
Technical Information

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in many countries.

Ludipress® LCE

Lactose-based direct compression excipient.

Description

Ludipress® LCE is a granulated excipient consisting of Lactose monohydrate and Povidone K30 (Kollidon® 30). The product consists of white to slightly yellowish, free-flowing powder for direct compression. It is odorless and has a neutral taste.

Applications

Ludipress® LCE was developed as an extension of the BASF range of direct compression excipients for use in chewable tablets and lozenges, for effervescent tablets and as bulking agent in hard gelatin capsules.

However, in combination with Kollidon® CL-F or Kollidon® CL as tablet disintegrant, all other types of formulation are possible. Moreover high-dose forms can be produced using Kollidon® VA 64 Fine.

Specification

See separate document: "Standard Specification (not for regulatory purposes)" available via BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

Regulatory status

No monographs exist. The components Lactose monohydrate and Povidone K30 (Kollidon® 30) are specified according to the current versions of Ph.Eur., USP and JP.

Guideline values

The Hausner ratio of the tapped density and bulk density is typically 1.20 ± 0.10 . The bulk density is typically $0.56 \pm 0.06 \text{ g/cm}^3$.

The particle size distribution for Ludipress® LCE shows the following typical values. The measurements were carried out in a sieve shaker.

< 63 µm	max. 20%
< 200 µm	40 to 65%
> 400 µm	max. 20%

Figure 1 shows an example of the particle size distribution measured by laser diffraction.

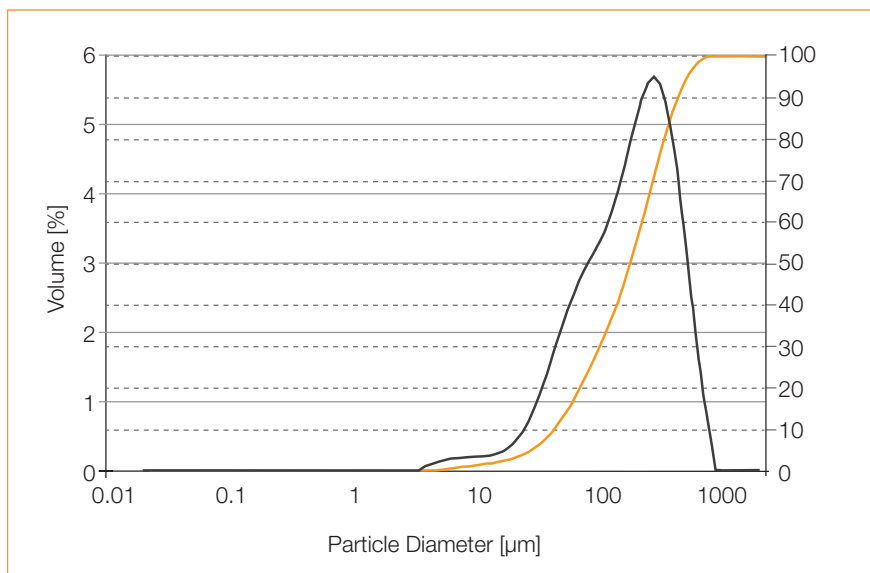


Figure 1: Particle size distribution of Ludipress® LCE (laser diffraction; dry measurement)

Hygroscopicity

Figure 2 shows the sorption isotherm for Ludipress® LCE at 20 °C. Ludipress® LCE adsorbs only very small amounts of water even at high humidities. The initial level of around 5 % represents the water in lactose monohydrate.

