

NEWS from

Nomeco HealthCare Logistics

DECEMBER

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Raw Materials and Analyses

Nomeco delivers raw materials for the Danish pharmaceutical and biotec industry. They can be weighed out in the desired amount and analysed.



It's all about meeting the needs...

By Jørgen Kelkjær & Henrik Kastrup

After more than 15 years of pursuing separate roads, Nomeco and Unikem chose to re-merge during the summer. The decision to include the three GMP related activities in Unikem was strongly driven by the need for our customers to gain “one point of contact” within the Nomeco group. As of July 2007, Unikem has become a fully integrated part of Nomeco's industry division, Nomeco HealthCare Logistics, which now counts nine services targeted at the Pharma industry and the hospital sector.

Over time we expect to gain further synergies from the merger than merely a more convenient communication setup. For example, our portfolio of services now spans from laboratory (governed by GLP) and manufacturing services (GMP), to clinical services (GCP) and our traditional logistically related services (GDP). This broad range of competencies allows us to apply approved business models, quality systems etc. to new services. The overriding aim is to increase our value proposition to our customers.

For more than a year our GMP Production area (including production, labelling and packaging services) has been subject to a streamlining process. We have sought to achieve a production service which will fit seamlessly with the range of our GCP and GDP services. The result has been a dramatically improved “flow” when it comes to repackaging trial medication and finished goods stored in Nomeco's central warehouses. The tangible benefit is a reduction of time to market and patients participating in clinical trials.

This issue of our Newsletter focuses on our services in the areas of pharmaceutical ingredients and laboratory analyses – services which over the next few months will be further integrated with Nomeco HCL. We offer a unique set of competencies, allowing our customers to maintain focus on their core business processes, a flexible capacity and short lead times. Do not hesitate to contact us if you wish to explore the possibility of a partnership!

Henrik Kastrup, Director Sales & Marketing,
Jørgen Kelkjær, Director,
Nomeco HealthCare Logistics

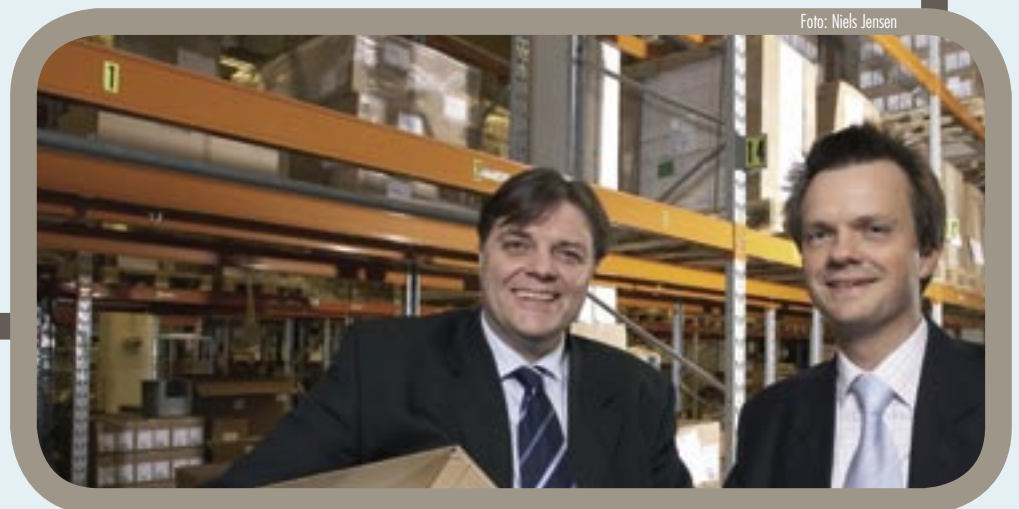


Foto: Niels Jensen

ANALYSES
Pharmaceutical Ingredients

GMP
LABORATORY



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RAW MATER

for more than 30 years

Nomeco supplies raw materials which are analysed and tailored to the pharmaceutical industry.

