Dr. Willmar Schwabe
Group of Companies Germany

Audit Report Quality Assurance	**Sonneborn Refined Products B. V.**	Code: 00QSAB018/19 Date: 12.11.2019 Cover Sheet: 1 out of 2

Company:	Sonneborn Refined Products B. V. (66072)
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Contact person:	Remco Kruger QA Officer Phone: + 31 20 3800 510 E-mail: remco.kruger@sonneborn.com
Operating activities:	☐ Manufacture of medicinal products ☐ Manufacture of intermediate goods or bulk materials ☐ Decanting, packing or labelling of medicinal products ☐ QC analyses (laboratory) ☐ Quality control and batch release ☒ Other: Manufacture of a pharmaceutical excipient
Participants from the audited company	Hessel van Tent Beeking — Manager QA & EHS Remco Kruger — QA Officer Jason Hall — Regional Sales Manager Dr. Stefan Balk — Head of Sales (TER Chemicals)
Auditors:	Dr. Martin Rothenhöfer — Quality Control SWA BK Dr. Ursula Dowe — Quality Assurance
Date of the audit:	12.11.2019

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Dr. Willmar Schwabe Group of Companies Germany		
Audit Report Quality Assurance	**Sonneborn Refined Products B. V.**	Code: 00QSAB018/19 Date: 12.11.2019 Cover Sheet: 2 out of 2

Summary and conclusion:

The company provides a good impression as manufacturer of excipients (namely petroleum jelly, syn. Vaseline) for pharmaceutical (and cosmetic) products. The overall compliance to GMP (with regard to the manufacture of excipients) of the company has been confirmed. Premises, facilities and processes are suitable for producing petroleum jelly for the Schwabe group of companies. Sufficient and adequately qualified personnel are available. Personnel are very well-informed and motivated.

Sonneborn Refined Products B. V. is released as a qualified manufacturer of a pharmaceutical excipient (petroleum jelly) for the Dr. Willmar Schwabe Group of Companies Germany.

Date, signature of the auditors

19.12.2019

Dr. Ursula Dowe
Dr. Willmar Schwabe GmbH & Co KG
(Lead Auditor)

19.12.2019

Dr. Martin Rothenhöfer
Dr. Willmar Schwabe GmbH & Co KG

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1 Brief description of the company

Ownership structure

The company is part of the group of companies of Hollyfrontier, which is an US-American holding specialized for lubricants and other specialties. Hollyfrontier has about 4000 employees all over the world. For the Sonneborn site in Amsterdam the new ownership stands for new investment in building, equipment, personnel and processes. This development could strengthen the company. Details can be read in the company presentation attached to this report.

Age/history of the site:

Sonneborn itself is a company with a long history, founded in 1903. It's a worldwide leading specialist for petroleum jelly (Vaseline), white oil or microwaxes. The company has two sites which manufacture Vaseline in the required quality: the site Amsterdam and the site Petrolia in USA. Both sites act as back-up for each other, so a break down due to force majeure of the one site can be covered by the production of the other side. Both sites are dedicated to the production of white mineral oil and Vaseline, whereas the site in Koog (NL) is dedicated to the production of microwaxes. Further details can be read in the company presentation attached to this report.

Number of employees:

The company Sonneborn has worldwide around 500 employees, whereof approximately 180 are working at the Amsterdam site.

Portfolio vs. products/APIs/services supplied:

The site is producing high quality grade white oil which and Vaseline, white oil. The company Sonneborn as a whole also manufactures microwaxes and other special products from hydrocarbons which are needed in other industrial branches.
The grade for the pharmaceutical excipients is always specified according to Ph. Eur. and / or USP. The same products with less detailed documentation is sold as raw material for cosmetics. Details can be read in the company presentation attached to this report.

Nature and extent of manufacture (regarding the products/services within the scope of the audit):

As Sonneborn site Amsterdam is delivering white Vaseline for the group of companies, only the relevant parts of the production plant and of the quality control lab was audited.

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2 Brief description of the audit

Scope of the audit / type of the audit:

- ☒ Audit for qualification (➔ full scope)
- ☐ Audit for re-qualification (➔ reduced scope / risk-based approach)
- ☐ Audit "for cause":

Standards and regulations concerned / regulatory basis:

EU-GMP guide with special regard to the GMP-risk assessment for pharmaceutical ingredients.

