on-Couvreur nv
eg 14, 2870 Puurs, Belgium
3 890 27 11 - F +32 3 890 27 17
RPR Mechelen - VAT BE0402134977

Alcon®

TO WHOM IT MAY CONCERN :

The undersigned, Patrick Reniers, Manager, Raw Materials & Systems of sa Alcon-Couvreur nv, Rijksweg 14, 2870 Puurs / Belgium, hereby confirms that the attached document is a copy of the:

Establishment Inspection Report (EIR) of Cedarburg Pharmaceuticals Inc., 870 Badger Circle, Grafton, WI 53024-9436 / USA, issued by the Food and Drug Administration / USA dd. September 06, 2016.

This certificate may not be reproduced and is solely destined to the Governmental Authorities of **CHILE**.

sa ALCON-COUVREUR nv
January 2017

Patrick Reniers,
Manager, Raw Materials & Systems

Seen for legalization of
the signature of
Patrick Reniers

Antwerpen, 06/01/2017

Notary Public

B 00036225 B 00036225

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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Department of Health and Human Services

Food and Drug Administration

Central Region
Minneapolis District
250 Marquette Ave, Suite 600
Minneapolis, MN 55401
Phone: (612) 334-4100
Fax: (612) 334-4134

September 6, 2016

Mr. Carey W. Case
Plant Manager
Cedarburg Pharmaceuticals, Inc
870 Badger Circle
Grafton, WI 53024

Dear Mr. Case:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at the address listed below on 07/11-15/2016 by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is closed under 21 CFR 20.64 (d)(3), it releases a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy being provided to you contains the narrative portion of the report. It may reflect redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting additional information available under the FOIA.

Please contact our office if you have any questions.

Sincerely,

Melissa J. Holz -S

Digitally signed by Melissa J. Holz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000358741, cn=Melissa J. Holz -S
Date: 2016.08.31 11:37:15 -05'00'

Melissa J. Holz
Supervisory Consumer Safety Officer

FEI:	3001655239
Inspection Date(s):	07/11-15/2016
Inspection Address:	870 Badger Circle Grafton, WI 53024

TABLE OF CONTENTS

SUMMARY

Ross J Grigsby (Investigator)

This comprehensive inspection of an active pharmaceutical ingredient (API) manufacturer was conducted under assignment for an ORA/CDER jointly developed Post Approval Inspectional Assignment (ORA Concurrence # MP15111601) and as part of the routine 2016 Minneapolis District work plan. Guidance for this inspection was obtained from compliance programs 7356.002F, Active Pharmaceutical Ingredient Process Inspection, and 7356.843, Post-Approval Compliance Program. During this inspection, manufacturing could not be observed due to a two week plant/manufacturing shut-down to perform renovations and capital improvements. The current inspection covered the firm's quality system, production system, and facilities and equipment system. Manufacturing processes and batch records for [redacted] and [redacted] were reviewed during this inspection. The post approval inspection concentrated on changes to manufacturing and process controls for [redacted]. Stability data, Annual Product Reviews, change controls, Quality Issues (QI's), CAPAs, test results, investigation reports, supplier qualifications, and complaints related to [redacted] were covered.

The previous inspection was conducted 4/1/2013 to 4/4/2013 and classified Voluntary Action Indicated (VAI). A one-item FDA 483 was issued for insufficient cleaning records and procedures. In a written

response dated April 24, 2013, the firm stated that they had hired two validation specialists to identify deficiencies in the current cleaning protocols and made appropriate corrections within SOPs to mitigate reoccurrence of the three "Quality Issue Identification Report" issues identified as supporting evidence for the FDA-483 observation. Current inspection revealed that the firm now relies on 100% residue detection as a verification of their equipment cleaning procedures. The firm has validated test methods for residue testing, but not validated cleaning procedures.

