Excipient Information Package (EIP)

Product group:	Lactose
Brand name:	SuperTab®, Lactopress®
Production Site:	Nörten-Hardenberg, Germany
Document No.:	PD-0740 Page 1 of 47

DFE Pharma GmbH & Co. KG
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Contents

Section 1 – General Product Information

This document is designed to provide all the regulatory product and supplier information for the products listed below.

Product Brand Name	Material Number	Packaging Size(s)
SuperTab® 21AN	743713	25 kg, Bag
SuperTab® 21AN	659165	50 kg, Drum
SuperTab® 22AN	743714	50 kg, Drum
SuperTab® 23AN	1220097	50 kg, Drum
SuperTab® 24AN	743723	35 kg, Drum
SuperTab® 30GR	743716	40 kg, Drum
SuperTab® 30GR	743715	25 kg, Bag
Lactopress® Granulated	743735	25 kg, Bag
SuperTab® 11SD	743720	40 kg, Drum
SuperTab® 14SD	743721	40 kg, Drum

Section 2 - Manufacturing, Packaging, Release Site and Supplier Information

DFE Pharma GmbH & Co. KG is the manufacturer of pharmaceutical excipients (brand names see section 1).

Our headquarters are located at:

Street address	Klever Strasse 187 47574 Goch Germany	Tel. Fax	+49 (0)2823 9288 770 +49 (0)2823 9288 7799
Post-office Box	P.O. Box 20 21 20 47568 Goch Germany		

DFE Pharma Brand lactose products as stated under section 1 are produced at the following production site:

DFE Pharma GmbH & Co. KG
Lauenförder Strasse 5
37176 Nörten-Hardenberg
Germany
[Health Mark: DE NI200 EG]

The manufacturing, processing, packaging, and part of the monograph testing of these products are performed at above mentioned production location. Release decision is taken by the Quality Assurance department of DFE Pharma.

Final product release testing is performed at the following qualified laboratories:

DFE Pharma
Transistorweg 5,
6534 AT Nijmegen, NL

FrieslandCampina Laboratory & Quality Services LQS*
P. Stuyvesantweg 1
8937 AC Leeuwarden, NL

Labor L+S AG*
Mangelsfeld 4
97708 Bad Bocklet, GER

* = ISO 17025:2005 accredited

Storage of the product before shipping is performed at the following qualified service provider:

Willems Logistic Services
Kempkens 2000
5465 NB Veghel
The Netherlands

Section 3 – Physico-chemical Information

CAS Numbers are stated on our MSDS.
CAS Number for Monohydrate Lactose is 64044-51-5
CAS Number for Anhydrous Lactose is 63-42-3

3.1 Material Safety Data Sheet-Monohydrate Lactose

This product is not a "dangerous" product according to the applicable EU-rules. The MSDS is provided as a service to our customers and there is no legal obligation to provide it in your national language and in the legally defined format.

This document should be read in conjunction with the Ingredient Declaration and the Product Specification for the relevant product or product category.

1. Identification of the substance/preparation and of the company/undertaking

Product name: SuperTab® 11SD/14SD (EU)
SuperTab® 30GR (EU), Lactopress® Granulated (EU)
Manufacturer/supplier identification: See section 2.

2. Composition/information on ingredients

See Ingredient Declaration and the Product Specification
For D-(+)-Lactose monohydrate the following CAS number is applicable:
CAS No.: 64044-51-5: Official quote in current Japanese Pharmacopoeia / Official in Brazil (Anvisa)

EC index No.: N.A.
EINECS No.: 200-559-2
RTECS No.: OD9625000
NFPA code: N.D.
Molecular weight: 360,3 g/mol
Formula: $C_{12}H_{22}O_{11} \cdot H_2O$

3. **Risk (Health Hazards)** No hazardous product as specified in the current EU legislation.

4. **First aid measures**

   After inhalation: fresh air
   After skin contact: wash off with plenty of water.
   After eye contact: rinse out with water.
   After swallowing (large amounts): get medical attention.

5. **Hazards Fire-fighting measures**

   This product will burn. Suitable extinguishing media: water, powder, spray foam, CO_2
   In adaptation to materials stored in the immediate neighborhood.

6. **Precautions**

   Avoid generation of dusts

7. **Handling and storage**

   Store in tightly closed packing protected from solvents. Dry preferable at + 5°C to +25°C.

8. **Exposure controls/personal protection**

   Respiratory protection required when dusts are generated. Eye protection is required.

   The use of hand protection is recommended. Wash hands after working with substance.

9. **Physical and chemical properties**
   For chemical and physico-chemical data see the Product Specification

10. **Stability and reactivity**
    Like any other powdered product, there is a risk of explosion in a confined cloud

LEL g/m³	Pmax Bar	Kst bar.m/s	MIE mJ
30 - 125	6.3 – 8,9	24 - 121	1000
MIT °C	Smoulder °C	Dust Explosion class	
360-470	300-360	ST1	

MIE for micronized lactose is 10 mJ, other values lie within above indicated intervals.

LEL= Lower explosion limit; Pmax= Maximum explosion pressure; Kst=Maximum rate of pressure rise; MIE= Minimum ignition energy; MIT= Determination of the minimum ignition temperature; Smoulder= Smoulder temperature

11. Toxicological information
No toxic effects are to be expected when the product is handled appropriately.

12. Ecological information

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Transport information
Not subject to transport regulations.

14. Regulatory information
Labeling according to EC directives; Keep away from sources of ignition – No smoking

15. Other information
none

3.2 Material Safety Data Sheet-Anhydrous Lactose

This product is not a "dangerous" product according to the applicable EU-rules. The MSDS is provided as a service to our customers and there is no legal obligation to provide it in your national language and in the legally defined format.

This document should be read in conjunction with the Ingredient Declaration and the Product Specification for the relevant product or product category.

1. **Identification of the substance/preparation and of the company/undertaking**
   Product name: SuperTab® 21AN/22AN/23AN/24AN
   (EU), Manufacturer/supplier identification: See section 2
2. **Composition/information on ingredients**
   See Ingredient Declaration and the Product Specification

CAS No.:	63-42-3		
EC index No.:	N.A.	NFPA code:	N.D.
EINECS No.:	200-559-2	Molecular weight:	342.3 g/mol
RTECS No.:	OD9625000	Formula :	$C_{12}H_{22}O_{11}$

3. **Risk (Health Hazards)**
   No hazardous product as specified in the current EU legislation.
4. **First aid measures**

After inhalation: fresh air
After skin contact: wash off with plenty of water.
After eye contact: rinse out with water.
After swallowing (large amounts): get medical attention.

5. **Hazards Fire-fighting measures**
This product will burn. Suitable extinguishing media: water, powder, spray foam, CO_2
In adaptation to materials stored in the immediate neighborhood.

6. **Precautions**
Avoid generation of dusts

7. **Handling and storage**
Store in tightly closed packing protected from solvents. Dry preferable at + 5°C to +25°C.

8. **Exposure controls/personal protection**
Respiratory protection required when dusts are generated. Eye protection is required. The use of hand protection is recommended. Wash hands after working with substance.

9. **Physical and chemical properties**
For chemical and physico-chemical data see the Product Specification

10. **Stability and reactivity**
Like any other powdered product, there is a risk of explosion in a confined cloud

LEL g/m³	Pmax Bar	Kst bar.m/s	MIE mJ
30 - 125	6.3 – 8,9	24 - 121	1000
MIT °C	Smoulder °C	Dust Explosion class	
360-470	300-360	ST1	

MIE for micronized lactose is 10 mJ, other values lie within above indicated intervals.