For more than 30 years, Nomeco has been delivering raw materials to the Danish pharmaceutical and biotech industries as well as to the hospital pharmacies production. In our portfolio you will find approx. 400 products permanently on stock. Products not in our standard assortment can be ordered upon request.

“We stock Active Pharmaceutical Ingredients (API) as well as excipients. Thus, we are capable of supplying our customers with the active ingredient as well as with the ingredients that give the product context, colour and taste. We are able to supply everything from A to Z; Acacia is the first item on our list and Zinc monohydrate the last. Moreover, we are completely product-neutral,” says Key Account Manager Steffen Schmitt Petersen, a specialist in the area of Pharmaceutical Ingredients and Analysis.

”When you purchase raw materials from us, they have been analysed at our own laboratory. As a result, the lead time is significantly reduced and the product can be used in the production sooner.”

All procedures are carried out according to cGMP (current Good Manufacturing Practise) and Nomeco holds a §39 GMP authorisation as well as an API-authorisation from the Danish Medicines Agency regarding handling and storing of API. The raw materials are released by one of the pharmacists from Nomeco’s Quality department.

Both small and large customers

Nomeco’s customers are often pharmaceutical companies without their own analysis laboratory. Moreover, the raw materials are typically delivered in specific quantities which are later modified to fit the batch sizes of the respective company. Besides the pharmaceutical industry, suppliers of dietary supplements, herbal medicines and cosmetics are also found in our customer portfolio as well as hospitals and pharmacies with own production.

As well as the established suppliers, our list of customers counts biotech and research companies who purchase raw materials from Nomeco in connection with their pilot productions.

IALS



”We have approximately 675 customers covering a wide field regarding size and specialisation. For instance, Ferring is one of the large companies who buys their raw materials in weighed out quantities, this also applies to the SAD Corporation. Smaller customers purchase excipients in smaller quantities for smaller batch sizes,” explains Steffen Schmitt Petersen.

The majority of the raw materials are delivered within Denmark’s borders, although some products are shipped abroad to countries such as Norway, Sweden, Finland, Germany, Switzerland and Malta.

Products are delivered fully analysed

Nomeco differs from other suppliers of raw materials by completing a certificate of analysis at their own §39 laboratory. “We are the only company in the country who supplies raw materials and has access to our own laboratory. This is a big advantage for our customers, since all they have to do is perform an ID-test on the products received. This is a task we may be of assistance with” says Steffen Schmitt Petersen.

continues ...

Key Account Manager Steffen Schmitt Petersen explains how raw materials from Nomeco can be analysed in their own laboratory and weighed out in desired amount.

Unikem is now Nomeco

For more than 30 years, Nomeco has been delivering raw materials to the Danish pharmaceutical industry. The warehouse, laboratories and additional facilities have always been located at Halmtorvet, where Mecobenzon once had their production. In connection with a merger in 1991, Mecobenzon became Nomeco and in 1995, the Raw Materials department separated from Nomeco as the subsidiary ‘Unikem’. On the 1st of June this year, Unikem re-merged with Nomeco, once again under the former name. The name of the locality is ‘Nomeco Site Halmtorvet’.



Morten Just Blangsted
Site Director



Let Nomeco be in charge of the warehouse

"The closer Nomeco is to the specific company's production, the shorter are the delivery- and lead times. Therefore, we are working on several new business models, which will create an even closer connection to our customers," states Site Director, Morten Just Blangsted.

The most extensive solution is when the manufacturer leaves the complete management of their raw materials stock to Nomeco. "This type of Nomeco-managed warehouse is used by the majority of our customers in the finished goods section which is now being expanded to include raw materials. This means that the customer does not need to spend time paying attention to the warehouse, order handling and calculation of analysis times, etc. All this is handled by Nomeco. Furthermore, we ensure that the raw materials will be at the manufacturer's warehouse at the time when they need them. This is easy and time saving," says Morten Just Blangsted.

