U.S. FOOD & DRUG ADMINISTRATION

New Jersey District Office
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Parsippany, New Jersey 07054
www.fda.gov

08/01/2018

Mr. Filipe Vicente
General Manager, Loures Plant
Hovione FarmaCiencia SA
Sete Casas
2674-506 Loures, Portugal

Dear Mr. Vicente,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at **Sete Casas 2674-506 Loures, Portuga on 05/14/2018 to 05/18/2018** by investigator Yvesna C. Blaise on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

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 C.F.R. Part 20. This, however, does not preclude you from requesting additional information available under FOIA.

If there is any question about the released information, feel free to contact Douglas Kovacs at 973 331-4936 douglas.kovacs@fda.hhs.gov

Sincerely,

Douglas C. Kovacs -S

Digitally signed by Douglas C. Kovacs -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300119506, cn=Douglas C. Kovacs -S
Date: 2018.08.01 13:12:09 -04'00'

Douglas Kovacs
Supervisory Consumer Safety Officer
Office of Pharmaceutical Quality Operations
Division 1, Investigations Branch 1
Office of Regulatory Affairs
U.S. Food and Drug Administration

See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

Establishment Inspection Report	FEI:	**3002807208**
Hovione FarmaCiencia SA	EI Start:	5/14/2018
Loures, (Lisbon), 2674-506 Portugal	EI End:	5/18/2018

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SUMMARY

This CDER request for pre-approval inspection of a non-sterile Active Pharmaceutical Ingredient (API) manufacturer was conducted as per FACTS Assignment ID# 11816612, FACTS Op ID# 9624833, and MARCS Op ID# 90889. The inspection was conducted in accordance with CPGM 7346.832, Pre-Approval Inspections and ICH Q7 Good Manufacturing Practices for Active Pharmaceutical Ingredients. The inspection profiles NEC (NDA [redacted]) and CSN (NDA [redacted]) were covered.

The previous pre-approval inspection was conducted from 03/13/2017 – 03/17/2017 and provided pre-approval coverage for NDA [redacted]PT-01". The inspection was classified as "VAI." An FDA 483, Inspectional Observations, was issued due to: 1) Inadequate corrective actions of deviations and inadequate mock recall procedure; 2) Deviation procedure is not clear and/or followed regarding determining if deviations have occurred before, documenting deviations open for more than 30 days, guidance for CAPA effectiveness and trend handling. In addition, there were no operating procedures or preventative maintenance for a scale used in the manufacturing area and lack of identification of cleaned utensils used in the manufacturing area; 3) Liquid Nitrogen distribution system is not qualified and routinely monitored and sampled; 4) Employees engaged in the GMP environment have not received GMP refresher training for more than two years; 5) Rejected materials were not placed in designated and restricted access area to prevent mix-up; 6) Gaps of various sizes on facility exit doors.

This current inspection focused on the pre-approval for NDA [redacted] and NDA [redacted]. The inspectional approach targeted a walkthrough of the firm's raw material warehouse, QC laboratory, and the two plants used to manufacture the subject non-sterile API product. Documents reviewed included, but were not limited to: registration and validation batch records; change controls; analytical data; complaint records; laboratory and production OOSs/investigations; employee qualification records; equipment qualifications and software validations; stability data; inspection of purified water system and maintenance records. General drug GMP coverage was not provided. On 05/18/2018, a closeout meeting was held and a FDA 483, Inspectional Observations, was issued to Mr. Guy Villax, Chief Executive Officer, for an investigation not being initiated for an out of specification result. The firm stated they would respond to the agency within fifteen (15) business days. During the closeout meeting, the firm was informed that a recommendation of approval would be made for NDA [redacted] and NDA [redacted], but that the final approval decision would be made by CDER. No samples were collected and no refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	Hovione FarmaCiencia SA
Location:	Sete Casas, Quinta S. Pedro Loures, (Lisbon), 2674-506 Portugal
Phone:	351219829000
FAX:	21 9829388
Mailing address:	Quinta S. Pedro, Sete Casas Loures, (Lisbon), 2674-506 Portugal
Dates of inspection:	5/14/2018-5/18/2018
Days in the facility:	5
Participants:	**Yvesna C Blaise, Investigator**