At the conclusion of the current inspection, a one-item FDA 483 was issued to management for the following observation: The cleaning procedures for glassware and laboratory equipment are not sufficiently detailed and cleaning failures are not captured in your quality system. Management agreed with this observation and by close-out, had already initiated a change control for SOP K4.14- Glassware and Laboratory Equipment Cleaning Procedure to include the following: a.) add a step-by-step sign off for each rinse step; b.) include a list of specific solvents to use for each process; c.) specify specific volumes of solvent based on glassware size; d.) add a procedure to capture failures in the 100% cleaning method and record them as Quality Issues (QI). In addition, six verbal items were discussed with management: 1. Corrective actions are being captured outside of the firm's CAPA system and lack adequate tracking and trending. 2. Timeframe for glassware cleaning during production should be better defined. 3. No verification exists for the glassware annealing process. 4. An old, unused hose from production was found outside the warehouse next to the loading dock. 5. Condensation was observed dripping from an overhead air handling equipment, near the walk-in door of the warehouse. 6. Master Batch Record 214 makes reference to cleaning SOPK1, instead of SOPK4. The firm immediately initiated voluntary corrective actions to address these issues and stated they would provide a written response to the district.

The firm is current for both human and veterinary drug registrations with the FDA. No samples were collected and no refusals were encountered. No complaints are on file with the FDA for this firm since the date of the last inspection.

ADMINISTRATIVE DATA

Inspected firm:	Cedarburg Pharmaceuticals Inc
Location:	870 Badger Cir Grafton, WI 53024-9436
Phone:	262-376-1467
FAX:	920-898-5424
Mailing address:	870 Badger Cir Grafton, WI 53024-9436
Dates of inspection:	7/11/2016-7/15/2016
Days in the facility:	5
Participants:	**Jesse P Romenesko, Investigator** **Ross J Grigsby, Investigator**

The FDA 482, Notice of Inspection, was issued to Carey W. Case, Plant Manager.
The FDA 483, Inspectional Observations, was issued to Carey W. Case, Plant Manager.

Credentials were displayed to Carey W. Case, Plant Manager; Shereen M. Nennig, Quality Director; Brian J. Kocchi, Operations Manager; Benjamin A. Schilling, Production Manager; Rafail Usatinsky, Ph.D. Analytical & Quality Control Manager, and John K. Lynch, Ph.D. Section Head, Process Chemistry.

This inspection was conducted by Investigators Jesse P. Romenesko and Ross J. Grigsby. Sections of this report written by Investigator Grigsby are identified with his name, all other sections were written by Investigator Romenesko.

HISTORY

Ross J Grigsby (Investigator)

Cedarburg Pharmaceuticals, Inc. is an active pharmaceutical ingredients (API) manufacturer for human and animal applications. All manufacturing is performed at 870 Badger Circle Grafton, WI 53024, also known as the Badger building. The 20,000 square foot building dedicates 9300 square feet to manufacturing and 1000 square feet to the QC lab. The firm also has a 20,000 square foot warehouse, 9300 square feet dedicated to GMP storage. The warehouse is located across the street and less than a block away at 900 Cheyenne Ave, Unit H, Grafton, WI, and is referred to as the Cheyenne building. In addition, the firm occupies office space at 900 Cheyenne, Unit A.

Since the last inspection the firm was acquired by Albany Molecular Research Institute (AMRI) in April 2014. In the fall of 2013, the firm closed the Hauser Pharmaceuticals facility, a former subsidiary of Cedarburg located in Denver, Colorado. In addition, the development chemistry research site, 9230 N. 107th St, Milwaukee, WI was closed in July 2014. Capital improvements since the last inspection include:

- A mezzanine was added to support a new 2000 amp service and provide access between first floor labs and second floor QC lab.
- New chemical hoods were installed in Labs 2 and 3
- The Delta V was expanded to Labs
- Key panel entries were added to lab doors
- Security cameras were added to the facility
- New reactor chiller plant and chiller lines were installed
- New Pink Thermosysteme Dryer
- Installation of a new 750 gallon reactor in Suite D.

Exhibit 1 is a complete list of all capital improvements made since the last inspection.

Correspondence should be addressed to: Carey W. Case, Plant Manager

Cedarburg Pharmaceuticals, Inc.

870 Badger Circle
Grafton, WI 53024

The firm employs approximately 80 people. They operate in three shifts, continuously.