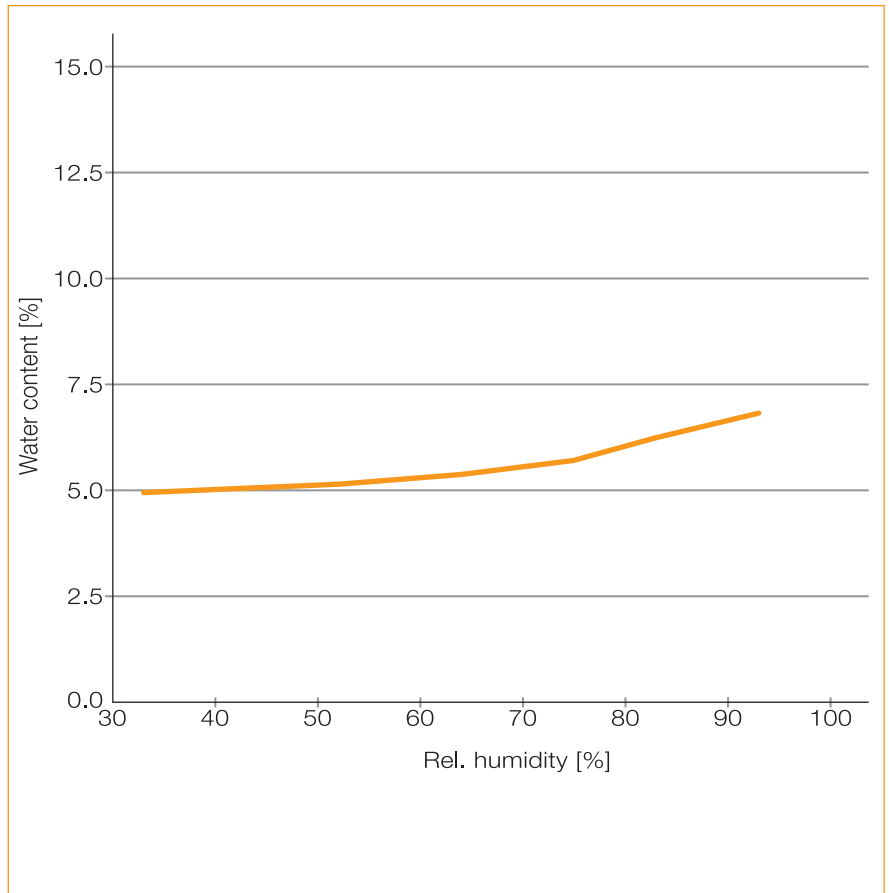


Figure 2

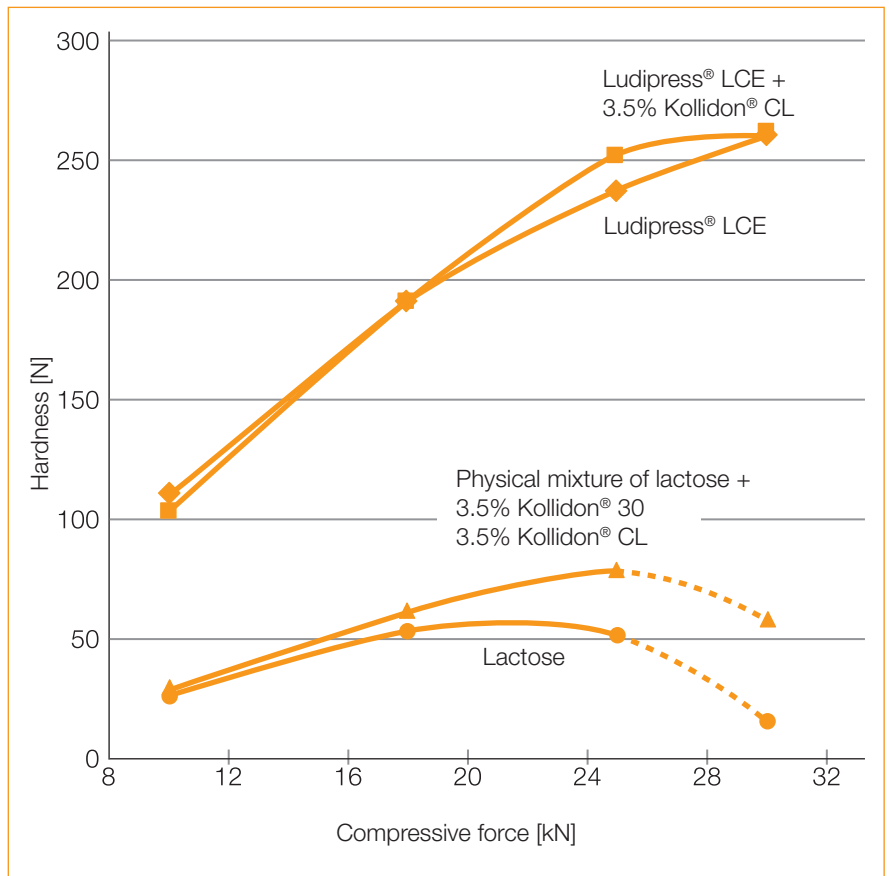


Figure 3

Tabletting characteristics

The behaviour of Ludipress® LCE on compression is shown in Figure 3, compared with a physical mixture consisting of Ludipress® LCE and Kollidon® CL and with lactose and the corresponding mixture with Kollidon® 30 and Kollidon® CL. The tablet hardnesses which can be achieved with Ludipress® LCE are distinctly higher.

Typical formulations

The following examples may serve as guidelines for formulations. The tablets were produced in a rotary press using the compression conditions and punches stated in each case.

Further formulations using BASF excipients for the pharmaceutical industry can be found in the compendium 'Generic Drug Formulations'. It is available on request as a loose-leaf file, or on diskette or CD-ROM.

1. Sublingual tablets and lozenges

1.1 Cetylpyridinium lozenge [2.5 mg]

1.1.1 Formulation

Cetylpyridinium chloride	2.5 g
Ludipress® LCE	370.0 g
Menthol, crystalline	6.0 g
Aspartame	1.5 g
Polyethylene glycol 6000, powder	20.0 g

1.1.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using low compression force.

1.1.3 Tablet properties

Tablet weight	402 mg
Diameter	10 mm
Form	biplanar
Hardness	80 N
Disintegration time	> 10 min
Friability	< 0.1%

2. Chewable tablets

2.1 Vitamin E chewable tablet [100 mg]

2.1.1 Formulation

Vitamin E acetate dry powder 50% DC	200.0 g
Ludipress® LCE	258.0 g
Polyethylene glycol 6000, powder	35.0 g
Aerosil 200	7.0 g

2.1.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using low compression force.