LEL= Lower explosion limit; Pmax= Maximum explosion pressure; Kst=Maximum rate of pressure rise;
MIE= Minimum ignition energy; MIT= Determination of the minimum ignition temperature; Smoulder= Smoulder temperature

11. **Toxicological information**
No toxic effects are to be expected when the product is handled appropriately.

12. Ecological information

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Products and Packaging

There are no uniform EC Regulations for the disposal of chemicals or residues. Chemical residues generally count as special waste. The disposal of the latter is regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities in charge or approved waste disposal companies which will advise you on how to dispose of special waste.

14. Transport information

Not subject to transport regulations.

15. Regulatory information

Labelling according to EC directives

Keep away from sources of ignition – No smoking

16. Other information

none

Section 4 – Regulatory Information Sheet

4.1 Allergen Information, Sugar

Herewith we certify the presence or absence of allergens in the above mentioned products. This information is based on the current ALBA list of the DATABANK ALBA, TNO in co-operation with the Dutch food and nutrition center. It includes all potential allergens mentioned in the EU and US food legislation.
Lactose is a carbohydrate, and as such a disaccharide. One molecule of lactose is built from one molecule each of two other carbohydrates, galactose and glucose. The galactose and glucose moieties are linked together through a so called beta-(1,4) glucosidic linkage.
The official chemical name of lactose, which is frequently encountered in regulatory documents is 4-O-β-D-galactopyranosyl, D-glucopyranose.

LeDa code	GS1 code	Allergen	Recipe without (Z)	Recipe contains (M)	May contain (and recipe without) (K)	Unknown (0)
		Legal allergens	X			
1.1	UW	Wheat	X			
1.2	NR	Rye	X			
1.3	GB	Barley	X			
1.4	GO	Oats	X			
1.5	GS	Spelt	X			
1.6	GK	Kamut	X			
1	AW	Gluten	X			
2.0	AC	Crustaceans	X			
3.0	AE	Egg	X			
4.0	AF	Fish	X			
5.0	AP	Peanuts	X			
6.0	AY	Soy	X			
7.0	AM	Cow's milk		X		
8.1	SA	Almonds	X			
8.2	SH	Hazelnuts	X			
8.3	SW	Walnuts	X			
8.4	SC	Cashews	X			
8.5	SP	Pecan nuts	X			
8.6	SR	Brazil nuts	X			
8.7	ST	Pistachio nuts	X			

LeDa code	GS1 code	Allergen	Recipe without (Z)	Recipe contains (M)	May contain (and recipe without) (K)	Unknown (0)
8.8	SM	Macadamia/ Queensland nuts	X			
8	AN	Nuts	X			
9.0	BC	Celery	X			
10.0	BM	Mustard	X			
11.0	AS	Sesame	X			
12.0	AU	Sulpher dioxide and sulphites (E220;E228) at concentrations of more than 10 mg/kg or 10 mg/l, expressed as SO2	X			
13.0	NL	Lupin	X			
14:0	UM	Molluscs	X			
		Additional allergens	X			
20:0	ML	Lactose		X		
21.0	NC	Cocoa	X			
22.0	MG	Glutamate (E620-E625)	X			
23.0	MK	Chicken meat	X			
24.0	NK	Coriander	X			
25.0	NM	Corn/maize	X			
26.0	NP	Legumes	X			
27.0	MC	Beef	X			
28.0	MP	Pork	X			
29.0	NW	Carrot	X			
*n.a.	*n.a.	Sucrose	X			
*n.a.	*n.a.	Aspartame	X			
*n.a.	*n.a.	Ethyl Alcohol	X			

*n.a.: not applicable

4.2 BSE/TSE

We herewith declare that our pharmaceutical grade lactose products have been produced from milk, that has been sourced from healthy cows in the same conditions as milk collected for human consumption. The sourcing of milk is supervised constantly by the competent authorities according to the EC milk hygiene Regulation 853/2004. Milk has been categorized by the Committee for Proprietary Medicinal Products (CPMP) and Committee for Veterinary Medical Products (CVMP) in its Guideline EMA/410/01 rev.3 as "Category IB: "Lower-infectivity tissues".
Our pharmaceutical grade lactose has been prepared, without the use of other ruminant material than calf rennet, according to the description as published in Public Statement EMEA/CPMP/571/02 of 27 February 2002. This Public Statement was, among others, based on EMEA/CPMP/BWP/337/02 and states the following:
"Taking all these factors and the scientific assessment performed by the Biotech Working Party into consideration, the Committee for Proprietary Medicinal Products (CPMP) concludes that **the BSE-risk in pharmaceutical grade lactose is negligible**.
Therefore our products mentioned above are considered safe regarding TSE."

4.3 Specified Risk Material Statement

Lactose is manufactured from cow`s milk and rennet (in part calf rennet). Both, milk and calf abomasum (source of rennet), is not considered to be specified risk material.

4.4 California Proposition 65 Information

DFE Pharma Brand lactose does not contain any known carcinogens, mutagens and/or reproductive toxins that are currently identified by California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act of 1986.

4.5 Certificate of Origin

All our pharmaceutical grade lactose qualities produced in Europe are made from cow's milk that may, according to our quality procedures, be sourced in Germany, Belgium, The Netherlands and Luxembourg. In the production of lactose calf rennet is used. The production of calf rennet complies with the requirements defined in Regulation 999/2001 (as amended) and other applicable EU legislation and is officially supervised by the Competent Authorities.

4.6 Certificate of Suitability (Ph.Eur./EDQM)

DFE Pharma does not have a Certificate of Suitability (CEP) for its excipients.

The monographs of the Ph. Eur. describe excipients like lactose and lactose monohydrate in enough detail. For a successful submission of a Medicinal Product in the European Union no reference to a Certificate of Suitability is necessary.

4.7 Compliance

4.7.1 Compendial

Our product conforms to the following Pharmacopoeia Monographs:

National Formulary/United States Pharmacopoeia (NF/USP) - Lactose Monohydrate or Anhydrous Lactose
European Pharmacopoeia (Ph.Eur.) - Lactose Monohydrate or Lactose
Japanese Pharmacopeia (JP) - Lactose Hydrate or Anhydrous Lactose

4.7.2 GMP & Regulatory

DFE Pharma has implemented a quality system in compliance with:
- ISO 9001:2015,
- The Joint Good Manufacturing Practices Guide For Pharmaceutical Excipients (IPEC Federation).

None of these regulations require a Site Master File nor is this document required by any supervising body according to any national requirements in which DFE Pharma manufacture.

Manufacturing of excipients is generally not supervised by regulatory bodies who issue GMP certificates.
DFE Pharma's Quality Assurance program ensures that the implemented quality system is maintained on the GMP-level for Pharmaceutical Excipients. All regulatory changes are evaluated and implemented when deemed necessary.

4.8 Contaminants (Aflatoxin and others)

Herewith we inform you about the presence or absence of substance listed below in the above mentioned products.

Result tested for specification level	Typical value	Unit
PCB's (total [1])	< 25	µg/kg fat [3]
Pesticides (total [2])	< 100	µg/kg fat
Dioxin	< 3	pg/g fat
Antibiotics	< 0.003	IU/ml
Aflatoxine M1	< 0.3	µg/kg

[1] Production sites in Veghel, The Netherlands and Nörten-Hardenberg, Germany
PCB 28, PCB 52, PCB 101, PCB 118, PCB 138, PCB 153, PCB180
Production sites in Borculo, The Netherlands
PCB 77, PCB 81, PCB105, PCB 114, PCB 118, PCB 123, PCB 126, PCB 156, PCB 157, PCB 167, PCB 169, PCB 189

[2] Dieldrin, heptachlor epoxide, hexachlorobenzene, α-hexachlorocyclohexane, ß-hexachlorocyclohexane, lindane, DDT-total

[3] Fat content < 0,01 %

4.9 Contaminants (Dioxin)

Herewith we certify that it is highly unlikely that the above mentioned products contain dioxins as contaminants.