Issues/departments within the scope of the audit:

QA-system
Manufacturing
Quality Control
Storage and Distribution

Issues/departments skipped (risk assessment):

Sales and distribution as far as under responsibility of distributor

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3 Findings and observations by the audit team

3.1 Quality Management

3.1.1 General

The QA department now comprises two members, who are also responsible for the topics of environment, health and safety (EHS).
The company is certified according to ISO 9001:2015, the current certificate expires on August 9th, 2021. Based on this certification, the QM-System of the company is also certified according to the EXCiPACT Good Manufacturing Practices for Pharmaceutical Excipients (2017) since 2006. The current certificate is valid until October 17th, 2022.

To maintain the quality management system and certification, regular inspections by auditing bodies take place. Additionally, the Amsterdam site is inspected by customers at least once a month.

3.1.2 Deviation Management

The handling of deviations and OOS test results is described in an SOP (08.18; version 9, 06.11.2019) of the quality assurance.
In case of an OOS result which is not due to analytical error (1st step of OOS investigation by QC), a further root cause analysis is performed for the production process and the QC checks whether there is another customer specification which is met by the material concerned. This not applies if the material does not correspond to the limits for contaminants. The decision for this procedure is made together with the responsible for QC and QA.

3.1.3 Change Management

The Management of Changes (MOC) is described in a detailed procedure (04.18, version 27, 28.06.2019). The procedure starts with a form ("Risiko Inventarisatie Formulier") in which all relevant departments must classify, by filling the questionnaire, the risk of the change regarding GMP and GDP, to environment, health and safety and regarding its relevance for customer notification. If there is a need for customer notification this ensured by the customer service department. Customers usually are only informed after the implementation of the change, not prior to give their approval. However, pre-implementation approval by customers will be sought, if there are relevant changes which may have regulatory impact to the dossiers of the customer (e. g. change of the antioxidants to a completely other component than alpha-tocopherol). The company has around 80 Change Control procedures per year.

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3.1.4 Validation (processes/cleaning)

Cleaning Validation

There was no cleaning validation performed. This is acceptable, because of the same product category which is produced, the dedicated equipment for the products and the high distance of pipelines (m. t. 1000 m). In addition, there is no cleaning with water or detergents necessary and any microbiological risk can be excluded.

Process Validation

A process validation master plan could be seen. All relevant steps in the manufacturing of the Vaseline have been validated i.e. blending of the white oil, the blending sheet (excel file), so it can be assured, that the product is constant in consistency and its analytical parameters.

3.1.5 Risk of (cross-)contamination/mix-ups

No risk of cross contamination was identified because there are only white oil, microwaxes and bleaching earth as components in the process which takes place in dedicated and closed systems.
A mix up between several batches is not a risk for customer safety or product quality because mixed batches will be homogenized and tested against the valid specification of the compendial monographs. Due to the fact, that all Vaseline types correspond to the compendial monographs, there is no risk with mix-ups.
Planned mix-ups take place with each batch because there is no cleaning between the Vaseline types.

3.1.6 Outsourced Activities

Outsourced activities were covered by the procedure "vendor assessment", which is done on a risk-based approach.
The following activities were outsourced by the company:

- Special contract manufacturing (if applicable)
- Pest control
- Special analytics (heavy metals, microbiology)
- QA consulting for internal audits
- Transport and logistics

3.1.7 Complaints and recall

Customer complaints

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The handling of customer complaints is described in SOP 01.15 version 039 "External complaint procedure". The sales management or the customer service fills the internal complaint form, which is subsequently handled by the quality assurance. The complaint is checked for other batches or customers that might be concerned and with regard to necessity to block saleable stock. Furthermore, an investigation is carried out, whether the root cause of the problem can be identified and whether the problem might occur again.
The QA defines corrective and preventive actions and closes the internal investigation. The customer is informed by using the response form.

3.1.8 Self-inspections

The relevant departments for GMP, GDP and EHS are part of the internal audit schedule. They are inspected on a yearly base. Internal audits are performed by an external consultant, who is trained to the in-house procedure for internal audits and qualified for this purpose. The procedure for internal audits / self-inspections is described in document 01.08 version 042.

3.2 Personnel

The Amsterdam site currently has approximately 180 employees. The production and laboratory people work in three shifts, 24 hours, 7 days a week. In the quality control the analysts work in five shifts
The entrance to the company is controlled by personnel of the plant security. Additionally, the entrance to each building is electronically access-controlled. By screens the persons currently present are listed in the entrance area of the respective building.