On 05/14/2018, I, Investigator Blaise, Pharma Division 1 at the New Jersey Office, presented my credentials to Mr. Filipe Rosa Vicente, Site Manager who identified himself as the most responsible individual on site. I explained to Mr. Vicente that the purpose of my visit was to conduct a pre-approval inspection for NDA [redacted] and NDA [redacted]. The following team members were present during the opening meeting:

Name	Title
Filipe Rosa Vicente	Site Manager
Gonçalo Lopes	QA Senior Specialist
Henrique Dolores	Head of Production - Pharm Operations

Joana Ferreira	Head of Quality Systems Management
João Alves	Site Quality Director
João Beirão	Head of Production - Pilot Plant
Joerg Gampfer	VP Quality
Luis Gomes	VP Technical Operations
Luisa Paulo	Corporate Quality Senior Director
Manuel Carvalho	Warehouse Coordinator
Paulo Castro	Quality System Manager (site)
Pedro Andara	Associate Engineer

On 05/18/2018, a closeout meeting was held and a form FDA 483, Inspectional Observations was issued to Mr. Guy Villax, Chief Executive Officer. Mr. Villax stated that the firm would respond in writing to the agency within fifteen (15) business days. Recommendation for approval of NDA [redacted] and NDA [redacted] were forwarded to CDER.

HISTORY
The firm operations and management have remained unchanged since the previous 2017 PAI inspection. Hovione FarmaCiencia SA (Hovione) was established by Ivan Villax in 1959. The firm continues to specialize in the manufacturing of active pharmaceutical ingredients, intermediates, bulk drug product and solid dosage forms. Hovione also provides services for customer API synthesis (typically complex multi-step high value items). The firm is privately owned and is located at Quinta S. Pedro, Sete Casas, Loures, Portugal, 2674 506. Hovione has manufacturing locations in Loures, Portugal; Taipa, Macau; East Windsor, NJ; and Cork, Ireland. See **Exhibit_4-YCB** for a list of Hovione sites and locations. Approved regulatory submission for the US market was provided as **Exhibit_1-YCB**. During the inspection, the firm provided a presentation on the company background information (**Exhibit_2-YCB**). The presentation covered topics such as the facility overview, organizational structure and approved commercialized products.

The Hovione FarmaCiencia SA facility is approximately 42,500 square meters. The Loures site has approximately 780 employees. The firm's FDA registration as an API manufacturer is current. Hours of operation continues to be 24 hours, Sunday – Saturday. Sales revenue for 2017 was approximately $172 million.

Post inspectional correspondence should be addressed to:
Filipe Vicente
General Manager, Loures Plant
Hovione FarmaCiencia SA
Sete Casas
2674-506 Loures, Portugal

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Hovione distributes API drug products outside of the United States. According to Mr. Gonçalo Lopes, QA Senior Specialist, the percentage of interstate commerce is 59 %. A list of all products and APIs manufactured and shipped for the US market are provided as **Exhibit_3-YCB**. The US agent for all US marketed APIs from Hovione has not changed since the last inspection:

US AGENT
Jenny Fong
Hovione LLC
40 Lake Drive
East Windsor, NJ 08520
Telephone: (609) 918 2484
Email: jfong@hovione.com

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
During the current inspection, several management team members and employees provided assistance, including but not limited to key individuals noted in **Exhibit_7-YCB**. These individuals were our primary contacts throughout the inspection and helped facilitate the inspection through the translation of documents, answered inspectional questions and/or provided relevant documents. They were present throughout the inspection except where noted. The organizational chart is provided as **Exhibit_8-YCB**.

Mr. Guy Villax, Chief Executive Officer and Co-Chairman of Hovione is the most responsible person at the Hovione FarmaCiencia SA site. Mr. Villax manages, directs and oversees all operational activities at Hovione FarmaCiencia SA site. He has the power and authority to correct any deficiencies at the site. Mr. Villax received the Form FDA-483, Inspectional Observations issued at the end of the inspection. Mr. Villax was only present at the closeout meeting on 05/18/2018.