The main reason for this is the preference of dioxins for lipid like media. All the mentioned substances are more or less hydrophilic. Furthermore, there is a system of contaminant monitoring in the EU and in New Zealand which on a regular basis analyzes agro-alimentary raw materials for the presence/absence of contaminants like dioxins. There is also a monitoring scheme in place at DFE Pharma to perform a contaminants monitoring of products.

4.10 Drug Master Files (DMF)

In discussions with the FDA DFE Pharma was informed that type IV Drug Master Files are not necessary and not helpful for excipients that are described in the USP-NF.
For excipients used in oral dosage forms reference to a DMF is not necessary because the monograph in the current version of the USP-NF describes the excipients in enough detail.
Nevertheless, DFE Pharma GmbH & Co. KG holds a type IV (excipients) Drug Master File at the FDA in the USA. More information is available on request.

4.11 Genetically Modified Organisms (GMO)

Herewith we confirm to you that we do not use genetically modified organisms (GMO's) or GMO derived products in the production of our pharmaceutical grade lactose qualities.
Referring to the current legislation in the European Union the products referenced above in section "Brand names" do not have to be labeled as GMO or GMO derived.

4.12 HALAL & Kosher Certification

DFE Pharma Brand Lactose manufactured at Nörten-Hardenberg, Germany is HALAL certified. Please find the certificate in Attachment 1. Kosher certification is not available.

4.13 Irradiation

Herewith we certify that none of our pharmaceutical excipients has been irradiated with gamma rays or has been treated with ethylene oxide. The same is true for all raw materials used.

4.14 Latex

Latex is not used in the production of our products and, to the best of our knowledge, none of the ingredients used or processing aids is based on latex. Within our facilities, our personnel may use latex gloves to protect both the product and themselves. However, contact with the ingredients or the finished product is minimal resulting in only negligible potential for latex contamination of our products due to the use of latex gloves.

4.15 Melamine

The FDA published "Guidance for Industry: Pharmaceutical Components at Risk for Melamine Contamination" identifies USP/NF Lactose as an "at risk" excipient for melamine contamination. Herewith we declare that Melamine and Cyanuric Acid are absent.
Additionally, a risk assessment was performed on raw material, contact material and production equipment to identify if there could be any in-process contamination risk. As melamine is not used as an ingredient, processing aid and additive or in any other way there is no possibility of contamination in the DFE Pharma manufacturing process.
For dairy based raw materials sourced outside DFE Pharma, documentation from the supplier is requested on the absence of melamine and cyanuric acid.
In the countries where the milk and whey for production of DFE Pharma lactose is sampled, no instances of adulteration with melamine have occurred. Monitoring is in place to confirm the safety of the produced dairy products including lactose. DFE Pharma does not test individual batches of its lactose products for the absence of melamine. Monitoring is part of the testing for raw milk. Furthermore, there is a monitoring program in place including raw materials (whey) and dairy based end products (lactose).

4.16 Metal catalyst and metal reagents residues

We hereby declare that no metal catalysts or metal reagents are used in the manufacture of our pharmaceutical grade lactose monohydrate with the brand names mentioned above.

4.17 Elemental Impurities (ICH Q3D)

In framework of the ICH Q3D guideline, DFE Pharma tested batches of pharmaceutical grade lactose, originating from the production site Nörten-Hardenberg, GER, representing the brand names mentioned above.
Neither class 1 or 2A, nor elements classified as 2B or 3, are intentionally added during the production process. Therefore DFE Pharma performed analysis on relevant elemental impurities categorized as 1 and 2A elements by the ICH Q3D guideline (according to table 5.1: Elements to be considered in the Risk Assessment – Oral Dosage Form). Analysis was performed using the analysis technique ICP-MS (Inductively Coupled Plasma-Mass Spectrometry) conform USP-NF<233>.
Values for all analyzed batches of lactose only excipients (SuperTab® (EU), Lactopress® (EU)) were below 30% of the limits (Limits are based on option 1 of the ICH Q3D guidelines, based on administration of not more than 10g of drug product per day).

A risk assessment was performed. This document is available for review during audits. Conclusion of the risk assessment is that all values obtained are below 30% of the limits and thus do not need additional control, the change control procedure of DFE Pharma is the key to maintain this situation. The levels of ICH Q3D relevant elemental impurities are monitored on regular basis.

4.18 Nutritional Information

Herewith we inform you about nutritional values of the above mentioned product.

Typical value	Lactose Monohydrate	Anhydrous Lactose	Unit
Energetic value (calculated):	1590	1675	kJ/100g
	380	400	kcal/100g
Proteins	0.02	0.02	g/100g
Carbohydrates	94.7	99.7	g/100g
- of which Lactose	100	100	g/100g
Fat	<0.01	<0.01	g/100g

4.19 Preservatives

Our pharmaceutical grade lactose is derived from 100 % bovine milk without the addition of any non-bovine animal products. In addition, we do not use additives or preservatives in the manufacturing process of pharmaceutical grade lactose.

4.20 Residual Solvent Information (formerly OVI)Information

For the manufacturing of our pharmaceutical grade lactose no other solvents than potable water and reverse osmosis water are used. This is certified with reference to the solvents listed in the "Q3C (R6) ICH guidelines on residual solvents (EMA/CHMP/ICH/82260/2006)" and USP general chapter <467>: no class 1, 2, 3 solvents are used in the raw materials, manufacturing process and product.
General test 5.4 of the European Pharmacopoeia is also applicable.
Since only potable water and reverse osmosis water are used the final product is only tested on presence of free water by the pharmacopoeia test 'Loss on Drying'.
Our pharmaceutical grade lactose complies with the current Ph. Eur. Requirements for Residual Solvents and USP requirements for Organic Volatile Impurities / Residual Solvents.

4.21 Viral Safety

Virus validation studies are only necessary in those cases where a substantial amount of viruses may be present in a product.
This might be the case in the following cases:

- products derived from in vitro cell lines of human and animal origin,
- products derived from in vivo culture of cell lines or from organs or tissues of human or animal origin,
- products derived from blood or urine or other biological fluids of human or animal origin.