INTERSTATE COMMERCE

All products are shipped in interstate commerce. [redacted], the starting material for [redacted], is received from Bridge Organics Co. 311 W Washington St, Vicksburg, Michigan. Finished [redacted] API is shipped to [redacted], Inc., Fort Worth, TX.

JURISDICTION

Ross J Grigsby (Investigator)

The firm manufactures finished APIs used to manufacture human and animal drugs. A comprehensive list of all of the firm's products is found in **Exhibit 2**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Ross J Grigsby (Investigator)

Upon arrival, we presented our credentials and issued a FDA-482 Notice of Inspection to Carey W. Case, Plant Manager for Cedarburg Pharmaceuticals. Mr. Case has held this position since November of 2014. All employees at the Grafton, WI locations report to him either directly or via dotted line **(see Exhibit 3, Cedarburg Pharmaceuticals Organization Chart)**. Individuals in EHS, IT, DEA and Facilities directly report to Mr. Case. Mr. Case reports to Dawn Von Rohr, Sr. VP of Operations, API, located at AMRI in Albany, NY. Shereen M. Nennig, Director,Quality, is responsible for compliance, the firm's quality system, and oversight of QA, QC, validation, and analytical services group. She has been with the company since December 2012. During the interview process of this inspection, Mr. Case and Ms. Nennig provided the majority of information for this report.

Brian J. Kocchi, Operation Manager, is responsible for the daily production activities. He has been with the company since 2007 and currently reports to Mr. Case. Mr. Kocchi was present for the first three days of the inspection and contributed information related to general manufacturing practices. Mr. Case, Ms. Nennig and Mr. Kocchi accompanied us and provided information during the walk-through inspection completed on day 1.

In addition, Benjamin A Schilling, Production manager was present for the final two days of the inspection and contributed information related to the manufacturing of [redacted]. Mr. Rafail Usatinksy, Ph.D., Manager, Analytical & Quality Control, was present on two separate occasions and answered questions related to QA/QC laboratory SOPs, plastic bottles/AMRI investigative report, QC standard stability. John K. Lynch, Ph.D., Section Head, Process Chemistry provided details relevant to a failure investigation related to a batch of [redacted]. All the employees listed were present at the close-out meeting with exception of Mr. Kocchi.

FIRM'S TRAINING PROGRAM

Ross J Grigsby (Investigator)

The firm's training program was reviewed during this inspection. Upon new-hire, employees receive Human Resource/corporate policy training, safety training, and GMP training. Initial GMP training covers general GMP topics and the firm's documentation practices. Employees are required to pass an exam.

Specific GMP training is the responsibility of each department's manager, and training is tailored to the job duties of the employee. New hires first read and understand SOPs. They are required to shadow experienced employees during first shift, and only allowed to work second or third shifts after competencies are demonstrated. Newly implemented SOPs are trainer trained. The firm incorporates a "read and understand" policy for revised SOPs. All training is documented on paper records and filed with document control. Training records are audited quarterly by QA and/or document control.

MANUFACTURING/DESIGN OPERATIONS

QUALITY

The firm's quality unit includes both quality assurance and quality control personnel. The responsibilities of the quality unit include batch record review, batch release, approval and implementation of standard operating procedures, internal audits, stability testing, employee training, qualifying/approving vendors, review and approval of validation processes, deviation investigations, change control procedures, and providing guidance on all quality related matters.

The firm has procedures in place for conducting investigations into process deviations, laboratory out-of-specification and customer complaints. Deviations are captured as Quality Issues as described in SOP 120.1- Quality Issues **(exhibit 4)**. Corrective and preventative actions are covered in SOP 118.6- CAPA Procedure **(exhibit 5)**.

Customer complaints, CAPAs, and quality issue investigations were reviewed during this inspection. Although investigations appeared complete and well documented, we found several instances where corrective actions were captured outside the firm's CAPA system **(see discussion item 1)**. For example, a review of complaint CMPT-16-001 **(exhibit 6)** regarding black particulates in a batch of [redacted], contains an investigative summary, a root cause and analysis, an impact assessment, and a corrective and preventive action. This investigation was closed inside the complaint without identifying it as a CAPA.