For each position in the company documents called "functional profile" exist. The functional profile for the position of the "Supervisor QC", dated 09/2017 was presented. In this document the required qualification, the tasks and responsibilities and the training schedule is fixed. The functional profile is signed by the owner of the position and the management or the supervisor, respectively.

Training
The training of the personnel is planned by the HR department. The planning includes internal and external trainings and is scheduled for one year and comprises GMP-topics, health and safety and other internally relevant topics. Due to the fact, that there are no hygienic areas, no hygienic training is done.
There is no procedure established, that new or revised documents (procedures or methods) must be trained. The employees are requested to use always the current version of a document, which is presented in the documentation system WIKI. If there a new document published by QA, the heads of the departments are informed, and they are responsible for teaching and training the employees concerned.

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3.3 Premises and equipment

3.3.1 On-site inspection

The results of the on-site inspection are described in the individual chapters below.

3.3.2 Room qualification

Manufacturing takes place in closed chemical reactors and pipes there is no need for a formal room qualification.

3.3.3 Environmental monitoring

Regarding the kind of products and with conditions for microbiological growth not given by product and manufacturing process, there is no environmental monitoring in place.

3.3.4 Equipment

The manufacturing of the Vaseline and filling to drums take place in three different plants within the site: The PER plant produces white oil from base oil, the equipment is dated from 1974. The BES reactor is used for the mixing of the components, for bleaching (to lighten the color of the product) and stripping (to reduce / eliminate the odor). This reactor is dated from 2010. For the equipment of the BES plant, a formal IQ, OQ and PQ was performed. Last, Vaseline is filled into trucks, IBCs or into drums in the BAS plant. The manufacturing takes place in chemical reactors. Hence, there is no need for further a formal equipment qualification.

3.4 Documentation

Documentation system

Documents of the quality management system are managed using a software called "Wiki". No paper-based distribution of procedures (SOPs) is implemented. All employees are requested to check the current version of documents in the system. Every employee has access to the electronical system. New documents are written by the QA department or the responsible persons for the relevant departments. This applies also to the correction or revision of documents.

Pest Control

Pest Control is outsourced to Rentokil. The monitoring comprises UV-traps for flying insects and traps for rodents. The service provider has fixed eight dates for control of the traps. They report to the members

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of QA. Sonneborn uses the online portal of Rentokil called "myRentokil". All results and actions taken are recorded in this validated database.

Supplier qualification

The supplier qualification is done by a risk-based approach and the procedure is laid down in document 03.16, version 27. Materials, that require supplier qualification are the starting materials (e. g. white oil), the bleaching earth and the drums for the packaging of the Vaseline.

For the critical starting materials, a supplier qualification is in place, including an on-site-audit in case, the material is not delivered from own sites (e. g. Koog, NL).

For the delivery of the drums from company Schütz there exists only a paper-based supplier assessment. For a detailed qualification an on-site-audit is planned for 2020.

For the supplier of the bleaching earth (Sepiolsa, Spain) no qualification is established.

A vendor rating is established and done on a yearly base (03.13).

Method validation

Validation documentation of the HPLC-method for the determination of alpa-Tocopherol was reviewed during the audit. The validation was performed from September 2018 to January 2019.

All relevant aspects were covered, i. e.

- Specificity
- Linearity
- Recovery
- LOD / LOQ (by S/N ratio)
- Precision (repeatability + intermediate precision)
- Uncertainty
- Robustness (e. g. regarding stability of solution, eluent, flow, temperature, column)

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3.5 Manufacturing and storage

3.5.1 On-site inspection

In-coming of goods

The relevant starting materials for the production of Vaseline (base oil, white oil and micro waxes) are delivered from own sites (Koog, NL) or from third customers.

If the material is delivered by truck, the truck driver must inform the personnel of of plant security. They inform the QC lab to organize the sampling of the material delivered by the truck.

By the lab, a quick check of viscosity, density and water content is performed. If the parameters meet the specification, the unloading to dedicated tank facilities takes place. The warehouse and storage are managed by SAP as ERP-System, the production process and laboratory data are managed by a MES-System.

Production

A description of the manufacturing process is given in the company presentation which is attached to the report.