These cases are defined by CPMP/BWP/268/95 (Validation of virus removal and inactivation procedures).
In chapter 2 of this guideline some cases of sources of viral contamination are mentioned. None of the contamination sources applies to milk (the source material for lactose). Furthermore, the milk used for the manufacture of lactose complies with the current health regulations in the EU. This means that the milk is derived from healthy cows and that it is fit for human consumption.
For the manufacture of lactose no virus validation studies have been performed, because:

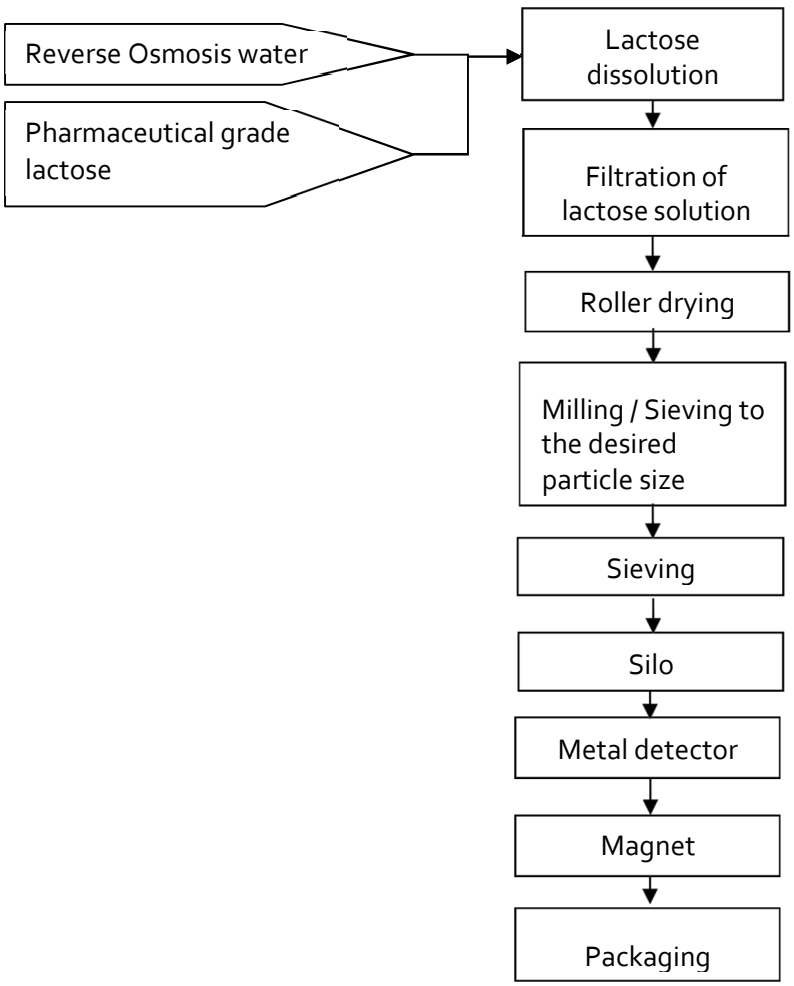
- The source material milk is not considered to be an (important) source of viruses, and is fit for human consumption,
- Virus validation studies could compromise the safety of our manufacturing equipment,
- All milk undergoes pasteurization. In case of the manufacture of lactose in addition to this the product is kept :
  - at least 95°C for on average 30 minutes in Europe
  - at least 90°C for at least 15 minutes in New Zealand
- It is a well-known fact that a double pasteurization (15 seconds at 72°C) kills all Foot and Mouth disease virus. Many studies have been performed on this subject.

Section 5 – Miscellaneous Product Information

5.1 Manufacturing Product Information

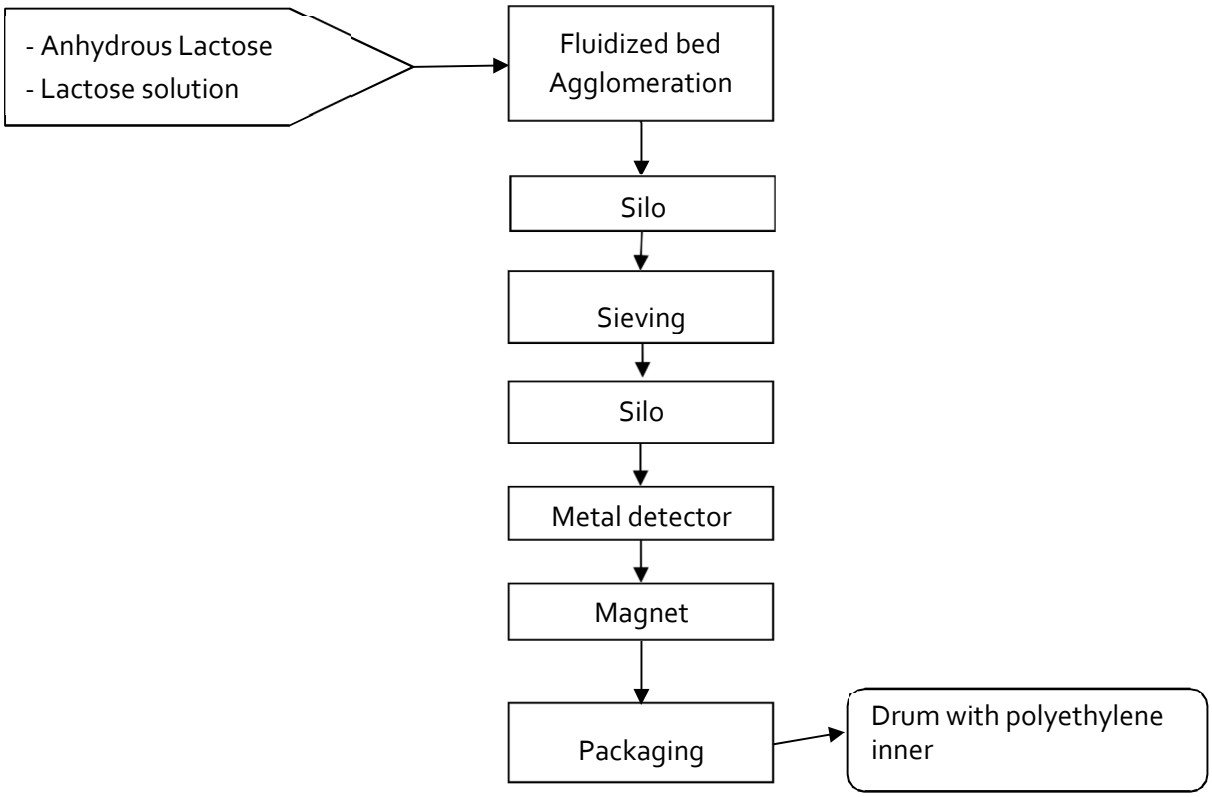
5.1.1 Process Flow chart

Anhydrous Lactose (SuperTab® 21AN/22AN/23AN)



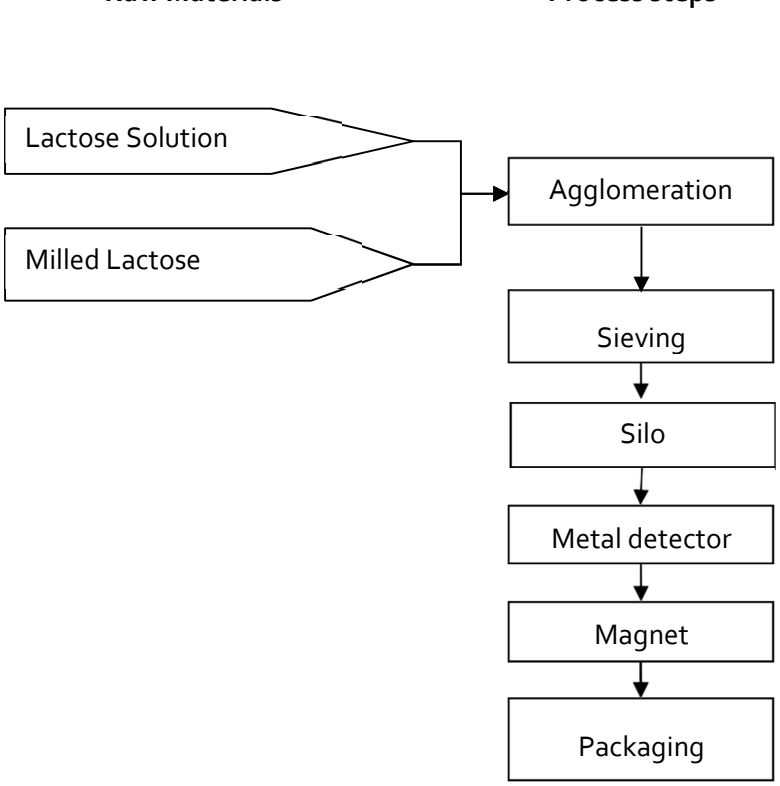
More detailed product- and production site specific "Process Flow Sheets" are available on request.