Mr. Filipe Rosa Vicente, Site Manager, manages, directs and oversees all operational activity at the Hovione-Loures site. He has the power and authority to correct any deficiencies at the site. He accompanied me throughout the inspectional walkthroughs. He was present throughout the inspection, including the daily wrap-ups and closeout meeting.

Mr. Paulo Castro, Quality Systems Manager is responsible for the oversight of all for quality management activities the site. Mr. Castro answered inspection related questions, assisted in providing requested information and had employees available when needed. He accompanied me throughout the inspectional walkthroughs. Mr. Castro was present throughout the inspection, including the daily wrap-ups and closeout meeting.

Mr. Gonçalo Lopes, QA Senior Specialist is responsible for the oversight of quality management activities for Hovione-Loures site. Mr. Lopes was the primary facilitator for the pre-approval inspection. He answered questions, accompanied me during the facility walkthrough, made

employees available when needed and assisted in providing relevant information during the inspection, including the daily wrap-ups and closeout meeting.

FIRM'S TRAINING PROGRAM

The firm has a formal written training program as outlined in procedure, HQ.CCO.COP007.7.EP, Training, Effective Date: 02/22/2017. Mr. Lopes provided us with an overview of the firm's training program at the facility. He explained that employee training consists of reading and understanding written procedures applicable to the assigned job function, training courses, task demonstration, and on-the-job training. Training records are maintained by Train Stream, Training Management system (TMS). In addition, if there is a major or minor change to an SOP, the employee is required to be re-trained on the new SOP changes. All employees are required to complete GMP refresher training annually as outlined in procedure, HQ.CCO.COP007.7.EP. GMP refresher training consists of reiterating the importance of cGMPs, providing applicable regulations and explaining how they are met by the company's procedures. My review of training records for personnel with initials SA, MM, BB, HU and BM revealed that they were trained in their specific responsibilities and in current good manufacturing practices (cGMPs), no deficiencies were noted with the training program and written procedures.

MANUFACTURING/DESIGN OPERATIONS

Hovione FarmaCiencia SA, Loures, Portugal is an active pharmaceutical manufacturer. The site is approximately 42,500 square meters and comprised of manufacturing production areas, packaging, warehouse, several QC laboratories located throughout the facility, and offices. During the inspection, we reviewed various related documents including: change control, deviations, method validations for drug substances and drug product, equipment qualification documents, raw data associated with exhibit/scale-up batches, laboratory incident reports, investigation reports and corresponding standard operating procedures pertaining to the following two (2) NDA's:

- NDA
- NDA

On 05/14/2018, I conducted an inspectional walkthrough of the warehouse (Building 8). The warehouse stores the raw materials, intermediate and finished products (active pharmaceutical ingredients, investigational medicinal products and medicinal products). The facility is temperature controlled and humidity monitored. The temperature and humidity are checked daily. Materials are received through the loading docks where materials are inspected for damage and an acceptable pallet format before being moved. The material is transferred to the receiving area where it is broken down to begin the receiving process. Warehouse personnel checks the packing slip to ensure the proper item was received from the correct vendor. Pertinent information is verified (e.g., supplier name, address, item description, and quantity ordered). The material is placed under quarantine until it is sampled, tested and released by QA for production. The products are sampled in the firm's sampling rooms located in the warehouse. During the walkthrough, I reviewed the sampling rooms logbook and confirmed that cleaning is completed and recorded after each sample is collected.

Additionally, each raw material is checked for appearance and specific ID tests. The contract suppliers that provide the raw ingredients are sourced by the client or the firm depending on the quality agreement. The firm performs full testing on all incoming materials as they are certifying the vendor and material. A receipt is then generated and filed, and labels are created to be placed on the product. The material then can be moved from the receiving location to any available pallet location in the warehouse based on the material's required storage requirements. No deficiencies were noted with the receipt of materials, sampling, and testing program.

During the inspection, I visited the QC laboratories. Analytical testing for the two applications consisted of raw material, intermediate, and finished product testing which was performed according to the firm's specific test method and specifications. The QC laboratories utilize LIMS system for logging and tracking of laboratory samples. Currently, Empower3 is used to run HPLC chromatography experiment. No deficiencies were noted during my review of the Empower 3 software.