The starting materials for Vaseline (petroleum jelly, PJ) are white oil and microwaxes. The white oil is manufactured also by the Sonneborn Amsterdam facility. As production aid, bleaching earth for the color and hot steam for the odor of the final product are used.

The different types of Vaseline vary in the quantity proportions of the components white oil and microwaxes. The first GMP-relevant step in the production of Vaseline is the mixing of white oil with microwaxes.

The production orders are given from the planning department into the MES system. Quality Control defines the components for the mixture regarding the analytical parameters of the white oil and of the microwaxes to achieve the customer specification. In QC a lab sample it prepared and checked against the customer specification. Afterwards, the recipe is put into the MES system with the module Aspen Process Employer.

A minimum process order covers an amount of 20 t, the process equipment routinely produces 5 t / h. 2 hours are necessary to prepare the equipment for production, around 3 hours are necessary for emptying. A cleaning step is not implemented because the equipment is dedicated to the production of Vaseline.

The mixing of the two components is done at 105 – 120 °C, after mixing and homogenizing the bleaching earth is added to the mixture. After mixing and homogenizing the Vaseline is filtered through different filter materials (stainless steel, filter bags e. g.). The last filtration step uses a filter with a mesh size of less than 1µm. After bleaching the Vaseline is treated with hot steam at 120°C at deep vacuum of 2.2 mbar. After that, the material is filled into a tank storage before it is finally filled into trucks (at around 85 °C) or is filled into drums. The drums are stored at room temperature. The maximum storage time for the material in the tank farm is around one week.

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Quality control samples are taken prior to filling into the tank farm as an in-process control and after packaging into the deliverable container.
If a material doesn´t meet the required specification, there is a possibility for reprocessing. However, this is done very rarely, it takes place not more than three times a year. Due to the very simple process and the only two different starting materials, every produced material normally meets the requirement(s) of and can be delivered to (at least) one customer.

The storage and production process are a contained process. The only moment, the containment is broken is the filling of the material into drums, which lasts about 10 min. The filling is done in a special filling cabinet, so there is no direct impact of the storage environment, but there are no environmental conditions fixed (microbiological, particles etc.). This can be regarded as not critical because there is no risk for microbiological contamination of Vaseline. The company has established a risk analysis on this topic.

Packaging
The Vaseline / Petroleum jelly can either be filled up into trucks or into drums with a maximum quantity of 185 kg. The upper third of the inside of the steel drums is covered with an inert coating. The coating is guaranteed to be Bisphenol A free. The drums are purchased at Schütz GmbH which is an established company for this kind of drums.
An internal project covers the supply of drums with a new coating to have a better product protection. As far as the new packaging material will be used the customers will be informed according to the Change Control procedure.

Stability
The shelf life of the material (Vaseline) is fixed for three years after production. The definition was not done based on ICH-Stability studies, but on the results of an in-house testing program. Each year at least one batch of Vaseline is tested for stability at storage conditions of 30 °C and 55% relative humidity.

Water for steaming
The steam for the last purification step of the manufacturing of the Vaseline is prepared from drinking water. The water meets the specification of the WHO for drinking water. The control is done by the local community. To reduce the corrosive impact of the steam, special anticorrosives are added to the steam, e. g. ACN Redline 524 or 631. The additives comply to the requirements of the regulations 1935/2004 EU and 1333/2004 EU for food additives.

The addition of the anticorrosive to the steam is evaluated in the document "risk assessment" (07.05. version 18 reg. 7.1.3 and 7.1.4 GMP/Exipact)

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Bleaching earth

The specification for the bleaching earth requires at least food safety quality. The relevant certification is presented by the supplier of the material on his website.

Sonneborn has only a specification for the supply of the material, but there is no testing established for the material in QC.

3.6 Quality Control

In general

The quality control lab is rather old. But according to the responsible persons of the company, one main effort of the new owner Hollyfrontiers is to modernize the lab structure. This project comprises new furniture, new laboratory equipment, new processes and a new structure for the analytical methods. The project is started due to the risk assessment of Hollyfrontier to ensure the supply chain for the customers. The project will start in January 2020.

Equipment

The laboratory is very well equipped with several HPLC- and GC-systems, with a broad spectrum of viscosimeters, rheometer, DSC etc.

The maintenance and calibration of the equipment is done either by specially trained senior analysts or by technicians of the supplier of the technical devices. Maintenance is done on a yearly base; a daily calibration (e. g. by using a standard fluid for the viscosimeters) is required to be done routinely by the analysts.

