



Product Description: **Novapure RS 4432/50 Gray - Small Quantity Packaging**

West Item #: Various Product Drawing#: Various

Control ID: PPS\_MSPEC: WPS-128 Rev.: 10

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## 1 Scope

- 1.1 This document provides product acceptance criteria for the physical, chemical, microbiological, and packaging properties of the NovaPure® small quantity packaging, Westar® RS, B2 coated stoppers with FluroTec®
- 1.2 The process operates under applicable cGMPs.
- 1.3 This specification will be used in lieu of a customer specification or for those portions not covered within a customer's specification.

## 2 Applicable Documents: (Current Versions)

- 2.1 ISO 2859: International Organization for Standardization: Sampling Procedures for Inspection by Attributes or ANSI/ASQ Z1.4: American National Standard: Sampling Procedures and Tables for Inspection by Attributes
  - 2.1.1 General Inspection Level II; Single Sampling Plans for Normal Inspection of attributes

## 3 Method/Procedure Titles: (Current Versions)

- 3.1 BIO-01: Ambient Microbial Load Determination of Elastomeric Closures
  - 3.1.1 BIO-10 reporting value of BIO-01 for total Bioburden results (CFU/20 stoppers)
- 3.2 BIO-25: Microbial Enumeration on West Items
- 3.3 BIO-22: Quantification of Endotoxins on Elastomeric Closures and Westar Lined Seals
- 3.4 PARTICL-21: Determination of Subvisible and Visible Particles on Rubber Closures by Clemex Imaging System
- 3.5 AA-29: Quantification of B-2 Coating on Rubber Closures
- 3.6 GC-41: Qualitative Determination of Semi-Volatile Extractables from 4432/50 Gray Materials Using Gas Chromatography with Flame Ionization Detection
- 3.7 LC-51: Limit Test on Residual Polysorbate 20 on Elastomeric Closure by RP-HPLC-ELSD (Finished Parts)
- 3.8 ESOP-7155: Dimensional Measurement of NovaPure Elastomeric Components
- 3.9 ESOP-6127: Circular Runout Inspection of Molded Parts

## 4 Packaging

Product packaging is depicted in Attachment 1.



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## 5 Labeling/Markings (minimum information)

### 5.1 ID Label

- 5.1.1 West item number
- 5.1.2 Item description / Formulation
- 5.1.3 Quantity

### 5.2 Use by Date Label

- 5.2.1 Date of manufacture
- 5.2.2 West item number
- 5.2.3 Item description / Formulation
- 5.2.4 Quantity
- 5.2.5 Batch number
- 5.2.6 West location name
- 5.2.7 Use by date

### 5.3 Carton Product Label

- 5.3.1 Date of Manufacture
- 5.3.2 West item number
- 5.3.3 Item description / Formulation
- 5.3.4 West batch number
- 5.3.5 Quantity
- 5.3.6 West location name
- 5.3.7 Use by date

### 5.4 Carton Shipping Label / Delivery Documentation

- 5.4.1 Customer name and shipping address
- 5.4.2 West sales order number
- 5.4.3 Master lot number
- 5.4.4 Customer purchase order number
- 5.4.5 Customer part number
- 5.4.6 West location name

## 6 Formulation Specification

### 6.1 4432/50 Gray

- 6.1.1 Elastomer Type: Chlorobutyl
- 6.1.2 Ash %: 44.6 - 48.6
- 6.1.3 Specific Gravity: 1.29 – 1.37



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## 7 Laboratory Specifications (The sample size is determined by each test method)

### 7.1 Microbiological Product Specifications

Test	Method	Specification
Bioburden*	BIO-10	≤ 4.41 CFU/20 stoppers (S2 serum) ≤ 5.11 CFU/20 stoppers (V2 Lyo) ≤ 9.68 CFU/20 stoppers (S10 Serum) ≤ 12.09 CFU/20 stoppers (V10 Lyo)
	BIO-01	≤ 5.00 CFU/100 cm <sup>2</sup> stopper
	BIO-25	≤ 5 CFU/100 cm <sup>2</sup> stopper surface area
Bacterial Endotoxins	BIO-22	≤ 1 EU/Piece

\* During transition to BIO-25, Quality Certificates will provide results by at least one of the bioburden methods.