Anhydrous Lactose (SuperTab® 24AN)



More detailed product- and production site specific "Process Flow Sheets" are available on request.

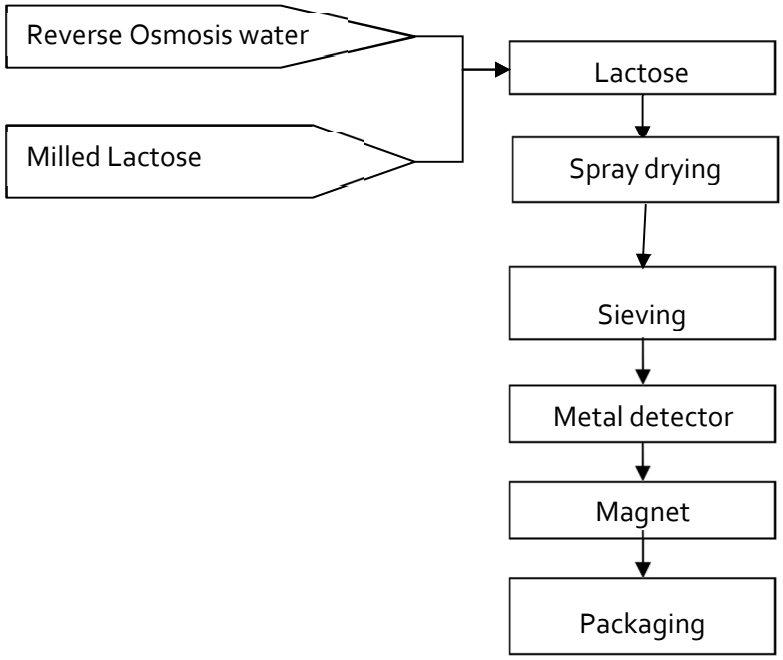
Granulated Lactose (SuperTab® 30GR/Lactopress® Granulated)



More detailed product- and production site specific "Process Flow Sheets" are available on request.

Spray-Dried Lactose (SuperTab® 11SD/14SD)

Raw Materials **Process steps**



More detailed product- and production site specific "Process Flow Sheets" are available on request.

5.1.2 Batch description

Please find the average batch sizes in below chart.

Product Brand Name	Material Number	Average Batch Size
SuperTab® 21AN	743713	> 50 t
SuperTab® 21AN	659165	> 50 t
SuperTab® 22AN	743714	> 30 t
SuperTab® 23AN	1220097	> 30 t
SuperTab® 24AN	743723	> 10 t
SuperTab® 30GR	743716	> 48 t
SuperTab® 30GR	743715	> 48 t
Lactopress® Granulated	743735	> 20 t
SuperTab® 11SD	743720	> 140 t
SuperTab® 14SD	743721	> 28 t

5.1.3 Batch numbering explanation

ERP (Enterprise Resource Planning) computer system (SAP) assigns a batch number. The batch numbering consists of 7 digits and alphanumeric (containing numbers and letters) e.g. 10007X5. This batch number will be displayed on the Certificate of Analysis and the product label.

5.1.4 Expiration

DFE Pharma has defined a shelf life for all of its products based on a stability testing program and guarantees that its products comply with all specifications up until the end of their shelf life period (expiry date) under the defined storage conditions.
Dates of production and expiry date / re-test date respectively are printed on every packing unit and on the corresponding Certificate of Analysis. For pharmaceutical grade lactose products the established shelf life is listed below:

Brand Name	Shelf Life	Expressed as Expiry Date / Re-test Date
SuperTab® 30GR	3 years	Expiry Date
SuperTab® 11SD/14SD	2 years	Expiry Date
SuperTab® 21AN/22AN/23AN/24AN	2 years	Expiry Date
Lactopress® Granulated	3 years	Expiry Date

SD: spray dried AN: anhydrous GR: granulated

The shelf life of the products as listed above is derived from results of stability studies.
DFE Pharma does not perform re-testing at the end of the shelf life period. It is the customer's responsibility to determine if the product can still be used in their application after the end of the shelf life period.

5.1.5 Packaging Sizes

See Section 1 for product codes and packaging sizes.

Section 6 – Revisions

Edition01: New. Issue date 02-May-2018.
Edition02: DFE Pharma logo change 12-March-2019
Edition03: Legal name change 17-May-2020
Edition04: Update 5.1.2; addition SuperTab® 23AN and full inhalation portfolio, formatting, Sales contact information

Section 7 – Contact Information

DFE Pharma Customer Support Officer (Quality) + 1 551 497 7311

Contents

II. SITE QUALITY OVERVIEW

Section 1 - Site Overview

Corporate Ownership: DFE Pharma

DFE Pharma GmbH & Co. KG has been established in 2006 and is a joint venture between Royal FrieslandCampina and CVC.
DFE Pharma is headquartered in Germany (Goch) and operates from several production facilities around the globe including Nörten-Hardenberg, Germany owned by DFE Pharma GmbH & Co. KG. In Nörten-Hardenberg pharmaceutical grade lactose (spray-dried, anhydrous, and granulated) is produced.
DFE Pharma holds global sales offices in Germany, the United States, Singapore, Japan, India, Brazil and China. Those are responsible for sales into more than 100 countries worldwide.
The company currently employs 360 people based in 9 countries.

DFE Pharma Brand lactose products as stated under section 1 are produced at the following production site:

DFE Pharma Corporate Office Location
Klever Strasse 187
47574 Goch
Germany

Manufacturing Site Location
DFE Pharma GmbH & Co. KG
Lauenförder Strasse 5
37176 Nörten-Hardenberg
Germany

Excipients covered by this document
SuperTab® 21AN/22AN/23AN/24AN
SuperTab® 30GR & Lactopress® Granulated
Supertab®11SD/14SD

Nörten-Hardenberg Site History

Until 1993, a sugar manufacturing plant was operating on the present day Nörten-Hardenberg site. The sugar factory was demolished and present day Nörten-Hardenberg facility was built in 1996. Nupron GmbH started manufacturing of protein hydrolysates from 1996 until 1998. Nupron was acquired by the dairy company Campina which is based in the Netherlands. Until 2002, Campina produced protein hydrolysates in Nörten-Hardenberg as part of the business line of Nutritionals. In 2002, Campina board decided to develop the Nörten-Hardenberg site as central site for the manufacturing of direct-compressible Lactose. First the transfer of the production of SuperTab® 11SD, SuperTab® 14SD and SuperTab® 21AN from Veghel site to Nörten-Hardenberg was realized. For this project a Validation Master Plan (VMP) was written to describe the validation approach in order to ensure that the whole plant would meet the applicable GMP guidelines.

In 2003, the manufacturing lines for spray-dried and roller-dried direct compressible Lactose were built. Since 2004, Nörten-Hardenberg plant is dedicated for the production of SuperTab® products. This was followed by SuperTab® 22AN which was launched in November 2004.

In 2005, a project was executed to realize the transfer of the production of agglomerated products from a toll-manufactured location to Nörten-Hardenberg and therefore manufacturing line for agglomerated lactose was built and thus production of SuperTab® 30GR started from Nörten-Hardenberg site then on. In 2010 a new product Lactopress® Granulated was introduced on the continuous agglomerator production line.
In 2011, a new silo to improve the handling of raw material was built. Also in 2011, a new product was introduced on the continuous agglomerator production line called SuperTab® 24AN, which is an unique anhydrous agglomerated product.
In 2019 manufacturing area was expanded and a second roller dryer was implemented.
SuperTab® 23AN was introduced in 2023.