Another option is for the company to buy the raw materials accompanied by an ID-analysis. The practical arrangements are tailored to fit the company's needs and opportunities while at the same time complying with the GMP regulations.

It is possible to have one's raw materials weighed to avoid handling heavy sacks of 25 kgs.

Nomeco is an expert in delivering the exact amount of the product required by the customer, and it can be used in production immediately thereafter, since all the analyses have been completed.



- If the raw materials are delivered fully analysed, this will reduce storage time, since the products may be used in production immediately. Nor does the customer risk having to return products which do not comply with the specifications or expiry dates.

Weighed out in the desired quantity

Nomeco is the only supplier of raw materials able to weigh out raw materials in smaller quantities. This is a popular service, utilised by both large and small customers. "You can just about have any quantity you wish. This is useful if you do not need a large amount – for instance for pilot trials, where only small amounts of the pharmaceutical are produced. Perhaps the customer wishes to have their raw materials weighed out in quantities to match their production. Another reason could be to avoid having to handle 25 kg sacks."

Thus, Nomeco is an expert in delivering the exact amount of the product required by the customer, which can immediately be used in production as all the analyses have been completed. "We have a strong and solid product offering, which supports a large number of Danish manufacturers of pharmaceuticals and their research. No task is too strange or too difficult for us – we are used to the customers' needs defining the assignment, explains Steffen Schmitt Petersen and adds that the goods may also be stored in consignment stock.

"Hence, we purchase a raw material, place it in storage and reserve it for a certain customer. When the product is in consignment stock, our ability to deliver is guaranteed."

mwh

GMP analysis and advice



Nomeco operates its own laboratory, which analyses raw materials and finished goods. Additionally, Nomeco offers advice in connection with tests, analyses and sampling.

No raw materials will leave Nomeco without a guarantee that they comply with the valid Pharmacopoeia. The analyses are carried out in Nomeco's own §39-approved laboratory which undertakes all types of chemical analyses.

"First and foremost we analyse our own raw materials; however, we also accept finished goods and raw materials from our customers for analysis. If the customer has a specific method for handling events or procedures they want us to comply with, we will take note and follow these. All products are returned with a certificate," says Laboratory Manager, Erik Zobel.

Our core competence is chemical analysis; however, Nomeco is also able to handle microbiological analyses in cooperation with other laboratories.

Guidance regarding analysis method

According to Erik Zobel, a typical case would be a company requesting an analysis according to European or American Pharmacopoeia standards. Nomeco receives an agreed amount of the raw

material or finished goods in question, which are then analysed in the lab. The customer will receive a certificate as a PDF file, as well as the original document by post.

Nomeco also offers guidance on choosing which analysis is required and which method should be used. "Many suppliers call us for advice on testing and analysing products, as well as sampling. We help the company find a validated analysis method which meets their requirements. If required, Nomeco may also perform a validation of the method."

Hospitals and pharmacies are among our customers

Several of our customers who make use of our analysis service are medium-sized or small companies without their own laboratory facilities. For instance, Nomeco sells raw materials and analyses to the hospitals' own production, as well as to the private pharmacies production of pharmaceuticals. The production includes everything from injection fluids to ointments and special medicines. The productions are typically small and therefore the raw materials are usually purchased in small amounts.

mwh



“Our core competence is chemical analysis, but we can also handle microbiological analysis”, says Erik Zobel, Laboratory Manager, M.Sci.Pharm.

GMP REGULATIONS

Herbal medicine is also subject to GMP-regulations

The Danish Medicines Agency requires manufacturers of herbal medicines to comply with the same GMP-rules as manufacturers of pharmaceuticals. According to the Agency, the identification and analysis must comply with EU GMP Annex 8 stating that all raw materials in question should be accompanied by an ID as well as an analysis complying with the regulations of this annex. In practice, this means that all manufacturers must use analysed and ID-controlled raw materials. These requirements are set by EU legislation. Upon inspection, the Danish Medicines Agency requires documentation hereof.

