Ludipress®

Technical Information

September 2016
Supersedes issue dated September 2008

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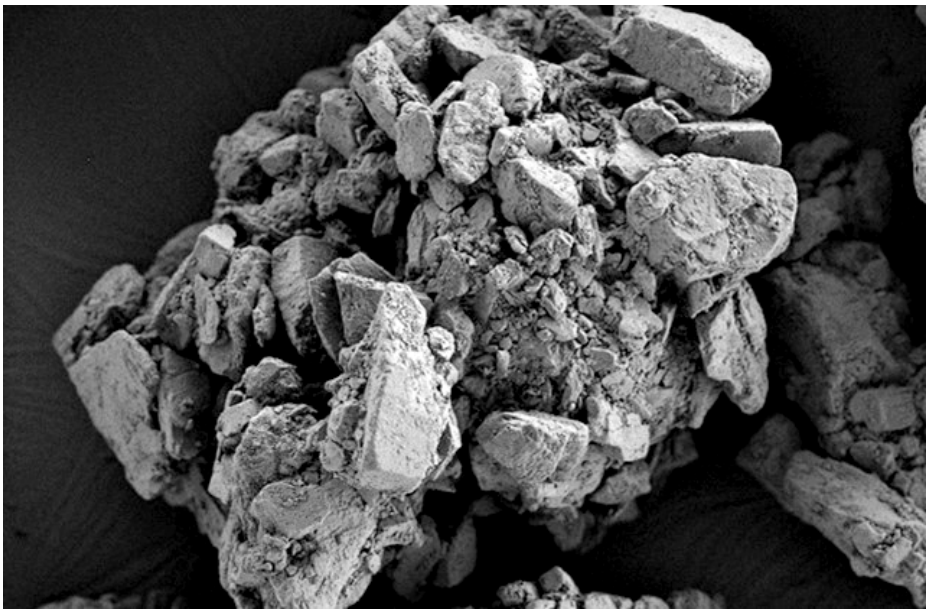
Last change WF-No. 131994

® = Registered trademark of BASF in many countries.

Excipient based on lactose monohydrate for direct tabletting.



BASF
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Nature

Ludipress® combines the three functionalities of a filler, binder and disintegrant in a ready-to-use excipient for tabletting using the direct compression technology.

Ludipress® is composed of Lactose monohydrate, Povidone K30 (Kollidon® 30) and Crospovidone (Kollidon® CL).

It is a white, free-flowing granulated powder that is odorless and tasteless.

Specification

See separate document: “Standard Specification” (not for regulatory purposes) available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

Analytical methods

Lactose monohydrate is determined using a polarimetric assay. For Kollidon® CL a gravimetric method is in place. Kollidon® 30 is determined photometricly.

Analytical methods are available on request.

Hygroscopicity

Fig. 1 shows the sorption isotherm for Ludipress®, expressed in terms of the dry weight. The initial value corresponds practically to the hydrate water of the lactose.

Owing to the ability of the Kollidon® CL disintegrant to swell, irregular surfaces may be formed when tablets prepared with Ludipress® are exposed for long periods to high humidities.

