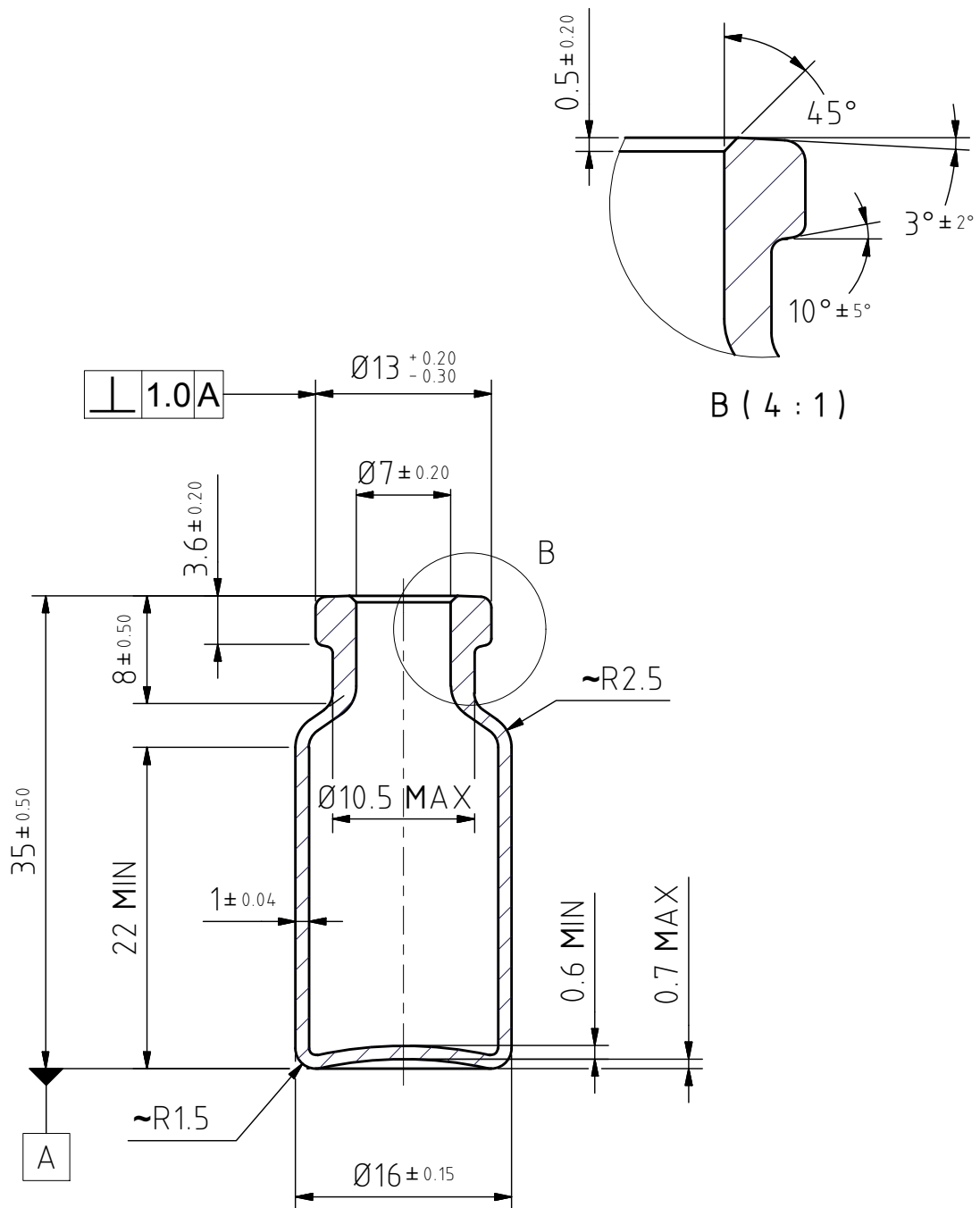
-

9 NOTE

NOTE DESCRIPTION
<ul style="list-style-type: none"> - Particle count (Light Obscuration Test): 35 particles/container $\geq 10\mu\text{m}$, 10 particles/container $\geq 25\mu\text{m}$ - Endotoxins (EP 2.6.14): $< 0.25 \text{ EU/mL}$

CHANGE HISTORY

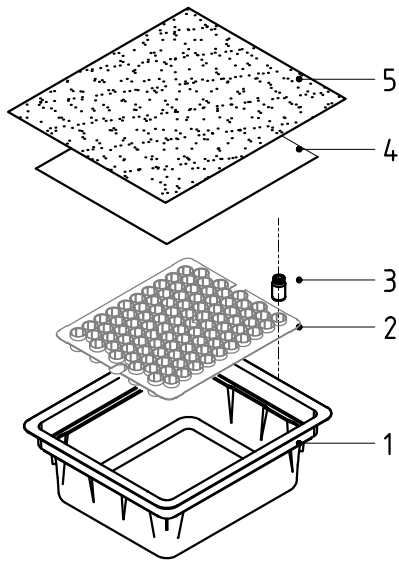
Ed	Date	Request	Change description	Signature
00	09/05/2023 18:29	2023-01628-T	First edition	Gianluca Crico