According to Knud Ryhl Bjørnson, Pharmaceutical Inspector from the Danish Medicines Agency, there are no precise consequences if the inspection reveals that the analyses do not meet the set requirements. “It depends on the conclusions drawn from the inspection. The worst case scenario is that the batches in question will be quarantined or recalled from the market,” he states.

CUSTOMERS

statements

Egalet has Increasing Needs for Analyses



Egalet a/s is an innovative, pharmaceutical research company developing special formulations of pharmaceuticals. At present, the Danish company is conducting Phase II-trials of pharmaceuticals for treatment of pain and coronary heart disease. They expect to introduce these products to the market within a few years.

In order to produce trial medication, you need raw materials which have been analysed and released. The raw materials as well as the analysis can be purchased at Nomeco and Egalet are diligent users of Nomeco's laboratory. Moreover, Egalet makes use of Nomeco's expertise in connection with their analyses.

"The number of completed analyses is steadily increasing. This is partly due to Egalet's increased activities and the fact that the development of the products is close to being finalized. Thus, the analyses are becoming increasingly specific and more and more tests are carried out during the development phase," says Mette Juul Poulsen, Quality Coordinator from Egalet.

"As a result, the requirements for everything we do are increasing. We expect to market the products on both the European and the American market, where the demands for analyses are different. Therefore, our raw materials are tested with regard to the requirements of Ph.Eur. and USP, respectively. Egalet has chosen not to have our own facilities or resources for analysing raw material. Instead, we have chosen Nomeco, with whom we have a very good cooperation, to carry out these activities for us," concludes Mette Juul Poulsen.



Nomeco has approximately 675 customers, which span widely in regards to size and specialisation.

Pharma-Vinci Purchases Small Quantities



Pharma-Vinci A/S
Care for health since 1941

Pharma-Vinci is a Danish pharmaceutical company known for their products UniKalk for strengthening of the bones and Vivag, products for intimate care for women.

Pharma-Vinci purchases a number of their raw materials for their pharmaceutical production from Nomeco. "We are a small pharmaceutical company and when we need raw materials, the supplier usually wishes to deliver an entire package. However, we often require smaller portions which Nomeco is able to weigh out for us," says Product Manager René Rust.

"We do not have our own laboratory where we can carry out analyses. As our raw materials need to be analysed to be used in pharmaceuticals production, we ask Nomeco to carry out these analyses for us before delivering the raw materials. So we can make do with carrying out an IR-control which means that via an infrared scanner we are able to verify that the profile of the raw material corresponds to our registered standard."

According to René Rust, another advantage is that the raw material is ready for use in production immediately. "Having been analysed, they are not kept in storage for long."

Ferring: Top Quality



"For years, we have worked with Unikem, now Nomeco, in connection with our purchases of raw materials. I have only positive things to say about our collaboration." These are the words of Ferring's Production Manager, Lise Martinsen. Ferring is a research-based, biopharmaceutical company with products in the following areas: obstetrics, urology, gastroenterology, endocrinology and osteoarthritis.

Lise Martinsen is responsible for the company's Pentasa-production, which is used for treating diseases of the bowel. Pentasa is available in different packaging sizes.

"We purchase regular raw materials as well as raw materials in specific weighed out amounts from Nomeco. Moreover, the products always comply with the GMP standards and are of top quality. Previously, we did most of the weighing ourselves, but when the new EU directive became effective, we became aware of the environmental issues weighing would involve. The directive pays particular attention to dust, as it may explode, and when we carried out the weighing procedure there used to be so much dust that we were covered in it from top to toe. Therefore we have asked Nomeco to handle this assignment," informs Lise Martinsen.

Ferring has their own laboratory and therefore performs their own id-tests of raw materials purchased from Nomeco. The raw materials are always delivered to Ferring analysed and with an accompanying certificate – this is a requirement for a GMP company which purchases raw materials. "Our supplier agreement with Nomeco includes a demand for analyses from Ph.Eur. and the Pharmacopoeia, in order for us to guarantee purity," explains Lise Martinsen, who is responsible not only for production for Denmark but for the international market.