DFE Pharma Mission Statement & Product Overview

We develop, produce and market leading excipient solutions that serve our customers, the pharmaceutical industry, and bring value to our stakeholders.
We bring together customer needs with our competences and capabilities in expertise, time to market and supply.
Building on our heritage in pharmaceutical grade lactose, DFE Pharma provides a wide range of excipient products and services for oral solid dose and dry powder inhalation formulations, and we do it on a global basis. We live up to our values to deliver the best, today, tomorrow, always.

Lactose	
Milled	***Sieved***
Lactochem® Coarse powder	Lactochem® Crystals
Lactochem® Regular Powder	Lactochem® Coarse Crystals
Lactochem® Powder	Lactochem® Fine Crystals
Lactochem® Fine Powder	Lactochem® Extra Fine crystals
Lactochem® Extra Fine Powder	Pharmatose® 50M
Lactochem® Super Fine Powder	Pharmatose® 60M
Pharmatose® 130M	Pharmatose® 70M
Pharmatose® 150M	Pharmatose® 80M
Pharmatose® 200M	Pharmatose® 90M
Pharmatose® 350M	Pharmatose® 100M
Pharmatose® 450M	Pharmatose® 110M
	Pharmatose® 125M

Excipient Information Package (EIP)

Product group: Lactose
Brand name: SuperTab®, Lactopress®
Production Site: Nörten-Hardenberg, Germany
Document No.: PD-0740

Direct compression Lactose		
Spray Dried	*Granulated*	*Anhydrous*
Lactopress® Spray dried	SuperTab® 30GR	SuperTab® 21AN
Lactopress® Spray dried 250	SuperTab® 24AN	SuperTab® 22AN
SuperTab® 11SD	Lactopress® Granulated	SuperTab® 23AN
SuperTab® 14SD	SuperTab® 40LL	Lactopress® Anhydrous
		Lactopress® Anhydrous Powder
		Lactopress® Anhydrous Fine Powder

MCC
Microcrystalline cellulose
Pharmacel® 101
Pharmacel® 102
Pharmacel® 112

Superdisintegrants
Sodium starch glycolate
Primojel®
Croscarmellose sodium
Primellose®

Starch
Native Potato starch
Solani® Amylum
Fully pregelatinized Potato starch
Prejel® PA5 PH

Inhalation	
Milled	*Sieved*
Lactohale® 200	Lactohale® 100
Lactohale® 201	Respitose® SV001
Lactohale® 206	Respitose® SV003
Lactohale® 210	Respitose® SV010
Lactohale® 220	Respitose® SV014
Lactohale® 230	
Respitose® ML001	
Respitose® ML003	
Respitose® ML006	
Micronized	*Anhydrous*
Lactohale® 300	Lactohale® 400

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Size & Age of facility

The site was built in 1996. Since 2002, the site is used for lactose production by DFE Pharma. Total Size of the Facility and Grounds is 8.270 m².

Introduction to the Site departments:

The Nörten-Hardenberg site provides all functions needed for manufacturing:

- Production building with all facilities for all products in scope of this document. Refer section 5.1.2
- Utility preparation building and area for the supply of utilities, such as steam, pressurized air, cooling and water.
- Plant for the treatment of waste water.
- Internal traffic roads
- Building has following functional suits:
  - Administration offices and meeting rooms
  - Maintenance department with spare part storage
  - Quality control lab

The site is fully dedicated to the manufacturing of directly compressible lactose and lactose-like products under ownership of DFE Pharma. The site is not shared with any other companies.

Materials of Construction

The manufacturing facility floors are mainly build of concrete with epoxy coating. Majority of the walls are a combination of concrete block and polypanel with epoxy coating.

Organization

DFE Pharma: DFE Pharma is a joint venture Royal FrieslandCampina and CVC. We are headquartered in Germany (Goch) and operate from several production facilities around the globe including New Zealand (Kapuni). The management consists of CEO and Leadership Team. It is responsible for development and implementation of company management system, continuous improvement of effectiveness and compliance with applicable regulatory and safety requirements.

Section 2 - Compliance evidence

Following Certification is available:

DFE Pharma head office in Goch, Germany is ISO 9001:2015 certified.
Nörten-Hardenberg Site in Germany has the following certifications:
ISO 9001:2015, ISO 50001:2011, HALAL, GMP+
Please see Attachment 1 for certifications.

IPEC GMP
DFE Pharma has implemented a quality system in compliance with Joint Good Manufacturing Practices Guide For Pharmaceutical Excipients (IPEC Federation).

Section 3 - Plant Quality Systems

QA/QC Quality Manual
DFE Pharma has a Quality Manual which details the quality policy and activities applicable for the whole value chain that operates on responsibility of DFE Pharma to manufacture pharmaceutical grade lactose. It describes the overarching Global Quality System which is continually enhanced through prevention, measurement and improvement initiatives. This is available to view during the site audit.

QA Responsibilities/Authority

In general the Quality Department is responsible for (not limited to the items mentioned below):

Raw Materials

Raw material Receipt

DFE Pharma production site Nörten-Hardenberg receives pharmaceutical grade lactose from FrieslandCampina Manufacturing Sites in Veghel and Borculo.
Other Raw Materials than pharmaceutical grad lactose are received from approved vendors in accordance to DFE Pharma's approved supplier program. Raw materials are accepted in accordance with approved SOP's that details receipt, inspection and acceptance criteria. Raw materials are stored at ambient temperatures and in dedicated locations.

Raw material Testing

Raw material testing and specifications have been developed based on their inherent nature and the requirements of their intended process. Raw materials which do not meet specification are segregated pending investigation and if deemed unacceptable are returned to the vendor.

Raw Material Release

If a raw material (i.e. packaging or processing aids) meet the specification requirements, it is released in SAP and available for production on a FIFO (First In First Out) basis.

Document Control

Document Review and Revision History

DFE Pharma applies a 3-years review cycle for its controlled documents like policies (POL), system procedures (SYS), standard operating procedures (SOP) and work instructions (WI). A revision history is maintained within each document. All revisions are reviewed and approved by Quality Assurance. Obsolete versions are archived.

Retention Policy

Raw Material and Finished Goods

Final product retain samples are kept for two years post the shelf life, then discarded.

Batch records

Master Batch records (MBR) are maintained in the document management system. Batch records are retained for 10 years and then destroyed through a contracted document destruction company.

Change Control

Management of Change (MOC)

DFE Pharma has implemented a procedure for change control in order to ensure that every intended change in products, processes, specifications, test methods, packaging, equipment or locations is carefully judged on the possible impact on quality and safety of the product.
As part of this procedure a classification is made of significant changes which require customers to be informed of the intended change or require customer approval before implementation.
The classification is based on the IPEC Significant Change Guide for Pharmaceutical Excipients.
All change requests are judged by a committee (Change Control Board) consisting of representatives of QA / Regulatory Affairs, Marketing, Technology & innovation, QC and Supply Chain / Operations. If necessary, additional experts from other departments (e.g. Product Group Management, Health & Safety or Sales) may be invited.
The change control procedure as implemented by DFE Pharma ensures that all intended changes are judged by a team of experts and are approved by QA. In this way DFE Pharma safeguards that all products consistently remain compliant with all quality and safety requirements and customer expectations.