PRODUCTION

A post-approval inspection was conducted for the API [redacted], which has an indication for treating glaucoma and hypertension in the eye. Cedarburg Pharmaceuticals has been manufacturing [redacted] since 2009. Production could not be observed during this inspection as the plant was on a scheduled shut down for maintenance and renovations. Management escorted us on walk through of the facility and explained the [redacted] manufacturing process. A summary of the process is as follows:

[redacted], the starting material, is converted through a four step conversion process into [redacted], the first intermediate. [redacted] is then converted into crude [redacted], the second intermediate. The crude [redacted] then undergoes a chromatography purification step. Fifteen fractions are generated from each chromatography run. There are typically fifteen runs per batch. The fractions are analyzed and categorized as *Purified* (marked fractions with < 0.10% area impurities); *Crude* (marked fractions with > 0.10 % area impurities) or *Dispose* (fractions with < 98% area of [redacted]). Recovered *Crude* [redacted] can be re-run through the chromatography purification step two additional times, after which it is categorized as *Dispose*. *Purified* fractions go on to be concentrated into the final API. A description of the manufacturing process was collected **(exhibit 7)**.

[redacted] records reviewed during this inspection included stability data, process cleaning validation reports, Annual Product Reviews (2014-2015), manufacturing records, change controls, Quality Issues (QI's), test results, CAPA's, investigation reports, quarantine procedures, supplier verifications and complaints. No observations were made with regard to these records.

As part of the Post Approval Inspection Assignment for [redacted], we reviewed CAPA 14.015: Actions Effectiveness and Closure Summary **(Exhibit 13)**. It was discovered that oil was leaching from plastic bottles into final [redacted] API during the final chromatography purification steps. An investigation was performed by the parent company, AMRI. Three major impurities were identified:1: Hexadecene, 1-Octadecene, and 1-Eicosene**(Exhibit 13, pages 16-17)**. The study quantitated the impurities under worst case scenario (longest fraction hold time of 10 days in plastic bottles) and quantities measured were below the reporting threshold (0.05%) **(Exhibit 13, pages 17-19)**. The investigation resulted in a change control for the manufacturing process, switching from plastic to glass containers used to collect fractions at the final chromatography purification step. A list of all change controls related to [redacted] was collected **(exhibit 8)**. A list of amendments submitted to the FDA was also collected **(exhibit 9)**.

FACILITIES and EQUIPMENT

The firm has two buildings located within sight of one another. The "Badger" building located at 870 Badger Circle and the "Cheyenne" building located at 900 H Cheyenne Avenue. API manufacturing takes place in the Badger facility. The Cheyenne location is used for warehousing and office space. Plant diagrams for both facilities were collected **(exhibit 10)**.

During our walk through of the Cheyenne warehouse, we observed condensate dripping from an overhead HVAC unit onto the floor, near a door leading to the solvent storage area. While there were no raw materials in the immediate area, we recommended that the duct work be insulated to prevent condensate from dripping onto product when it is moved into the room **(see discussion item 5)**. We also observed several hoses stored outside the warehouse, near the loading dock **(see discussion item 4)**.

As mentioned previously, The Badger facility was shut down for scheduled maintenance and renovations during our inspection. No production activities were taking place. The main floor of the facility consists of four manufacturing labs, four manufacturing suites, drying and packaging, and a controlled substance room for the product [redacted]. The second floor houses office space, a quality control lab, a R&D lab and an employee break room.

We toured manufacturing suites A, B, C and D, which house chemical synthesis reactors. The reactors are all glass-lined and range in size from 50-500 gallons. A new 750-gallon reactor was being installed in Suite D during this inspection. Management estimated the installation would be completed within a couple weeks.

We also toured GMP Lab 2 and GMP Lab 3 where [redacted] is manufactured. In GMP Lab 3 we observed glassware containing a white residue. The glassware was identified "MBR: 121.7 Batch 16/075 Continue @ Step 76". Management stated that the glassware was being used in a production campaign of [redacted] that was suspended due to the plant shutdown. I questioned how long glassware could sit without cleaning. Management replied that chemical synthesis reactors can sit for 7 days before a rinse to remove gross residuals is required, but admitted there was no established time frame for laboratory glassware **(see discussion item 2)**.