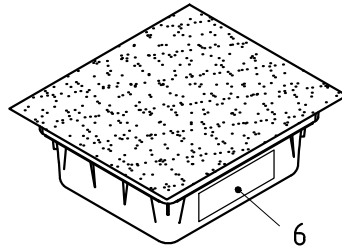
NOTES:

- Vial according to ISO 8362-1 2R

Rev.	Notes	Signature	Date	Dimensions without tolerances ISO 2768-				
				Tolerances basing on ISO 8015				
04-02	Updated 3D version	Made by MMI	13/03/2018 16:48	Format	Unit		Scale	
04-01	Updated template and notes	Approved by PTN	13/03/2018 16:49					
		Made by MMI	12/03/2018 12:00	A4	mm		2:1	
		Approved by MRG	12/03/2018 13:36	Ex		Lang.	EN	
		Material: -		Code	Version	Rev.		
Description		2R GLASS VIAL		0560	A	04-02		
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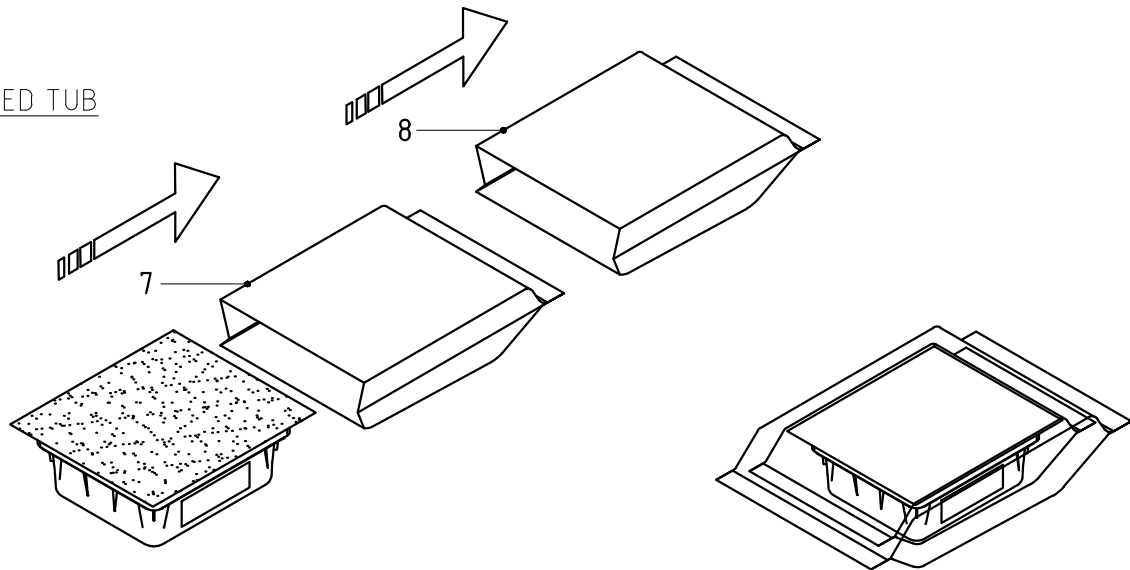
COMPONENTS



SEALED TUB

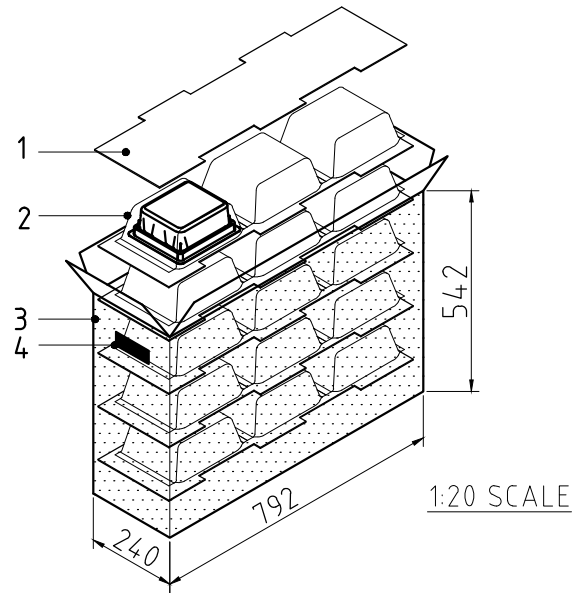
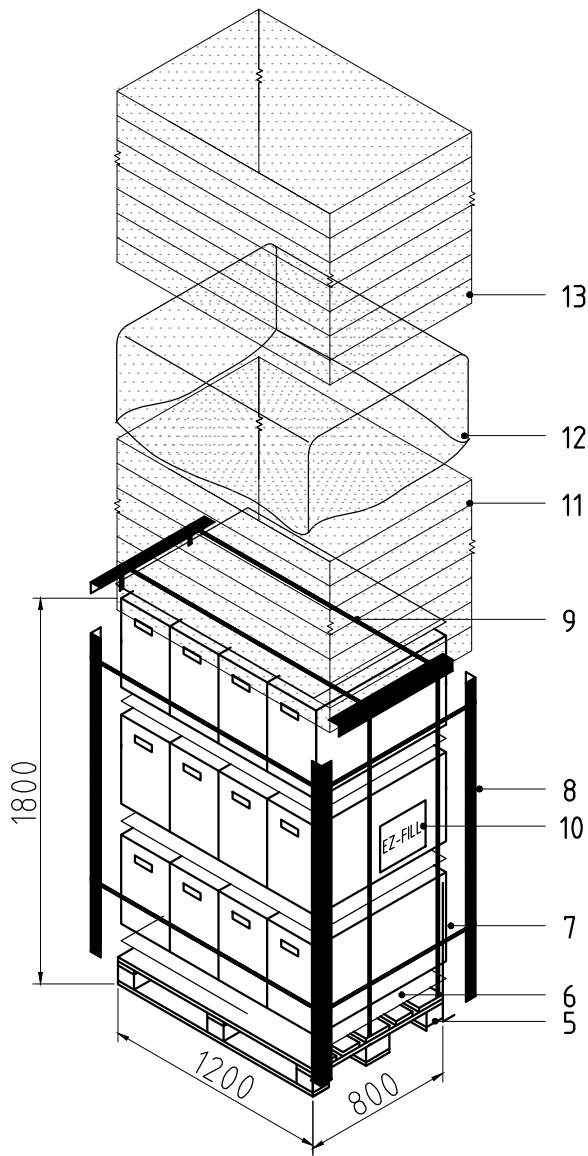
ID	DESCRIPTION
1	Tub 3"
2	Nest 100 pcs
3	Assembled vial
4	Nest cover
5	Tub lid
6	Printing of ID data
7	First Steribag
8	Second Steribag