### 7.2 Chemical/Extractable Product Specifications

Test	Method	Specification
B2 Level	AA-29	26 – 63 µg/part(S2 -13mm Serum) 23 – 68 µg/part(V2 -13mm Lyo) 63 – 138 µg/part (20mm)
Extractable Fingerprint Profile	GC-41	Compares to Reference Chromatogram
Residual Detergent	LC-51	≤ 5 mcg/cm <sup>2</sup>

### 7.3 Subvisible and Visible Particle Specifications

Particle Size	Method	Specification
≥ 5.0 µm but < 10.0 µm	PARTICL-21	≤ 200.0 particles/10 cm <sup>2</sup>
≥ 10.0 µm but < 25.0 µm		≤ 120.0 particles/10 cm <sup>2</sup>
≥ 25.0 µm but < 50.0 µm		≤ 13.0 particles/10 cm <sup>2</sup>
≥ 50.0 µm but < 100.0 µm		≤ 3.5 particles/10 cm <sup>2</sup>
≥ 100.0 µm		≤ 0.2 particles/10 cm <sup>2</sup>

## 8 Dimensions

### 8.1 125 piece sampling plan

Dimensions	Method	Specification
Flange Thickness (H2)	ESOP-7155	≥ 1.33 Cpk
Flange OD (D1)		
Plug OD (D2)		
No-Pop Ring OD (D3) – Serum Only		



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## 8.2 Drawings

- 8.2.1 19700317 - 13mm Serum NovaPure RS SP S2F451 4432/50 Gray  
Product drawing – Attachment 3
- 8.2.2 19700575 - 13mm Serum NovaPure RS SP S2F451 4432/50 Gray  
Product drawing – Attachment 3
- 8.2.3 19700319 - 13mm Lyo NovaPure RS SP V2-F451W 4432/50 Gray  
Product drawing – Attachment 2
- 8.2.4 19700318 - 20mm Serum NovaPure RS SP S10F451 4432/50 Gray  
Product drawing – Attachment 4
- 8.2.5 19700484 - 20mm Serum NovaPure RS SP S10F451 4432/50 Gray  
Product drawing – Attachment 4
- 8.2.6 19700320 - 20mm Lyo NovaPure RS SP V10F597W 4432/50 Gray  
Product drawing – Attachment 5

## 8.3 Sampling plan in accordance to ISO 2859 or ANSI/ASQ Z1.4, Special Inspection Level S-4.

Measurement	Method	Specification	AQL
Eccentricity	ESOP-6127	≥ 0.010" (0.254 mm), Circular Runout ≥ 0.020" (0.508 mm)	1.0



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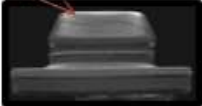
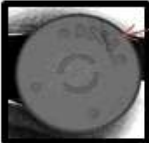
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## 9 Attributes

Category	Attribute	PPM Spec	Cumulative AQL	Attribute Description
<b>Critical</b>	Mix-up	0	0.010	
	Contamination of biological origin such as hair or insect (visible with naked eye)	0		
	Metal contamination (>0.1 mm <sup>2</sup> )	≤ 1		
	Defect leading to non-sterility	≤ 1		
	Fibers > 10 mm	≤ 10		
	Gross contamination (oil, grease) > 1mm <sup>2</sup>	≤ 10		



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<b>Major</b>	Loose / embedded foreign matter $\geq 0.2 \text{ mm}^2$	$\leq 50$	0.015	
	Fibers $\geq 2 \text{ mm}$	$\leq 250$	0.040	
	Defects potentially leading to non-sterility	$\leq 250$		
	Defects impairing processing	$\leq 250$		
	Loose / embedded foreign matter $\geq 0.05 < 0.2 \text{ mm}^2$	$\leq 1,000$	0.10	
	Fibers $\geq 0.5 \text{ mm} < 2.0 \text{ mm}$	$\leq 2,500$	0.25	
<b>Minor</b>	Cosmetic defects not impairing function / sterility	$\leq 15,000$	2.5	
	Cosmetic defects not impairing processing	$\leq 15,000$		