Pre-approval Coverage for NDA

As part of the pre-approval coverage, I reviewed executed protocols/reports, exhibit batch records, deviation reports, laboratory testing results for finished drug products, stability studies, and proposed commercial process validation reports. The Hovione-Loures site is where the product was formulated and where all three (3) strength engineering, PPQ and scale-up batches were developed.

An overview presentation of the application was provided as **Exhibit_13-YCB**. The process for manufacturing the 17KJ01, API) is produced by chemical synthesis at the Hovione-Loures facility and is prepared from commercially available using a four-step process. In the first step, is converted to isolated intermediate in three telescoped chemical steps. An is formed at the derivative. The second intermediate is isolated by crystallization and is tested and released prior to further processing and then converted in two steps. In the step, the third intermediate is converted to an alkylation with , creating the final intermediate. The final intermediate is isolated by crystallization and converted to . The final product is isolated by spray drying of the amorphous salt 17KJ01, API) from aqueous solution. The firm provided copies of the process flow charts as **Exhibit_7-YCB**. Formulation and manufacturing were first established on a pilot scale 70,000 kg batch size and then on NDA batch scale 108 kg batch size. The proposed commercial batch is 280 kg batch size. No deficiencies were noted.

I review the finished product CoA and supporting raw data files for NDA batches 17KJ01HQ00009, 17KJ01HQ0012, and 17KJ01HQ00015. This includes identification, assay, pH, content uniformity and related compounds. Additionally, I reviewed the finished product CoA, laboratory notebooks, stability and finished product release testing protocols, and raw chromatographic data for stability and release testing. I did not note any deficiencies. I also reviewed the Analytical Method Validation Report for residual solvents report, related compounds report and the HPLC chromatographic data

for related substances testing. I did not note any deficiencies.

During the inspection, I reviewed OOS investigations and did not note any deficiencies.

Additionally, as part of the inspection the following areas and documents were reviewed:
-Product development history
-Process area and equipment inspection for the manufacture of the submission batches and proposed commercial batches
-Cleaning Verification report
-Preventive maintenance of the V-blender
-Change Controls
No deficiencies were noted for any of the documents reviewed.

An approval recommendation for NDA was provided.

Pre-approval Coverage for NDA

Solid Dispersion Intermediate (Hovione Internal Code 19IO01) is a critical intermediate manufactured at Hovione and intended for further formulation, to be used in Oncology patients. NDA is a solid dispersion prepared with theoretical 50% (w/w) drug substance , theoretical 50% (w/w) carrier polymer – pharma grade as a process solvent. The solution is prepared with a target 15% (w/w) of total solids content. The solid dispersion is obtained by spray drying the solution. The product is stored in a storage condition at or below 30°C. The firm provided copies of the process flow charts as **Exhibit_8-YCB**. No deficiencies were noted.

An overview presentation was provided for NDA . The pre-approval inspection coverage focused on the conformance to the application, data integrity and readiness for commercial manufacturing of . As part of the pre-approval coverage, we reviewed executed protocols/reports, exhibit batch records, deviation reports, laboratory testing results for finished drug products and change controls. According to Ms. Maria Carlos, Central Stability Group Leader the firm has not performed any stability testing for NDA .

I review the finished product CoA and supporting raw data files for NDA batches 19IO01HQ00012, 19IO01HQ00022, and 19IO01HQ00031. This includes identification, assay, pH, content uniformity and related compounds. Additionally, I reviewed the finished product CoA, laboratory notebooks, stability and finished product release testing protocols, and raw chromatographic data for stability and release testing. I did not note any deficiencies. I also reviewed the Analytical Method Validation Report for residual solvents report, related compounds report and the HPLC chromatographic data for related substances testing. I did not note any deficiencies.

During the inspectional review of batch record 19IO01HQ00012 for , it was noted a deficiency was observed. See **Objectionable conditions** for additional information.

During the inspection, I reviewed OOS investigations and did not note any deficiencies.

Additionally, as part of the inspection the following areas and documents were reviewed:
Product development history
Process area and equipment inspection for the manufacture of the submission batches and proposed commercial batches
Cleaning Verification report
Change Controls
No deficiencies were noted.