SEALED TUB



SEALED STERIBAG

Rev.	Notes	Signature		Dates	Dimensions without tolerances ISO 2768-vK			
					Tolerances basing on ISO 8015			
00	First edition	Made by	AFE	15/01/2018 16:43	Format	Unit		Scale
		Approv. by	MMI	15/01/2018 16:44				
		Made by			Ex	Lang.	EN	Rev.
		Approv. by						
		Material:			SC04146		A	
		Description			TUB CONFIGURATION			





1:20 SCALE

ID	DESCRIPTION
1	PP alveolar spacer sheet
2	Sealed tub (placed upside down)
3	PP alveolar box
4	ID label (on both sides) with sterility indicator
5	Wooden pallet
6	Alveolar PP sheet
7	EZ-fill box (4 per layer)
8	Cardboard corners
9	Strapping
10	IID data labels on both sides
11	PE stretch film cover the load (after sterilization)
12	PE sheet or PE hood over the load (after sterilization)
13	PE stretch film cover the load (after sterilization)

Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO 2768				
				Tolerances basing on ISO 8015				
01	Added poin 11-12-13	Made by MMI Approv. by PTN	02/04/2020 16:25 02/04/2020 16:28	Format A4	Unit mm		Scale 1:40	
00	First edition	Made by YSI Approv. by JMI	05/12/2016 08:53 06/12/2016 08:42					
		Material: Description SECONDARY PACKAGING SCHEME		Ex	Lang.	EN		
				Code PA04028	Version A	Rev. 01		
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PALLET LABEL

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CUSTOMER:		CUSTOMER PO NUMBER:		FORM_CONT_EN_0079 FORM_CONT_EN_0080 FORM_CONT_EN_0078
CUSTOMER ITEM CODE:				
DELIVERY ADDRESS:	□	ESTIMATED GROSS WEIGHT (Kg):	BATCH NUMBER:	
				FORM_CONT_EN_0222_01
				FORM_CONT_EN_0078
		 BATCH NUMBER + PALLET NUMBER		FORM_CONT_EN_0222_01
DESCRIPTION:				
ITEM CODE:	QUANTITY PER BOX (PCS):	BOXES PER PALLET (PCS):	QUANTITY PER PALLET (PCS):	
BATCH NUMBER:	□	PALLET NUMBER:	 BATCH NUMBER + PALLET NUMBER	
				FORM_CONT_EN_0075_02

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MADE IN ITALY



Nuova Ompi S.r.l. unipersonale
Via Molinella, 17 - 35017 Piombino Dese - Padova - Italy
Phone: +39 049 9318111 - Fax: +39 049 9366151
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ADHESIVE BOX LABEL

60



Nuova Ompi S.r.l.
Piombino Dese - ITALY


DESCRIPTION:

ITEM CODE:

BATCH No.:

QTY:

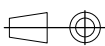

DATE: LABEL No.:



Mod. EZ129-A sem.00

STERILIZATION INDICATOR

107

Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO -			
06	CC-21-00139: Sterilizer removed	Made by: PTN	19/10/2021 08:49	Tolerances basing on ISO 8015			
05	Customer P.O. number added	Approved by: AFE	19/10/2021 08:53	Format	Unit		Scale
		Made by: PTN	02/08/2018 16:55	A4	mm		1:2
		Approved by: MMI	02/08/2018 16:57	Ex	Lang.	EN	
		Material: -		Code	Version	Rev.	
Description		LABEL AND ID LABEL		LB00115	A	06	
-							
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