Change Notification

As part of the Change Control procedure a classification is made of significant changes which require customers to be informed of the intended change or require customer approval before implementation. The classification is based on the IPEC Significant Change Guide for Pharmaceutical Excipients.

Auditing

Customer Audits

DFE Pharma`s manufacturing site Nörten-Hardenberg can accommodate customer audits. Key customer, or qualifying audits may have priority over small volume customers if the audit calendar is full. All findings are logged into a local CAPA log for follow up and trend analysis.

Vendor Audits

DFE Pharma manages an approved supplier program for its vendors.
The program is based on risk management principles. The risk category determines the need for, and frequency of an audit. Details can be viewed during audit.

Internal Audits

DFE Pharma developed its own formal internal audit approach. This approach can be viewed during on site audit.

Expiry Date and Stability Data

Expiry Date

DFE Pharma has defined a shelf life for all of its products based on a stability testing program conforming to IPEC Excipient Stability Program Guide 2010. DFE Pharma guarantees that its products comply with all specifications up until the end of their shelf life period (the expiry date) under the defined storage conditions.
Dates of production and expiry date are printed on every packing unit and on the corresponding Certificate of Analysis. **See section I - 5.1.4 Expiration for details.**

Customer Complaints

Complaint System

Customer complaints are logged into DFE Pharma`s SAP system via the Customer Management Officer and are forwarded to Nörten-Hardenberg production site for investigation. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Customer within a reasonable time after receipt of the complaint.

Environmental Monitoring

Water Systems

Potable water is supplied to the site from the Harzwasserwerke GmbH which meets the requirements of the German Drinking Water Standard. To start every production with the same kind of water quality, the water undergoes the reverse osmosis membrane followed by sterile filtration. The reverse osmosis water is analyzed internally on a biweekly basis. Samples are taken from various sample locations around the site. The conductivity is measured inline and the alarming is linked to the process control system.
Water for Laboratory testing is supplied by a reverse osmosis unit.

Air Monitoring & Other Environmental

Air Monitoring

In accordance with the internal environmental monitoring program, Air sampling is completed on a biweekly basis for 9 locations throughout the plant. The environmental monitoring is conducted on a weekly basis by QC. Locations encompass all main manufacturing, processing and packing areas according to the respective SOP.

Packing rooms

Packing rooms are strictly separated from wet processing area's and are monitored for temperature and relative humidity. The temperature and relative humidity is consistently monitored and recorded in the process control system.

Filters
Filters are changed in accordance with the frequency set out in the site filter rosters, which are recorded and signed once completed. The packaging rooms are classified according to ISO 14644-1, class 8. The compliance to this classification is regularly verified.

Computer Systems/Data Storage

Laboratory
The Nörten-Hardenberg laboratory uses a paper based system to capture and monitor the raw materials, in-process and final product testing. Furthermore, SAP is used to record final product testing data. This system is validated. Data in SAP is backed up and stored off-site.

Logistics/Supply Chain
DFE Pharma stock management system (SAP) provides complete traceability of all items into, during and out from storage and throughout the supply chain. Data is backed up to the Disaster Recovery (DR) Database on daily basis and stored off-site. There is also a second alternative backup, which is extracted each night/early morning.

Master Sanitation Plan
DFE Pharma manufacturing site Nörten-Hardenberg has an sanitation plan for the site. Also departmental cleaning plans related to their area and function and are recorded in checklists. In addition, the cleaning process of the facility and equipment is prescribed in the respective document.

Pest Control
DFE Pharma manufacturing site Nörten-Hardenberg has a pest management in place and utilizes the services of a contracted pest control provider to manage the routine monitoring and recording of all pest activity. The results of activity are provided in a report. All pest activity is recorded and trended. Recommendations are made to the site by the pest provider should there be any increase in activity.

Finished Product Testing

Sampling Plan
Samples for final product testing are taken via an auto sampler and/or manually. Samples are taken for every unit manufactured and retained.

Analytical Testing
All analytical tests as shown on the CoA (Certificate of Analysis) are tested on each batch at a pre-determined frequency.
Particle size analysis and test for foreign particles are performed as in-process controls by manufacturing operators. The results are verified during release analysis by QC.

Microbial Analysis
Microbial analysis is performed on each batch.

Internal Limits
Internal or Specification limits, have been established for all QC testing performed. If testing results exceed the established limits, an out-of-specification investigation is thoroughly conducted in accordance to the system procedure for out-of-specification results.

Control Charts
DFE Pharma uses a statistical tool for trending finished product parameters. All products produced on the site in Nörten-Hardenberg are incorporated using this tool.

Training
All personnel whose activities may affect product quality will have appropriate GMP training to enable them to perform their assigned function. All site staff are required to complete annual refresher training for food safety & quality (according to the German Law for protection of infections), hygiene, GMP, health & safety, environmental and any other relevant subject at that time.

Personal Hygiene
There are clear terms and conditions of hygiene entry requirements and SOP's to enter the plant. All operators are issued clean gowning daily. These are laundered by an outside contracted laundry company. No food, drinks or gum are permitted in our manufacturing areas. There are dedicated lunchroom/canteen facilities for site personnel to use. Smoking is only permitted in a dedicated area outside the manufacturing facility. There are facilities that provide cleaning washing and toilet amenities with hot and cold running water, soap, towels and showering facilities.

Section 4 – Miscellaneous Site Information

4.1 Compliance information – Validation

Cleaning Validation
DFE Pharma manufacturing site Nörten-Hardenberg is a dedicated facility for manufacturing lactose and lactose like products. Cleaning of equipment is typically done using automated cleaning-in-place (CiP) processes. Cleaning validation has been completed for all cleaning processes.

Equipment Qualification
Equipment qualification has been completed as per the DFE Pharma site Nörten-Hardenberg Validation Master Plan and DFE Pharma's validation procedures.
Concurrent or prospective validation and qualification is used for new equipment, systems, utilities or materials.

Process Validation
Process validation is performed as per the DFE Pharma site Nörten-Hardenberg Validation Master Plan and DFE Pharma's validation procedures. This is completed at full scale production using the same raw materials, systems, equipment, and procedures and processes as for commercial production. Prospective Validation is used.

Method Validation
Validation on all laboratory methods is completed.

4.2 Manufacturing

Equipment

Material of Construction
All equipment is built according to hygienic design principles. Product contact surfaces are by standard constructed of stainless steel 304 or stainless steel 316L, depending on the application. Elastomers used for seals and gaskets are restricted to FDA-certified materials.

Grease and Lubricants
All maintenance compounds such as grease and lubricants used on or in the manufacturing equipment are food grade complying to FDA 21 CFR 178.3570 (NSF H1). Equipment is built in a way that contact between lubricant and product is avoided.

Equipment Dedication
DFE Pharma`s manufacturing site Nörten-Hardenberg is primarily manufacturing lactose products and lactose like products.

Calibration

All equipment and associated instrumentation requiring calibration are scheduled in a data base. Instruments are calibrated at a frequency recommended by either the criticality of the instrument and/or the manufacturer recommendations.
All process instruments are calibrated in accordance with recognized approved methods using specified test equipment. All critical process instrument on site is clearly tagged with its assigned identification code.
Calibration records are retained for 10 years past the life of the instrument.

Preventative Maintenance

A Preventative Maintenance Program is in place for the purpose of caring and servicing of equipment, facilities and statutory requirements so that they are operating appropriately.

Process

Process Control

The process and equipment used to manufacture pharmaceutical grade lactose is controlled primarily through PLCs (Programmable Logic Controller). All process parameters are continuously monitored, logged and archived. Critical process parameters are defined for each process step and recorded, reported and reviewed on batch level.