GMP Lab 2 and GMP Lab 3 are predominantly used for the production of [redacted]. Other products are also made in these labs, but on a very infrequent basis. I requested a list of other products manufactured in GMP Labs 2 and 3 since the previous inspection. Management provided **exhibit 11** identifying [redacted] (MBR 291.2) manufactured in 2014, [redacted] (MBR 296.0, 296.1) manufactured in 2014, and [redacted] (GLP) manufactured in 2015. Attention was given to the firm's cleaning procedures for laboratory glassware since it was not dedicated to [redacted] production. I reviewed SOP K4.14- Glassware and Laboratory Equipment Cleaning Procedure **(exhibit 12)**, which covers the cleaning of laboratory glassware. The following observations were made regarding this procedure:

The stated purpose of the cleaning procedure is to standardize methods for cleaning laboratory glassware and equipment; however; the procedure is deficient in that it does not identify specific amounts of detergents and cleaning agents to be used **(see FDA 483 Observation 1)**.

The firm relies on 100% residue detection as a verification of their equipment cleaning procedures. The firm has validated test methods, but not validated cleaning procedures. Per SOP K4.14, laboratory glassware is cleaned and a sample is submitted to QC for residue analysis. If a sample fails to meet the residue acceptance criteria, the cleaning procedure is repeated and a new sample is submitted. These cleaning failures are not being documented as Quality Incidents and are not captured in the quality system for

tracking and trending **(see FDA 483 Observation 1)**.

SOP K4.14 requires that glassware be cleaned and residue tested, or annealed by a third party, prior to being used in production of a different product. According to the procedure, glassware may be annealed by heating at 575C for a minimum of 20 minutes. After this treatment it will be considered equivalent to "new glassware". Beste Scientific Glass performs the glass annealing for Cedarburg. Returned glassware is accompanied by a checklist containing a description/identification of the glassware. There is no accompanying certificate, statement, or other verification that the glassware has actually been annealed **(see discussion item 3)**.

MANUFACTURING CODES

Ross J Grigsby (Investigator)

Each production run is assigned a batch number consisting of two digits representing the year followed by the sequential run for the year. For example, 16/042 would be the 42nd batch for 2016.

Lot codes are assigned to raw material and finished products. For example Lot E09801B:

"E" represents year (A=2013, B=2014, C=2015, [D n/a], E=2016, F=2017 etc.)

"098" Julian Date sampled by QC

"01"order received by QC

"B" facility code (B=Badger building, C= Cheyenne warehouse)

COMPLAINTS

The firm has not received any complaints involving [redacted] since the previous inspection. There were no complaints on file for this firm prior to initiating this inspection.

RECALL PROCEDURES

The firm has a formal recall procedure in place. No products have been recalled since the last inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

CSO Grigsby and I held a closeout meeting with firm management on 7/15/16. The following individuals were present:
-Carey W. Case, Plant Manager

-Shereen Nennig, Quality Director
-Benjamin Schilling, Production Manager
-Rafail Usatinsky, Ph.D., Analytical & Quality Control Manager
-John K. Lynch, Ph.D., Process Chemistry Section Head

A one-item FDA 483, Inspectional Observations, was issued to Mr. Carey Case, the firm's most responsible person on-site. The observations and the firm's response are described below:

Observation 1: The cleaning procedures for glassware and laboratory equipment are not sufficiently detailed and cleaning failures are not captured in your quality system.

-SOP K4.14 [Glassware and Laboratory Equipment Cleaning Procedure] and SOP K 4.14 - Attachment 3 [Product-Specific Cleaning Procedure - [redacted] and [redacted] & [redacted]] do not identify specific amounts of cleaning agents and solvents to be used.

-A 100% cleaning verification is performed on glassware but failures are not captured in your quality system as a "Quality Issue" or deviation for traceability.