9.1 Specification for attributes are expressed as ppm values. AQL relates to a sampling inspection, where a random sample is taken from the batch and each unit classified is acceptable or defective, following ANSI/ASQ Z1.4 or ISO 2859, General Inspection Level II, Single Sampling Plans for Normal Inspection for final release by West and customer incoming inspection.



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## 9.2 Attribute Classification Definitions

- 9.2.1 **Critical:** A defect that represents a potential risk to adversely affect product identity or critical quality characteristics that would render the product unusable.
- 9.2.2 **Major:** A defect that represents a potential risk to adversely affect quality characteristics that may hinder the usability of the product.
- 9.2.3 **Minor:** A defect that is a minimal potential risk to adversely affect quality characteristics that have little or no bearing on the usability of the product.

## 10 Change Notification

- 10.1 West will notify the customer of changes in accordance with the Statement on Change Notification for Components. A copy may be obtained on West's website, [www.westpharma.com](http://www.westpharma.com), (Support/Quality Support/Global Change Policy)

## 11 Certification

- 11.1 A Quality Certificate will accompany every shipment.

## 12 Disposition of Non-conforming Lots

- 12.1 Disposition of non-conforming lots shall not occur until West is notified.
- 12.2 West has the option to re-sample or, upon agreement with the customer, have the customer resample the product to a mutually agreed upon sampling plan pertinent to the applicable non-conformance.
- 12.3 Only agreed to product and quantity(s) can be returned to West after obtaining a Return Goods Authorization. This authorization must appear on all documentation and product shipping containers related to the return.
- 12.4 All returned products must be in the original West cartons with West traceability maintained.

## 13 Legal

- 13.1 The information contained in this specification is the property of West Pharmaceutical Services, Inc. and will not be divulged to a 3rd party without first receiving written approval from West Pharmaceutical Services, Inc.
- 13.2 NovaPure® and Westar® are registered trademarks of West Pharmaceutical Services, Inc. in the United States and other jurisdictions.
- 13.3 FluroTec® and B2-Coating technology are licensed from Daikyo Seiko, Ltd.

## 14 Revision History

<u>Revision</u>	<u>Date</u>	<u>Change</u>
10	As assigned in MasterControl	Added BIO-25 to Sections 3 and 7. (SAP 200005191). Removed BIO-05 and BIO-09 as BIO-22 transition is complete. Updated Statement on Change Notification for Components in Section 10 and removed from Section 2. Removed drawing reference in Section 1.1. Updated Section 5 for label alignment (SAP 200000191).



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		Removed "Packaging" from Section 8 title. Adjusted line spacing and minor formatting throughout.
9	14 Dec 2022	Replaced local reference for dimension test with global in Sections 3.8 and 8.1 (SAP 200001079). Updated Attachment 3 - WS-873 (SAP 200017883)
8	10 Feb 2022	Updated Attachment 2 – WS-875 (SAP 200007871)