RAP: Producing Pharmaceuticals

for a Critical Market

The Danish hospital pharmacies produce a large number of pharmaceuticals. 6 different hospital pharmacies produce a total of 221 registered SAD-products. 'Region Hovedstadens Apotek', also known as RAP, produces 74% of these compounds. Measured on turnover, the production of sterile SAD-products (including injection-, infusion- and rinsing fluids) makes up 80% of the total production. RAP not only produces to their own hospitals but also supplies additional hospital pharmacies with certain pharmaceuticals.

"We make products for a critical market which is sensitive with regards to delivery time. For a number of the products we produce, there are no alternatives. Therefore, we have a list of products for which it is essential to avoid back orders. On this list you may for instance find an anaesthetic for which we have experienced back orders. The former supplier of raw materials was no longer in a position to deliver, and the new supplier could not live up to our quality requirements and thus was not approved by the Danish Medicines Agency. The anaesthesia department was desperate to get hold of the product since no alternative existed. This example illustrates our dependence upon a reliable and stable supplier of raw materials, who lives up

'Region Hovedstadens Apotek' produces pharmaceuticals when there is often no alternative. Thus, it is critical that the supply of raw materials is guaranteed.

to our quality standards," explains Trine Schnor, Pharmaceutical Manager for production at RAP.

Extensive requirements for raw materials

RAP purchases both raw materials in weighed out portions and in bulk, all of which are analysed by Nomeco. Furthermore, there are strict requirements concerning the quality of the raw materials and the Danish Medicines Agency must approve the supplier from which Nomeco purchases the registered pharmaceuticals, also called SAD pharmaceuticals. As the example illustrates, it may be crucial if a supplier discontinues their production:

"SAD and the hospital pharmacies are responsible for supplying the necessary documentation to the Danish Medicines Agency, while Nomeco is responsible for notifying us if a supplier intends to discontinue production in the near future. If this happens, we cooperate in the process of approving a new supplier as this may be a time consuming procedure," explains Trine Schnor.

This, along with a number of analyses, is the authorities' guarantee that the raw materials comply with the quality in the approved specification. During production it is solely the responsibility of





Trine Schnor
Pharmaceutical Manager
Region Hovedstadens Apotek



Foto: Niels Jensen

What do the hospital pharmacies produce?

The hospital pharmacies produce SAD-pharmaceuticals, which are registered and thereby approved according to the Danish Medicines Agency's requirements. The raw materials, primarily purchased from Nomeco, must be delivered by a supplier approved by the Danish Medicines Agency. These products may be sold to hospital and private pharmacies if there are no alternatives.

Moreover, hospitals may, through their own production, produce pharmaceuticals for their own use. The principles of quality are very similar to those which the SAD pharmaceuticals must comply with; nevertheless, Nomeco may switch to another raw material supplier without the approval of the Danish Medicines Agency. A few hospital pharmacies produce patient specific medication (typically 1-2 bottles per time), which is often medication for children.

Furthermore, hospital pharmacies may produce the so-called service products, which are not mixed from scratch but are prepared industry compounds. These may include cytostatics mixed for the individual patient.

Finally, the hospital pharmacies produce branded goods such as lotions and ointments which are a part of the patient's treatment.

continues ...



RAP

REGION HOVEDSTADENS APOTEK

REGION H Apoteket

RAP is Northern Europe's largest hospital pharmacy, employing approximately 95 people engaged in the production of pharmaceuticals, branded goods (lotions and ointments), as well as non-medical products (e.g. disinfectants). The pharmacy produces infusion fluids, tablets, ampoules and vials. RAP produces mainly for the hospitals in the metropolitan area but some compounds are sold throughout the country. RAP is the only hospital able to produce tablets.