An approval recommendation for NDA [redacted] was provided.

MANUFACTURING CODES
The firm's system for lot number assignment did not change since the previous inspection. The firm utilizes SAP to assign a unique product code for each batch that is an alpha-numerical batch number. The following is an example of manufacturing lot number coding system: 17KJ01HQ00004: where Material Group of the API, KJ01 is the Material code, HQ is the manufacturing site (Loures) and 000004 is the batch number.

COMPLAINTS
There were no complaints received in reference to the two pre-approval products: NDA [redacted], [redacted] and NDA [redacted]. There have been no changes to the firm's complaint handling procedure since the last inspection.

RECALL PROCEDURES
During the inspection, I reviewed the firm's procedure on product recalls HQ.CCO.COP030.2.EN, Product Recall, Effective Date: 04/07/2017, which outlines the procedures followed in the instance of a recall. The firm has not conducted any recalls since the previous inspection. I did not notice any deficiencies with the firm's recall procedure.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483
OBSERVATION 1

Written records are not always made of investigations into unexplained discrepancies.

Specifically,
The batch record 19IO01.HQ00012 for NDA [redacted] contained out of specification results during the drying in-process check for F-sweep parameters, at 10:43 am and 11:43 am with out of range results of 83 l/min (Specification Limit: 84-86 l/min). The firm failed to initiate an investigation to determine the impact of the out of range parameters on the product.

Supporting Evidence and Relevance:
Exhibit_09-YB is copies of manufacturing batch record 19IO01.HQ00012. Page 20 of the exhibit shows the out of specification result during the in-process check for the nitrogen sweep flow rate parameters. This was not captured by the reviewer of the batch record (on the first page, the batch record was approved and reviewed by the quality assurance team on 03/23/2016.

Exhibit_10-YB is HQ.CO.SOP126.0. EN, Quality Deviation records, Effective Date 3/23/2018, which outlines the procedure for managing deviations and associated corrections, corrective or preventive actions and even improvement actions.

Exhibit_11-YB is the Quality System Reports, HQ.QSR.RE668.0EN, 19IO01 – Process Criticality Analysis, Effective Date: 03/13/2017 use justify the important critical parameter. However, during this nonconformance event (occurred on 02/26/2016), these critical parameters were not established.

Exhibit_12-YB is the deviation report ID 66864 opened as a result of the discrepancy.

Discussion with Management:

On 05/16/2018, during the review of the batch record 19IO01.HQ00012 for NDA [redacted] I noted that the firm failed to document or investigate an out of specification result (**Exhibit_09-YB**). This was specifically observed in the spray drying process testing review performed by Tiago Baptiste, Manufacturing Technical Expert- Pharma Operations. The nitrogen sweep flow rate was outside the pre-defined range (84 to 86 l/min) on 02/26/2016 from 10:43 am to 11:43 am. The process parameter value during this period was 83 l/min. In addition, a deviation was not initiated per, SOP HQ.CO.SOP126.0EN, Quality Deviation Records, Effective Date: 03/23/2018 **(Exhibit_10-YB)** under section 3, Introduction, which reads as follows:

A nonconformity is considered to be a deviation if:
- It is an unplanned event that is a departure from approved instructions/processes, approved standards/procedures, a departure from defined specification limits or acceptance criteria or even, presence of unexpected material;
- and is not listed as Quality incident.

All deviations should be fully recorded and investigated with the objective of determining the root-cause and implement appropriate corrective and preventive actions for those root-causes.
In order to avoid recurrence, it is essential to complete corrective and preventive actions in a timely and effective manner. Independent records should be issued for different occurrences. Records

should be written in a concise and clear way, being accurate, complete and timely.
All deviations, actions and action's plans should be approved in writing by the Quality Assurance Unit.

Furthermore, Mr. Baptiste and the firm management explained that the nitrogen sweep was not listed as a predefined critical parameter as per Quality System Reports, HQ.QSR.RE668.0EN, 19IO01 – Process Criticality Analysis, Effective Date: 03/13/2017 (**Exhibit_11-YB**). I explained that the Quality System Reports HQ.QSR.RE668.0EN was established and made effective after the batch record 19IO01.HQ00012 was approved and was not captured by the reviewer of the batch record or by the quality assurance team on 03/26/2016. Additionally, these critical parameters were not established during the review of batch 19IO01.HQ00012. I readdressed my concern that an investigation should be performed for all nonconformance results to determine the root cause of the out of specification.