Response: Management agreed with the observations and promised correction. Ms. Nennig stated that SOP K4.14 will be updated to include a range of solvent volumes to be used for each piece of glassware. Also, cleaning failures will now be documented as Quality Issues in their quality system to allow tracking and trending. A change control has been initiated for SOP K4.14- Glassware and Laboratory Equipment Cleaning Procedure to include the following: a.) add a step-by-step sign off for each rinse step; b.) include a list of specific solvents to use for each process; c.) specify specific volumes of solvent based on glassware size; d.) add a procedure to capture failures in the 100% cleaning method and record them as Quality Issues.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

The following observations were also discussed with firm management during the inspection or at the closeout meeting:

1) CAPA documentation- Investigations and corrective and preventative actions are not always being documented as CAPA's in the firm's quality system. We observed several instances where investigations and their associated corrective and preventative actions were completed as QI's (Quality Issues), or as a complaint follow-up. These investigations were never identified as CAPA's in their quality system, even though they contained a root cause analysis and a corrective and preventative action.

Response: Management agreed with the observation and promised correction. They are proposing changes to the system to ensure CAPA's are appropriately captured.

2) Time limits for glassware cleaning- During this inspection, we observed glassware containing a white residue in GMP Lab #3, where [redacted] is made. The glassware was being used in a [redacted] production campaign that was suspended due to plant renovations. The firm's SOP 437-Policy For Use of Plant Equipment -requires a rinse to remove gross residual after 7 days for chemical synthesis reactors, but it does not address laboratory glassware used in manufacturing [redacted].

Response: Management agreed and promised correction. The SOP will be updated to include all equipment used in the manufacturer of APIs, not just the reactors. This will be covered under change control # CED-CR-0042.

3) Glassware annealing verification- The firm contracts with an outside party to have laboratory glassware annealed. Glassware is returned with a simple checklist identifying the glassware in the shipment. There is no certificate or other assurance that it has actually gone through the annealing process. Additionally, there is no written quality or service agreement between Cedarburg Pharmaceutical and the glassware annealer. We recommended that some sort of verification be obtained to ensure glassware is being annealed.

Response: Management acknowledged our concern and stated they would look into requesting a more formal verification from the glassware annealer, possibly a certificate.

4) During the walk through inspection of the Cheyenne warehouse, we observed hoses lying outside by the loading doors.

Response: Management confirmed with employees that the hoses were not used in any production activities and instructed them to cut up the hoses and put them in a trash receptacle.

5) During a walk through of the Cheyenne warehouse, we observed condensate dripping from HVAC duct work.

Response: The firm installed insulation on the HVAC unit prior to the conclusion of this inspection.

6) Master Batch Record 214 makes reference to cleaning SOP K1, instead of SOP K4.

Response: Management confirmed that the SOP reference was an error and promised correction.

SAMPLES COLLECTED

No samples were collected during this inspection.

EXHIBITS COLLECTED

1(JPR) Capital Improvement list, 1 page
2(JPR) API List, 1 page
3(JPR) Organization Chart, 1 page
4(JPR) SOP 120.1- Quality Issues , 24 pages
5(JPR) SOP 118.6- CAPA Procedure, 11 pages
6(JPR) Complaint CMPT-16-001, 4 pages
7(JPR) [redacted] Manufacturing Process, 26 pages
8(JPR) [redacted] Change Control List, 5 pages
9(JPR) [redacted] Amendments, 5 pages
10(JPR) Plant Diagrams, 3 pages
11(JPR) Lab Usage, 1 page
12(JPR) SOP K4.14- Glassware and Laboratory Equipment Cleaning Procedure, 17 pages
13(JPR) CAPA 14.015: Actions Effectiveness and Closure Summary , 29 pages

ATTACHMENTS

1(JPR) FDA 483, Inspectional Observations
2(JPR) FDA 482, Notice of Inspection (870 Badger Circle), 3 pages
3(JPR) FDA 482, Notice of Inspection (900 H Cheyenne Avenue), 3 pages

8/26/2016	8/29/2016
X Jesse P. Romenesko	X Ross J. Grigsby
Signed by: Jesse P. Romenesko -S	Signed by: Ross J. Grigsby -S
X	X
X	X
X	X