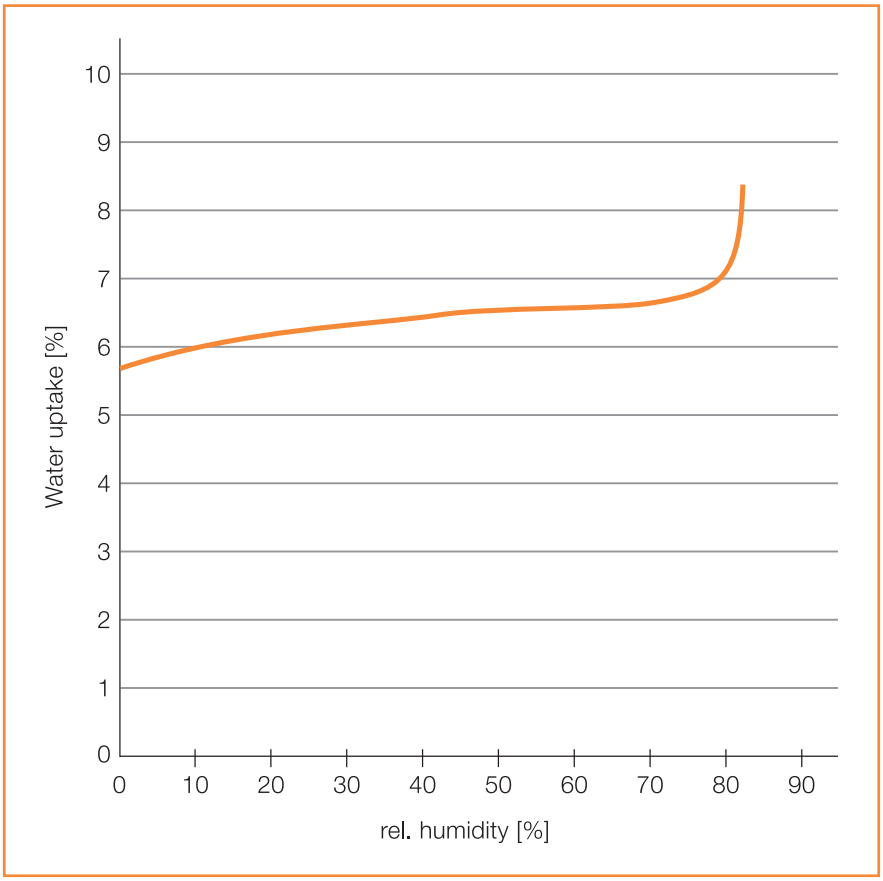

Fig. 1: Sorption isotherm of Ludipress® at 30 °C

Grain size distribution

The following typical values are based on measurements using a screen tower:

15% max. < 63 µm
40 – 60% < 200 µm
90% min. < 400 µm

Fig. 2 shows an example of a particle size distribution as determined by laser diffraction techniques and dry sample preparation.

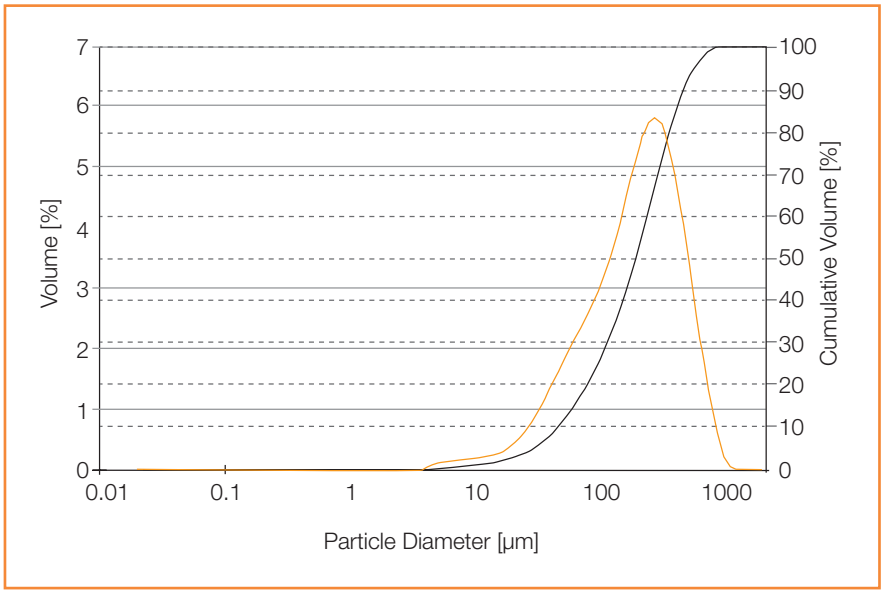

Fig. 2: Ludipress® particle size distribution as measured by laser diffraction techniques

Tabletting properties

Fig. 3 shows the behaviour of Ludipress® in the press in comparison to a physical mixture of the same composition.