Product selection is a balancing act

First and foremost, the hospital pharmacies produce pharmaceuticals which are not found elsewhere. However, they also produce infusion fluids for which alternatives exist. "It is a balancing act. We have production machinery which we need to keep running to ensure that we do not encounter a deficit. Moreover, we need to maintain the competencies of our employees, and training a new employee is time consuming. Therefore it does not work if employees are required to produce pills, for instance, only once a month. So we produce a number of compounds with already existing alternatives on the market. Finally there is the question of readiness: In case of an emergency we have to be able to deliver the necessary products. Thus, we need to keep the production machinery up-to-date and the competencies intact."

In conclusion, Trine Schnor points out that e.g. infusion fluids are manufactured from a patient safety perspective. "A number of products may easily be confuse



Foto: Niels Jensen

- the hospital pharmacy to comply with procedures and requirements. Obviously, the quality of the end product must be the same; however, the hospital pharmacy is responsible for drawing up and approving the specifications.

Until now, RAP has left the id-analyses in the hands of Nomeco. From the 1st of September, the Danish Medicines Agency have tightened their requirements, and as a result hereof a test must be drawn from every single container. The procedure is even more time-consuming if the raw materials are purchased in weighed out portions. Moreover, this means stricter requirements if the hospital pharmacies to a greater extent choose to carry out the id-analyses themselves.

Ensuring consistency of supply

According to Nomeco's agreement with SAD and the hospital pharmacies, Nomeco must always have a supply of raw materials available for the production of registered pharmaceuticals. Nevertheless, it may be difficult to predict the amount needed in order to prevent back orders.

To avoid this in the future and to establish a better product flow, Denmark's hospital pharmacies and Nomeco are negotiating a system whereby the pharmacies will receive a collective forecast of their expectations for the years to come. Moreover, this system will be able to determine which portions need to be delivered (in bulk or smaller portions),

as well as who will carry out the id-analysis. Thereafter Nomeco will ensure storage of these raw materials in a specific part of the warehouse from which they cannot be sold to others. The hospital pharmacies are obviously able to continuously purchase raw materials from the rest of Nomeco's warehouse. All this is coordinated by SAD who expects to finalize the agreement with Nomeco shortly.

Locating special raw materials

"One of the areas in which we have daily contact with Nomeco is when we need a rare and special raw material. For instance, if a new product is needed for an individual patient who is being tested for allergies at a dermatological department. Here Nomeco helps out by procuring the raw material if it is not on stock. If the product is sold only in large amounts and all we need is 200 grams, Nomeco can be of assistance by informing us if and when another hospital pharmacy has received the product. We are then able to contact them to inquire if they can spare a small amount," states Trine Schnor.

Thus, Trine is responsible for a very varied production spanning from large amounts of one product for all Danish hospitals, e.g. infusion fluids, to the production of patient specific medicine in small quantities. "Because of the variation we depend upon a stable and flexible supplier of raw materials," concludes the Pharmaceutical Manager.



Foto: Niels Jensen

Henriette Vindmar
Quality Director
Nomeco A/S

New Quality Director at Nomeco

On the 1st of October 2007 M.Sci.Pharm. Henriette Vindmar was appointed Nomeco's new Quality Director. Henriette has previously worked for NNE where her focus was advising the industry with regards to the GMP regulations. Before this, Henriette worked as a Pharmaceutical Inspector for a few years. Moreover, she has been involved in quality tasks in a number of other companies, including H. Lundbeck for five years. In addition, Henriette may include pharmacy experience on her C.V. as she had a temporary job as a Pharmacist when she was newly qualified.

Appointing a Director to the quality area illustrates Nomeco's increased focus on this area. "The future involves thinking quality into our processes to allow us to present the best possible solutions to our customers and meet the requirements from the industry. Moreover, it is important for us to carry out our procedures uniformly, irrespective of where you are placed within Nomeco," explains Henriette Vindmar.

Henriette will bring extensive knowledge concerning GMP, GDP and GCP to Nomeco. At present she is working on her first assignment: approving the CTSM-area in Sydhavnen.

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