In-Process Testing

In-Process testing is performed at certain critical processing steps as determined as identified in the Master Batch Record. In process results are reported and recorded within the batch record.

Manufacturing Deviations

Where a non-conformance or issue is identified which is key to product safety, regulatory compliance or quality, the issue is managed using the documented non-conformance process. This process enables tracking of actions through to closure in a timely manner, and aims to prevent a repeat incident.

Contamination Prevention

Microbial Contamination Prevention

All pharmaceutical grade lactose raw material supply sites, which are FrieslandCampina owned, are in need to supply within specified microbial limits.

Particulate Contamination

Contamination controls used with the DFE Pharma manufacturing site Nörten-Hardenberg are required to eliminate or minimize food safety risks from metal and other physical contaminants, product residues, pests and incoming materials. This is achieved by numerous in-process sifter screens and filters, in-line magnets throughout the wet and dry process and final packing magnets, metal detectors, inspections of incoming packaging for potential contaminants, water, air and steam filtration.

4.3 Packaging, Labeling, and Lot Number Information

Packaging

All packaging materials are sourced from approved suppliers and are inspected prior to use, using documented procedures and checklists.

Product Brand Name	Material Number	Packaging Size(s)
SuperTab® 21AN	743713	25 kg, Bag
SuperTab® 21AN	659165	50 kg, Drum
SuperTab® 22AN	743714	50 kg, Drum
SuperTab® 23AN	1220097	50 kg, Drum
SuperTab® 24AN	743723	35 kg, Drum
SuperTab® 30GR	743716	40 kg, Drum
SuperTab® 30GR	743715	25 kg, Bag
Lactopress® Granulated	743735	25 kg, Bag
SuperTab® 11SD	743720	40 kg, Drum
SuperTab® 14SD	743721	40 kg, Drum

Product packed in bags containing 25 kg, for instance SuperTab® 21AN/30GR and Lactopress® Granulated, are fully lined with a PE liner.

All product packed in drums (35/40 or 50 kg), for instance SuperTab® 11SD packaging is a 40 kg drum, is fully lined with a PE liner and closed with a cable tie by a so called gooseneck. This protective and robust packaging guarantees complete protection of the products and its integrity, when stored at ambient conditions. Pictures of drum/bag are available on request.

Labeling

All products are individually labeled with the batch number, manufacturing date and expiration date. Once palletized and stretch wrapped, SAP pallet labels, which are printed in-house, are applied to each pallet.
Please see product labels in Attachment 1.

Batch information

ERP (Enterprise Resource Planning) computer system (SAP) assigns a batch number. The batch numbering consists of 7 digits and alphanumeric (containing numbers and letters) e.g. 10007X5. This batch number will be displayed on the Certificate of Analysis and the product label.

Customer Specifications Revisions

All customer specification revisions or changes are managed via a change control process started by quality assurance department of DFE Pharma.

Section 5 – Revisions

Edition01: New. Issue date 02-May-2018.
Edition02: DFE Pharma logo change 12-March-2019
Edition03: Legal name change 17-May-2020
Edition04: Update 5.1.2; addition SuperTab® 23AN and full inhalation portfolio, formatting, Sales contact information

Section 6 – Contact Information

DFE Pharma Customer Support Officer (Quality) + 1 551 497 7311

Contents

III. SITE AND SUPPLY CHAIN SECURITY OVERVIEW

Section 1 – Scope

Corporate Ownership: DFE Pharma

DFE Pharma GmbH & Co. KG has been established in 2006 and is a joint venture between Royal FrieslandCampina and CVC.
DFE Pharma is headquartered in Germany (Goch) and operates from several production facilities around the globe including Nörten-Hardenberg, Germany owned DFE Pharma GmbH & Co. KG. In Nörten-Hardenberg pharmaceutical grade lactose (spray-dried, anhydrous, and granulated) is produced.
DFE Pharma holds global sales offices in Germany, the United States, Singapore, Japan, India, Brazil and China. Those are responsible for sales into more than 100 countries worldwide.
The company currently employs 360 people based in 9 countries.

DFE Pharma Brand lactose products as stated under section 1 are produced at the following production site:

DFE Pharma Corporate Office Location
Klever Strasse 187
47574 Goch
Germany

Manufacturing Site Location
DFE Pharma GmbH & Co. KG
Lauenförder Strasse 5
37176 Nörten-Hardenberg
Germany

Excipients covered by this document
SuperTab® 21AN/22AN/23AN/24AN
SuperTab® 30GR & Lactopress® Granulated
Supertab®11SD/14SD

Section 2 - Supply Chain Security

Bio-Terrorism Act Registration

DFE Pharma holds a Bio-Terrorism Act Registration number for Nörten-Hardenberg site.
This registration number is considered to be confidential information.

C-TPAT Participation

DFE Pharma Nörten-Hardenberg site does not participate in C-TPAT.

3rd Party Food Audits

As part of the German regulatory model, DFE Pharma manufacturing site Nörten-Hardenberg has regular inspection by the local authority Lower Saxony State Office for Consumer Protection and Food Safety. In addition, the site is also inspected by the Halal feed and food inspection authority to maintain HALAL certification status.

Contingency Planning for Business Interruption

Business Continuity Planning is a vital activity for DFE Pharma. Our activities in this field of responsibility start with considering the impact of a potential disaster (e.g. force majeure risk, pandemic outbreak) as well as understanding the underlying risks.
Based on this DFE Pharma is actively identifying the essential business functions and assessing the disaster risks that could adversely affect our business continuity.
DFE Pharma has systems in place to guarantee good communication with our customers should such a disaster cause a change to DFE Pharma normal business practice. It is our base principle to endeavor to maintain supply to our customers by rapid implementation of the necessary actions plans for incident management and disaster recovery.

Product Security, Packing Room & Product Integrity

Entry into the dry process building and subsequent packing rooms is access controlled. Registration of personnel entry, including any items taken into the plant, is recorded upon entering the building. In first instance primary packaging is closed with a cable tie by a so called gooseneck. Drums are closed with metal clamp and sealed with a sealing where the DFE Pharma logo is impressed. Bags are sewed up. The protective and robust packaging guarantees complete protection of the products and its integrity, when stored at ambient conditions.

Transportation Security

Before loading the final packed product into trucks and railroad cars these are inspected on cleanliness and integrity. All trucks, transport and shipping containers for final packed product are sealed and/or tagged.

Section 3 – Security Information

Roles and Responsibilities

The Site Operations Manager is responsible for overall site security and the effectiveness of the established sites production system. The Maintenance Manager is responsible for ensuring the Security Systems and the preventive maintenance program are operating effectively. The QC lab manager is responsible for the release analysis and the lab compliance.
Site Security and Safety Training is included in site and departmental inductions with each of the area owners.

Site Access Control

All Gates and accesses into DFE Pharma manufacturing site Nörten-Hardenberg require codex access for staff and contractors that have been fully inducted. The site perimeter is fenced.
Access into all buildings on site are managed by the site-specific access control system and access codex are individually loaded with the areas that an employee or contractor will be working in, other areas on site will not able to be accessed. These people are annually re-inducted.

Visitors

All visitors must report to the main reception which is only accessed by access codec or unlocked by the receptionist during office hours. Visitors have to fill in the visitors register and be accompanied at all times while on site. They must leave via the main reception again and sign out on the control register.

Section 4 – Safety & Environmental Information

DFE Pharma site Nörten-Hardenberg is ISO 50001 : 2011 certified. Please see Attachment 1 for certification.

Section 5 – Revisions

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Excipient Information Package (EIP)

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