PREPARER Emily Hollander, Specialist, Quality Systems

APPROVER Iris Bavaj, Vice President, Quality Ops  
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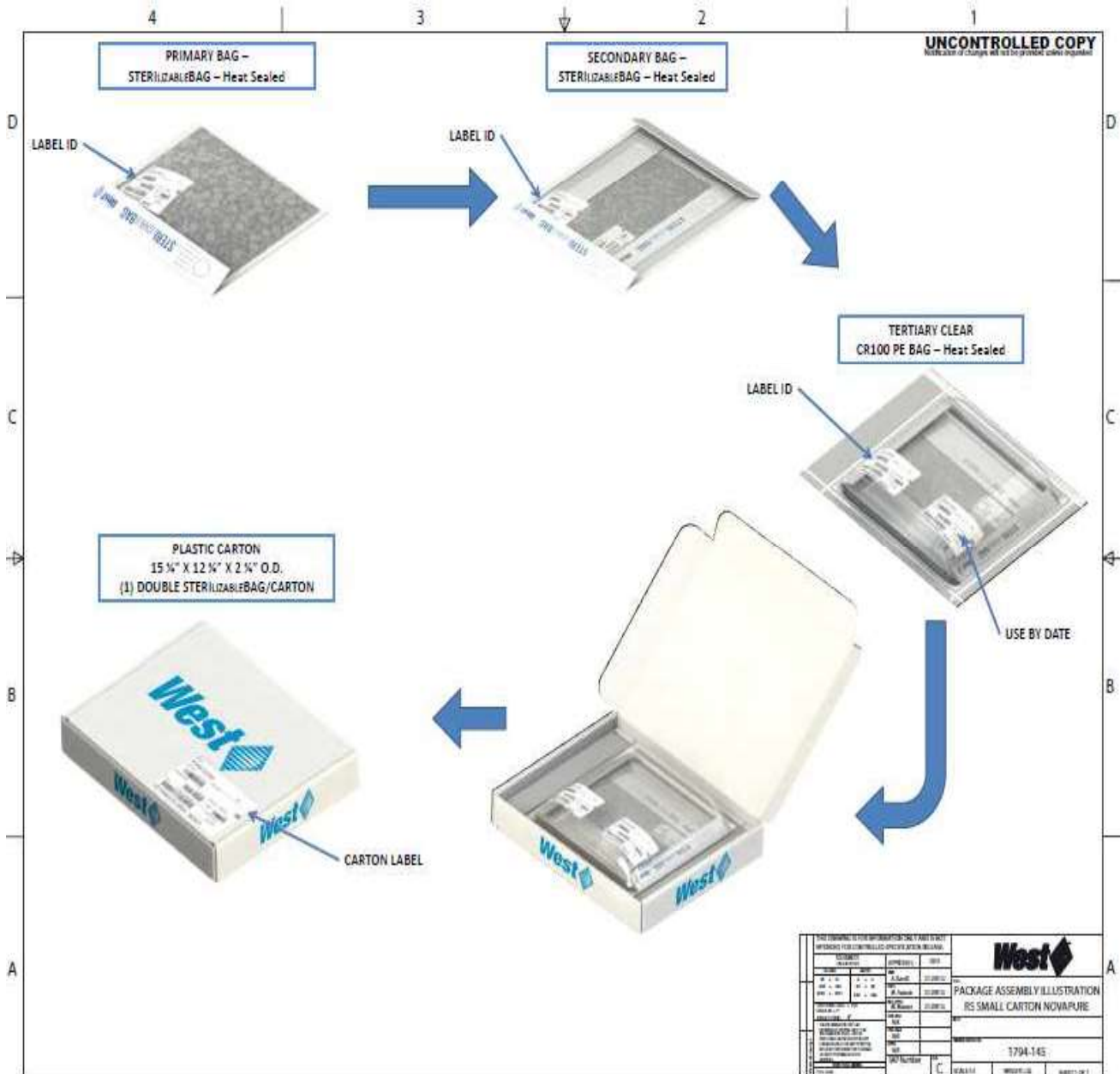
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**Attachment 1**





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## Attachment 1- continued

### 13mm NovaPure 4432/50 Gray

- 1) 1000 stoppers are packed in a primary heat-sealed STERILIZABLEBAG with ID label
  - a. Primary Bag Dimensions: 325 x 325 mm (outside dimension)
- 2) Primary STERILIZABLEBAG is placed in a heat-sealed secondary STERILIZABLEBAG with an ID label
  - a. Secondary Bag Dimensions: 320 x 450 mm (outside dimension)
- 3) Double STERILIZABLEBAGs are placed in a tertiary heat-sealed Class 100 Polybag with an ID label and Use by Date label.
  - a. Tertiary Bag Dimensions: 15.00 x 13.25 inches / 381 x 336.55 mm (Inside dimension)
- 4) One tertiary bag is placed in a small plastic carton with a Carton Product label and sealed with West logo tape.
  - a. Small Plastic Carton Dimensions: 14 x 11.75 x 2 inches / 355.60 x 298.45 x 50.8 mm mm (Inside dimensions)
- 5) Shipping carton
  - a. A single plastic carton will ship in a UPS express shipping carton with a Carton Shipping label
  - b. Small plastic cartons will be shipped in a large shipping carton with Carton Product label and a Shipping Carton label.