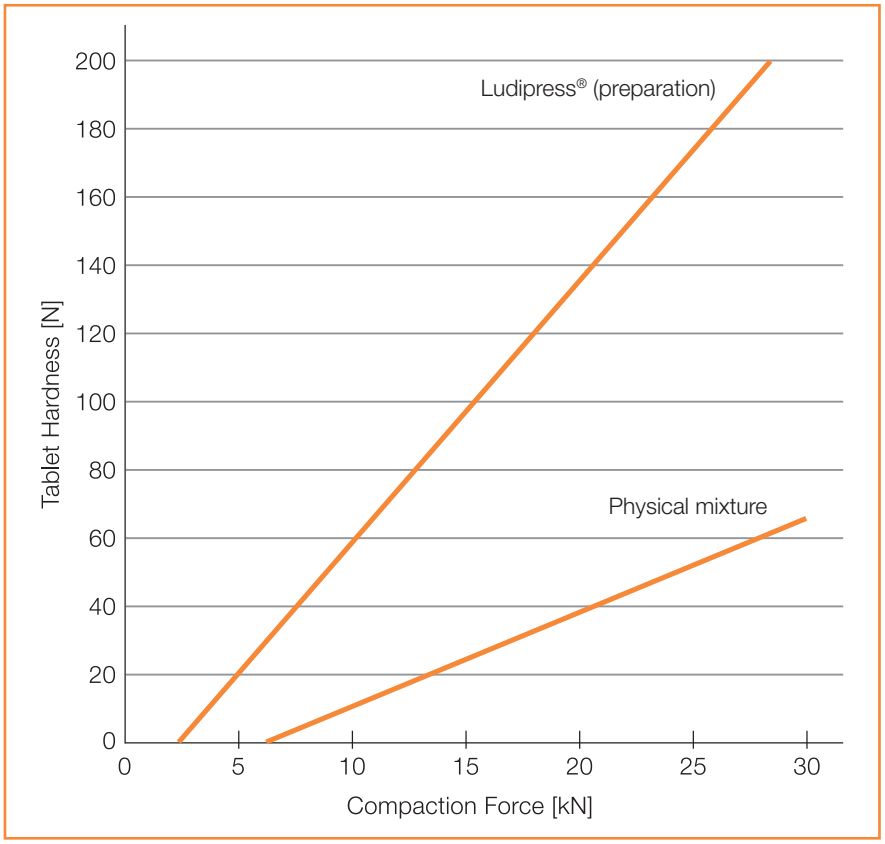

Fig. 3: Ludipress® Compression behavior in comparison to a physical mixture

Regulatory status

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

Microbiological status

The microbiological status is determined according to Ph. Eur. 2.6.12:

less than 1,000 viable aerobic counts/g
less than 100 yeasts and fungi/g
Absence of pathogenic nuclei
E. coli/g
Salmonella/10 g
Pseudomonas aeruginosa/g
Staphylococcus aureus/g
less than 100 other entero bacteria/g

Application

Ludipress® has been specially developed for direct tabletting, but is also very suitable as a filler for hard gelatine capsules.

The addition of a disintegrant may be indicated when there is a high amount of active matter in the formulation. Also an addition of a dry binder like Kollidon® VA 64 Fine may improve tablet hardness in this case.

The following examples of formulations may serve as a guideline. A rotary tabletting press was used at the compaction force indicated in each formulation.

Formulation 1

Acetylsalicylic Acid Tablets (400 mg)

Acetylsalicylic acid, crystalline	400 g
Ludipress®	99 g
Stearic acid	1 g
Kollidon® CL	15 g

Mix all components, pass through a 0.8 mm sieve and press with low compression force.

Tablet properties

Weight	516 mg
Diameter	12 mm
Form	biplanar
Hardness	90 N
Disintegration	<1 min
Friability	0.4%
Dissolution, 10 min	84%
30 min	97%

Chemical stability

Storage time	RT	40 °C
0 months	100.0%	100.0%
16 months	100.0%	100.0%
12 months	98.4%	99.1%

The content of free salicylic acid remained always below 0.2%.

Formulation 2

Vitamin E Chewable Tablets (100 mg)

Vitamin E acetate SD 50	200 g
Ludipress®	493 g
Aerosil 200	7 g

Mix all components, pass through a 0.8 mm screen and press with high compression force.

Properties

Weight	727 mg
Diameter	12 mm
Form	biplanar
Hardness	102 N
Disintegration	15 min
Friability	0%

Formulation 3

Ibuprofen Tablets (400 mg)

I. Ibuprofen	400 g
Aerosil 200	4 g
II. Ludipress®	342 g
Kollidon® CL	8 g
Magnesium stearate	8 g

Mix I, add the components of II, and press with low compression force.

Properties

Weight	727 mg
Diameter	16 mm
Form	biplanar
Hardness	112 N
Disintegration	2 – 3 min
Friability	0.4%
Dissolution, 10 min	82%
15 min	91%

Physical stability (20 – 25 °C)

	6 Months	8 Months	12 Months
Hardness	–	121 N	120 N
Disintegration	–	2 – 3 min	–
Friability	0.4%	0.4%	0.2%
Dissolution, 10 min	85%	–	89%
20 min	87%	91%	88%

Formulation 4

Famotidine Tablets (40 mg)

	No. 1	No. 2
Famotidine	40 g	40 g
Ludipress®	105 g	104 g
Magnesium stearate	3 g	–
Stearic acid	–	2 g
Aerosil 200	4 g	4 g

Mix all components, pass through a 0.8 mm sieve and press with low compression force.

