

SOP BEGL87

Addendum 32

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Abbvie Pharmaceuticals Ireland

DISINFECTANT CERTIFICATE OF ANALYSIS

Name: **Proklenz**

PM# **D49**

R.M#: 02639

Manufacturer: Steris

Manufacturers Lot# 318037

Supplier Steris

Receiving #: DA9024

Quantity 08 Labels

Date Received: 26 Jul 2023

Criteria	Specifications	Results Acceptable Y/N	Attachment	Analyst / Date
Review of Manufacture CoA	Tests on CoA meet manufacture specifications.	Y	✓	DCH 26 Jul 2023

Approved Manufacturer: Steris

Reviewed by: Denise Kenny Date: 26 Jul 2023 Expiry Date: 01 Feb 2025
~~01 Feb 2025~~

Final

Disposition: meets spec

CoA

Approved by:

Namrata Gadi Date: 27 Jul 2023

Special Notes : ① Clerical Error DCH 26 Jul 2023



CERTIFICATE OF MANUFACTURE/ANALYSIS

Product Size:	<u>5 Gallons</u>	Product Name:	<u>ProKlenz Booster</u>
Manufacturing Date:	<u>February 28, 2022</u>	Product ID:	<u>1609-05</u>
Expiration Date:	<u>February 1, 2025</u>	Lot No.:	<u>318037</u>

I. The product listed above is made per the current issue of the following documentation

Raw Material Quality Control Specifications
Finished Product Master Formula
Manufacturing Instructions
Packaging Specifications
Finished Product Quality Control Specifications

Copies of this documentation are on file at STERIS Corporation, St. Louis Operations and will be provided as required to the applicable regulatory agencies.

II. The product listed above has been analyzed. The release specifications and results are shown below.

<u>Test Name</u>	<u>Method No.</u>	<u>Results</u>	<u>Specification</u>
Color	110	Light Straw	Colorless to Straw
Clarity	107	Clear	Clear
pH	106	5.62	4.5 - 6.0
Analyzable Surfactant Assay	LC23	5.0%	4.5 - 5.5%
Hydrogen Peroxide Assay	252	5.1%	4.5 - 5.5%
Specific Gravity (@ 25°C)	114	1.040	1.035 - 1.045

Based on these results the product is released for shipment to all STERIS Corporation distribution points.

Signed:

E. Ensson

Date:

March 1, 2022

Quality Representative

D49
D49.024
6 Drums
26 Jul 2023
[Signature]

Diana Henry
26 Jul 2023

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Release Checklist

P.M.# 049 Rec.# 049024 R.M.# 02639 Name premier2
Booster

	Yes, No or N/A
Check that all data is fully completed on the Certificate of Analysis	Yes
Check that the manufacturer's Cert. of Analysis conforms to Abbvie specifications. Check that the certificate is signed off and attached.	Yes
Check that the Abbvie expiry date does not exceed the manufacturer's expiry	Yes
Check that the manufacturer is an approved manufacturer	Yes
Check that a release label is attached to the Certificate of Analysis containing all the correct data and that the label contains two initials	Yes
Check that the laboratory notebook has been dispositioned acceptable and is cosigned	N/A 0 Yes
Check that all the relevant information has been filled into the Disinfectant Logbook	Yes

Tested By: Denise Kenny Date: 26 Jul 2023

Reviewed By: Nawneet Cad Date: 27 Jul 2023

① Critical Error DCU 26 Jul 2023