### 20mm NovaPure 4432/50 Gray

- 1) 500 stoppers are packed in a primary heat-sealed STERILIZABLEBAG with ID label
  - a. Primary Bag Dimensions: 325 x 325 mm (outside dimension)
- 2) Primary STERILIZABLEBAG is placed in a heat-sealed secondary STERILIZABLEBAG with an ID label
  - a. Secondary Bag Dimensions: 320 x 450 mm (outside dimension)
- 3) Double STERILIZABLEBAGs are placed in a tertiary heat-sealed Class 100 Polybag with an ID label and Use by Date label.
  - a. Tertiary Bag Dimensions: 15.00 x 13.25 inches / 381 x 336.55 mm (Inside dimension)
- 4) One tertiary bag is placed in a small plastic carton with a Carton Product label and sealed with West logo tape.
  - a. Small Plastic Carton Dimensions: 14 x 11.75 x 2 inches / 355.60 x 298.45 x 50.8 mm mm (Inside dimensions)
- 5) Shipping carton
  - a. A single plastic carton will ship in a UPS express shipping carton with a Carton Shipping label
  - b. Small plastic cartons will be shipped in a large shipping carton with Carton Product label and a Shipping Carton label.



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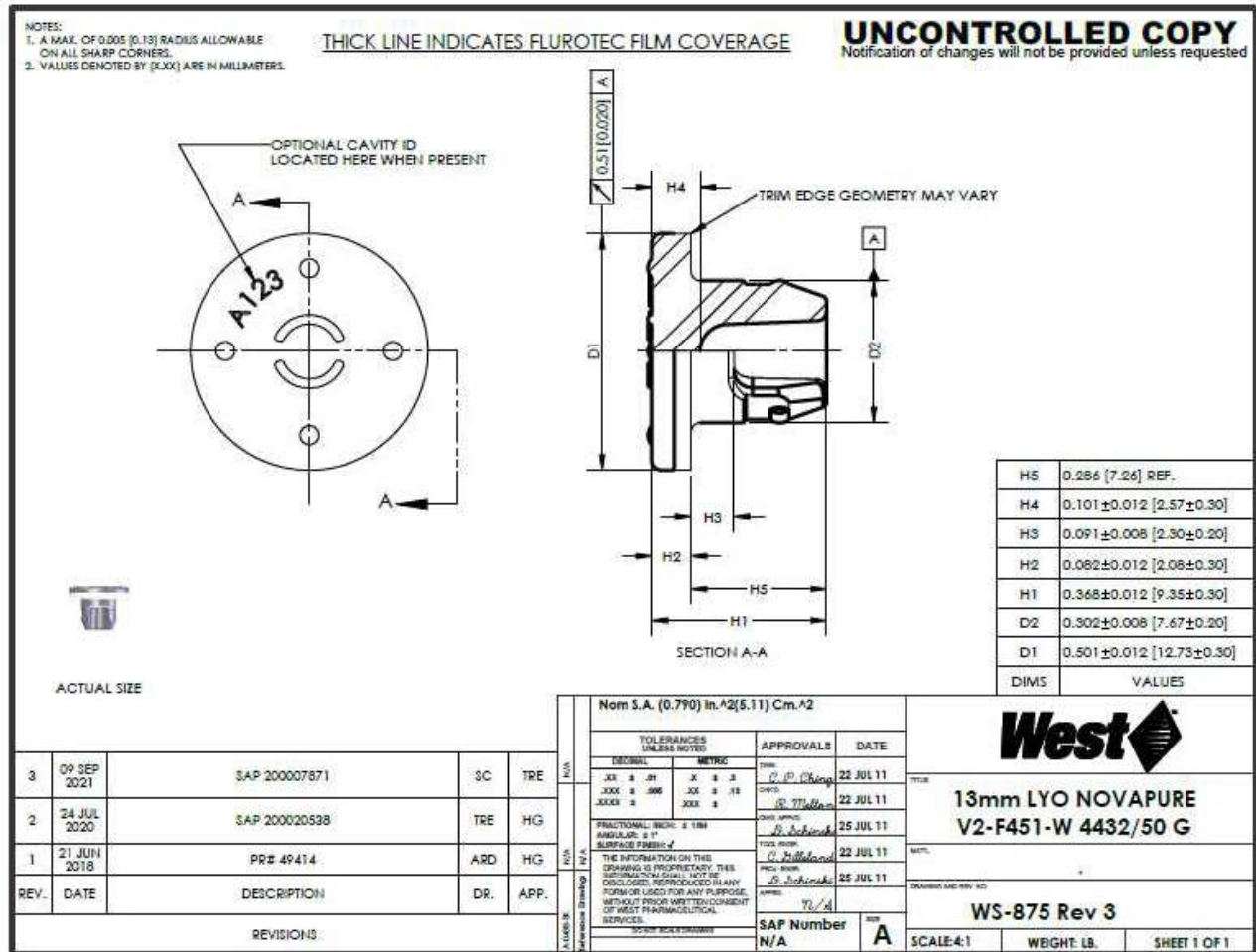
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**Attachment 2**