Properties

	No. 1	No. 2
Weight	149 mg	148 mg
Diameter	8 mm	8 mm
Form	biplanar	biplanar
Hardness	74 N	49 N
Disintegration (gastric juice)	3 min	1 min
Friability	< 0.1%	0.3%
Dissolution, 10 min	63%	not tested
30 min	95%	not tested

Formulation 5

Glibenclamide Tablets (5 mg)

	No. 1	No. 2
Glibenclamide, micronized	5.0 g	–
Glibenclamide	–	5.0 g
Ludipress®	120.0 g	194.0 g
Magnesium stearate	0.5 g	1.0 g

Mix all components, pass through a 0.8 mm sieve and press with low compression force (about 10 kN).

Properties

	No. 1	No. 2
Weight	125 mg	201 mg
Diameter	7 mm	8 mm
Form	biplanar	biplanar
Hardness	80 N	107 N
Disintegration	2 – 3 min	3 – 4 min
Friability	< 0.2%	< 0.1%
Dissolution, 10 min	50%	–
30 min	69%	–
60 min	75%	–

Influence of the compression force on the physical tablet properties (No. 2)

	Compression force			
	5 kN	10 kN	20 kN	25 kN
Hardness	47 N	107 N	158 N	191 N
Disintegration	2 – 3 min	3 – 4 min	3 – 4 min	5 min
Friability	< 0.1%	< 0.1%	< 0.1%	< 0.1%

Formulation 6

Propranolol Hydrochloride Tablets (10 mg, 50 mg and 100 mg)

	No. 1	No. 2	No. 3
Propranolol hydrochloride	10 g	50 g	100 g
Ludipress®	490 g	450 g	400 g
Magnesium stearate	2.5 g	2.5 g	2.5 g

Mix all components, pass through a 0.8 mm sieve and press with low compression force.

Properties

	No. 1	No. 2	No. 3
Weight	514 mg	496 mg	505 mg
Diameter	12 mm	12 mm	12 mm
Form	biplanar	biplanar	biplanar
Hardness	112 N	86 N	101 N
Disintegration	2 min	2 min	3 min
Friability	0.1%	0.2%	0.1%

Remarks

– In the case of formulation No. 1 or No. 2 the amount of Ludipress® and the tablet weight may be reduced.

These formulations may be also used for tablet cores.

Formulation 7

Vitamin C Tablets (200 mg), Addition of Dry Binder Kollidon® VA 64

	No. 1	No. 2
Ascorbic acid, powder	200.0 g	200.0 g
Ludipress®	256 g	256.0 g
Kollidon® VA 64	–	25.0 g
Magnesium stearate	2.5 g	2.5 g

Mix all components, pass through a 0.8 mm screen and press with medium compression force (18 kN).

Properties

	No. 1	No. 2
Weight	475 mg	499 mg
Diameter	12 mm	12 mm
Form	biplanar	biplanar
Hardness	56 N	73 N
Friability	3.2%	0.4%
Dissolution, 30 min	> 90%	> 90%

Formulation 8

Multivitamin Tablets

Vitamin A Acetate Dry Powder 500.00 I. U./g	10.0 g
Thiaminmononitrate	2.2 g
Riboflavin	2.2 g
Nicotinamide	16.5 g
Calcium D-pantothenate	11.0 g
Pyridoxinhydrochloride	2.2 g
Cyanocobalamine 0.1% SD	6.0 g
Ascorbic Acid, Powder	85.0 g
Vitamin E Acetate Dry Powder SD 50	31.0 g
Ludipress®	321.0 g
Magnesium stearate	3.0 g
Saccharin-Sodium	2.5 g
Orange Flavor	7.2 g

Mix all components, pass through a 0.8 mm sieve and press with a medium compression force.

Properties

Weight	500 mg
Diameter	12 mm
Form	biplanar
Hardness	68 N
Disintegration	5 min
Friability	0.2%

Packaging

20 kg cardboard boxes with PE inner liners

Storage

Keep containers tightly closed at <25 °C.

Storage stability

Retest period of the product in original unopened containers is at least 24 months if they are properly stored.

PRD-No.

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Disclaimer

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