2.1.3 Tablet properties

Tablet weight	500 mg
Diameter	10 mm
Form	biplanar
Hardness	87 N
Friability	< 0.1%

2.2 Calcium chewable tablet [200 mg Ca]

2.2.1 Formulation

Calcium gluconate	845.0 g
Calcium citrate	500.0 g
Ludipress® LCE	297.5 g
Citric acid, anhydrous	100.0 g
Polyethylene glycol 6000, powder	80.0 g
Orange flavour	30.0 g
Aerosil 200	17.0 g
Aspartame	5.0 g

2.2.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using low compression force.

2.2.3 Tablet properties

Tablet weight	2417 mg
Diameter	20 mm
Form	biplanar
Hardness	201 N
Friability	0.2%

3. Effervescent tablets

3.1 Beta-carotene + vitamin C + vitamin E effervescent tablet [12 mg + 150 mg + 25 mg]

3.1.1 Formulation

Lucarotin® dry powder 10% CWD G/Y	120 g
Ascorbic acid, crystalline	150 g
Vitamin E acetate dry powder 50% DC	50 g
Ludipress® LCE	705 g
Kollidon® VA 64	50 g
Citric acid, anhydrous	450 g
Sodium bicarbonate	320 g
Polyethylene glycol 6000, powder	75 g
Aspartame	30 g
Orange flavour	50 g

3.1.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using high compression force at a maximum relative humidity of 30%.

3.1.3 Tablet properties

Tablet weight	2045 mg
Diameter	20 mm
Form	biplanar
Hardness	95 N
Disintegration time (water)	3 min
Friability	0.9%

3.2 Cimetidine effervescent tablet [400 mg]

3.2.1 Formulation

Cimetidine	400 g
Ludipress® LCE	680 g
Sodium bicarbonate	600 g
Tartaric acid	450 g
Aspartame	30 g
Polyethylene glycol 6000, powder	90 g
Orange flavour	q. s.

3.2.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using high compression force at a maximum relative humidity of 30%.

3.2.3 Tablet properties

Tablet weight	2250 mg
Diameter	20 mm
Form	biplanar
Hardness	107 N
Disintegration time (water)	4 min
Friability	1.0%

3.4 Multivitamin effervescent tablet with beta-carotene

3.4.1. Formulation

Lucarotin® dry powder 10% CWD G/Y	23.0 g
Vitamin E acetate dry powder 50% DC	40.0 g
Thiamine mononitrate	2.0 g
Riboflavin	2.0 g
Nicotinamide	22.0 g
Calcium D-pantothenate	11.0 g
Pyridoxine hydrochloride	2.0 g
Cyanocobalamin 0.1% SD	6.0 g
Ascorbic acid, powder	85.0 g
Ludipress® LCE	477.0 g
Sodium bicarbonate	600.0 g
Tartaric acid	400.0 g
Polyethylene glycol 6000, powder	90.0 g
Orange flavour	60.0 g
Aspartame	30.0 g

3.4.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using high compression force at a maximum relative humidity of 30%.

3.4.3 Tablet properties

Tablet weight	1850 mg
Diameter	20 mm
Form	biplanar
Hardness	91 N
Disintegration time (water)	1 min
Friability	0.6%

4. Sustained release tablets

4.1 Propranolol sustained release tablets

4.1.1 Formulation

Propranolol HCl	160.0 g
Methocel K 15 M	80.0 g
Ludipress® LCE	100.0 g
Aerosil 200	3.4 g
Magnesium stearate	1.6 g

4.1.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using low compression force.

4.1.3 Tablet properties

Tablet weight	345.0 mg
Uniformity of mass (s rel.)	1.75%
Diameter	10.0 mm
Form	biplanar
Hardness	145 N
Friability	0%
Release	
(paddle, 50 rpm, 2 h gastric fluid pH 1.2 then intestinal fluid pH 6.8)	2 h: 30%
	4 h: 44%
	8 h: 64%
	12 h: 81%
	20 h: 97%

4.2 Verapamil sustained release tablet

4.2.1 Formulation

Verapamil HCl	240.0 g
Ludipress® LCE	230.0 g
Methocel K 15 M	75.0 g
Talc	75.0 g
Aerosil 200	2.5 g
Magnesium stearate	5.0 g

4.2.2 Production (direct compression)

The components are mixed, passed through a sieve with 0.8 mm mesh size and compressed using low compression force.

4.2.3 Tablet properties

Tablet weight	627.5 mg
Uniformity of mass (s rel.)	0.6%
Diameter	12 mm
Form	biplanar
Hardness	100 N
Friability	0.1%
Release	
(paddle, 50 rpm, 2 h gastric fluid pH 1.2 then intestinal fluid pH 6.8)	4 h: 35%
	8 h: 51%
	12 h: 62%
	16 h: 73%
	20 h: 81%
	24 h: 90%

PRD-No.	30063934
Packaging	20 kg cardboard boxes with PE inner liners
Storage/Shelf life	Store at room temperature in tightly closed containers. Ludipress® LCE can be stored for 24 months under these conditions.
Safety data sheet	A Safety data sheet is available.
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