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**Attachment 3**

NOTES:  
 1. A MAX. OF 0.005" [0.13] RADIUS ALLOWABLE ON ALL SHARP CORNERS.  
 2. VALUES DENOTED BY [X.XX] ARE IN MILLIMETERS.

**THICK LINE INDICATES FLUOROTEC FILM COVERAGE**

**UNCONTROLLED COPY**  
 Notification of changes will not be provided unless requested

H5	0.165 [4.19] REF.
H4	0.103±0.012 [2.62±0.30]
H3	0.077±0.008 [1.96±0.20]
H2	0.083±0.012 [2.11±0.30]
H1	0.248±0.020 [6.30±0.51]
D3	0.305±0.008 [7.75±0.20]
D2	0.298±0.008 [7.57±0.20]
D1	0.502±0.012 [12.75±0.30]
DIMS	VALUES

CAVITY ID LEGACY FORMAT  
 CAVITY ID UPDATED FORMAT

SCALE 1 : 1

REV.	DATE	DESCRIPTION	DR.	APP.
2	23AUG22	SAP 200017683	TRE	HG
1	21 JUN 2018	PR# 49414	ARD	HG
REVISIONS				

N/A		N/A		N/A		N/A	
TOLERANCES UNLESS NOTED		APPROVALS		DATE		TITLE	
DECIMAL	METRIC	OWN				13mm SERUM NOVAPURE S2-F451	
X.X ± .01	X ± .3	C. P. Ching		22 JUL 11		MATERIAL: 4432/50 G	
X.XX ± .006	X ± .18	DRG		22 JUL 11		DRAWING AND REV. NO: WS-873 Rev 2	
X.XXX ±	X ±	D. M. Han		25 JUL 11		SCALE: 4:1	
FRACTIONAL: INCH: ± 1/64		D. Schimanski		25 JUL 11		WEIGHT: LB.	
ANGULAR: ± 1°		C. Hillstead		25 JUL 11		SHEET 1 OF 1	
SURFACE FINISH: ✓		D. Schimanski		25 JUL 11		SIZE: A	
THE INFORMATION ON THIS DRAWING IS PROPRIETARY. THIS INFORMATION SHALL NOT BE DISCLOSED, REPRODUCED IN ANY FORM OR USED FOR ANY PURPOSE WITHOUT PRIOR WRITTEN CONSENT OF WEST PHARMACEUTICAL SERVICES.		APPROVED		DATE			
		SAP Number		DATE			
		N/A		A			