This observation was discussed at length during the inspection and immediately addressed through a deviation. The firm acknowledged the failure to address any nonconformance results. Mr. Baptiste provided a copy of the Deviation Report into this discrepancy as **Exhibit_12-YB**. The firm management stated a detailed response would be submitted to the agency in 15 business days.

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

On 05/18/2018, I, Investigator Yvesna Blaise, conducted a closeout meeting with Mr. Guy Villax, Chief Executive Officer and issued him an FDA 483, Inspectional Observations form. Also present were Mr. Filipe Rosa Vicente, Site Manager; Mr. Gonçalo Lopes, QA Senior Specialist; Mr. Henrique Dolores, Head of Production - Pharm Operations; Ms. Joana Ferreira, Head of Quality Systems Management; Mr. João Alves, Site Quality Director; Mr. João Beirão, Head of Production - Pilot Plant; Ms. Luisa Paulo, Corporate Quality Senior Director; Mr. Jorge Moreira, Group Leader, Quality Control; Ms. Ilda Chasqueira, Head, QA Equipment & Facilities; Ms. Susana Ramos, Team Leader, RD DPD - Analytical Development and Mr. Manuel Carvalho, Warehouse Coordinator.

I discussed the following one deficiency as a verbal observation during the closeout meeting and throughout the inspection:

Documentation and Review of Equipment Logbook:
On 05/16/2018, during the review of several records, it was noted the 2nd person verification was completed and solely signed off by the same person. This was seen in Batch record 17KJ01HQ00012, during the review of step 19, Distillation. The same operator completed the task and verified the calculation. No further detail was provided in the observation sections of the batch

record. I bought this concern to Mr. Pedro Andara, Process Engineer that reviewed and approved the batch record. Similarly, during the review of the equipment log book SD361, Stainless spray dryer used in the production of product 17KJ01. On 04/01/2018, the equipment was cleaned and verified by the same operator. Per SOP HQ.GQ.IOP039.4.PO, Livros de Registo de equipmamento de process e salas da area productive, Effective Date: 10/30/2018 states under Section b. Record of the cleaning of the equipment/room, an operator different from the one who carried out the "Visually Clean" at the end of the cleaning, should fill in the field "verification (visually clean)" of the respective logbook of the equipment. The firm understood my concerns and assured that management will take corrective action.

VOLUNTARY CORRECTIONS

The previous PAI inspection was conducted from 03/13/2017 – 03/17/2017 and classified as VAI. That inspection provided pre-approval coverage for NDA [redacted] "PT-01". Six objectionable conditions were cited on a FDA 483, Inspectional Observations. During the cGMP inspection conducted from 10/30/2017 -11/03/2017 the corrections implemented by the firm to address the observations were verified.

EXHIBITS COLLECTED

1 Approved regulatory submission for the US market , 4 pages
2 Company Presentation, 35 pages
3 A list of all products and APIs manufactured and shipped for the US market, 5 pages
4 A list of Hovione sites and location, 2 pages
5 Inspection Attendees, 2 pages
6 Organizational Charts, 3 pages
7 Process Flow Chart of NDA [redacted], 12 pages
8 Process Flow Charts of NDA [redacted], 1 page
9 Batch Record #19IO01.HQ00012, 44 pages
10 HQ.CO.SOP126.0.EN, Quality Deviation records, Effective Date 3/23/2018, 36 pages
11 Quality System Reports, HQ.QSR.RE668.0EN, 19IO01 – Process Criticality Analysis, Effective Date: 03/13/2017 , 17 pages
12 Deviation report ID 66864 , 3 pages
13 Overview Presentation of NDA [redacted], 19 pages

ATTACHMENTS

1 Upload Issued Form 483

X Yvesna C Blaise
Investigator
Signed By: 2001768948
Date Signed: 07-25-2018 16:43:05