The software for the chromatography is Open Lab / ChemStation which is provided by the supplier of the equipment.

Incoming of goods

Incoming materials are delivered in truck loads and handled as described before. The samples are labelled with barcode, time of incoming, name of the supplier and process order. A batch number will be given for the materials which are delivered to customer or to stock but not for incoming goods or for batches which are produced. These materials are identified by the number of the process order.

After having tested the samples of the incoming goods as a quick check, the analyst puts the result into the MES system and releases the material for transfer from truck to tank. For incoming goods there is no double check of analytical results.

A double check of results is established for all materials which are delivered to stock or to the customer. The check takes place when the data from the MES-system are manually transferred to the SAP system. The transfer and double check are documented on the first page of the raw data documentation.

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The analysts in the QC lab are fully qualified for the task of Quality Control. A diploma in laboratory working is required for this position. For all kind of jobs, job descriptions are in place.

The tests in the QC lab are performed according to the current version of the Ph. Eur. or USP. The review of new version of the compendial methods is done by the Quality Assurance personnel who inform the head of QC that there is a need to change or adapt analytical methods. As told by the head of QC, all methods for testing Vaseline Ph. Eur. are done according to the current version exept the method for PAH (polyaromatic hydrocarbons). For this UV method the dimension of the cuvettes differs from the Ph. Eur.

Documentation

A raw data documentation for Vaseline W Enorm could be seen during the audit. It was version 006 dated 17.11.2016. The cover sheet of the documentation gives the specification, the needed analytical procedure (SAM), the customer specification and the results. The methods are coded "SAM" which means Sonneborn Analytical Methods, this is the Dutch translation of the compendial methods.
Page 3 to 5 of the laboratory documentation is for the documentation of all analytical parameters for the testing methods as a kind of in-process controls (e. g. temperature, measuring time) and the results for the material checked.

The SAM 168 "HPLC bepeeling van alpha-tocoferol in witte oil" version 2, revision date June 18th, 2019 was presented as print out. However, the check of the WIKI system showed version 1 from 2016 as the current version.

3.7 Sales and distribution

Not part of the audit because sales and distribution are performed by the TER Group. The material is shipped from Amsterdam to the Schenker warehouse on behalf of the TER Group in Leverkusen and then distributed to the customer sites.

The certificate of analysis is issued by Sonneborn, the Ter group is only responsible for sales and distribution. The responsibility for the product remains at Sonneborn / Ter Group until delivery to the Schwabe site Ettlingen (Incoterm CPT Ettlingen). The transport of the material is done unconditioned.

4 Information on previous audits

Not relevant

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5 List of observations and deficiencies

Classification of observations and deficiencies:

1. *Critical observation/deficiency:*
   The observation/deficiency potentially or actually affects the quality of the product, leading to a product that is potentially life-threatening or may be seriously harmful to health of patients.
2. *Major observation/deficiency:*
   The observation/deficiency potentially or actually affects the quality of the product but does not fulfill the criteria of a critical deficiency (1).
3. *Other observation/deficiency:*
   The observation/deficiency has no recognizable impact on the quality of the product (proper quality of the product is proven). The deficiency evidently does not pose any significant risk and does not fulfill the criteria of a critical (1) nor major (2) deficiency.

5.1 Critical observations/deficiencies

No critical observations.

5.2 Major observations/deficiencies

No major observations.

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5.3 Other observations/deficiencies

I. The rooms and furniture in the quality control lab is functional but should be renewed. As explained by the company, a project was initiated to reorganize the laboratory processes, the methods and the equipment. This is only possible with the new holding of Hollyfrontier.

II. The documentation system is prone to error. Within the QC Lab a method for the determination of alpha-Tocopherol via HPLC in version 2 dated 18.06.2019 was presented. In the WIKI System the version from 18.06.2016 could be found as current version.

III. The validation of the HPLC-method for the determination of alpha-Tocopherol in Vaseline via HPLC was documented in a validation report. A validation protocol fixing the validation parameters was not established.

IV. The filling of the Vaseline drums is done in a nearly closed system. After opening the drums, a chain is used for the control of the height of the vessel. In a worst-case a part of the chain could fall in the open drum without noticing this by the operator. A better technical solution should be established.

5.4 Re-audit ahead of schedule

☒ not required
☐ required; time frame:

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