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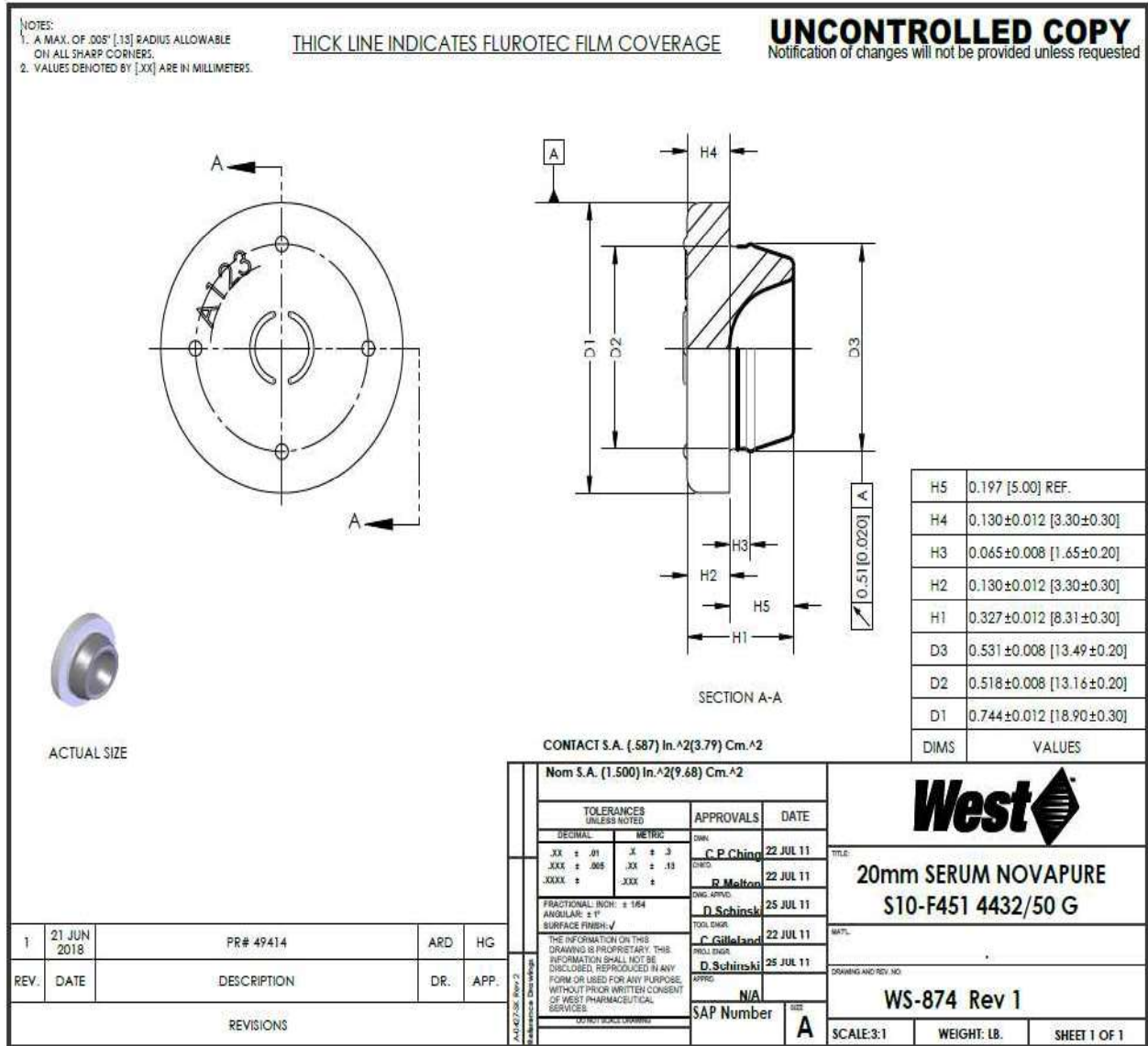
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**Attachment 4**





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**Attachment 5**

