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## Technical Information

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® = Registered trademark of BASF SE

# Ludipress®

**Excipient based on lactose monohydrate for direct tableting.**

  
The Chemical Company

Pharma  
Ingredients  
& Services



**Nature**

Ludipress combines the three functionalities of a filler, binder and disintegrant in a ready-to-use excipient for tableting 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 odourless 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.

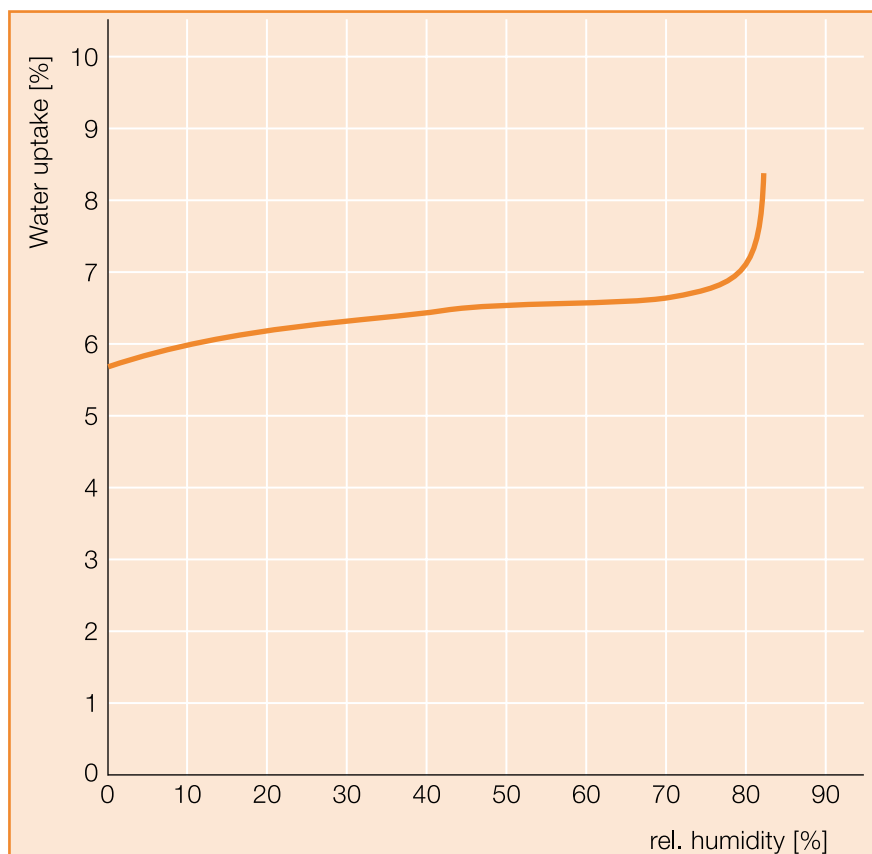


Fig. 1: Sorption isotherm of Ludipress at 30°C

**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.

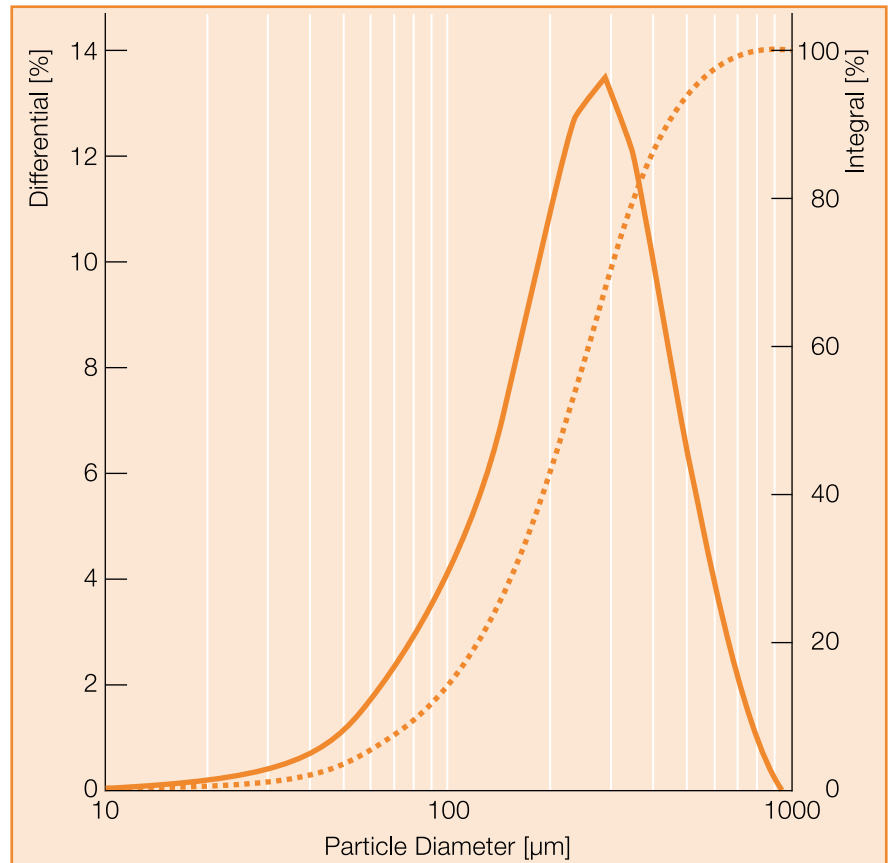
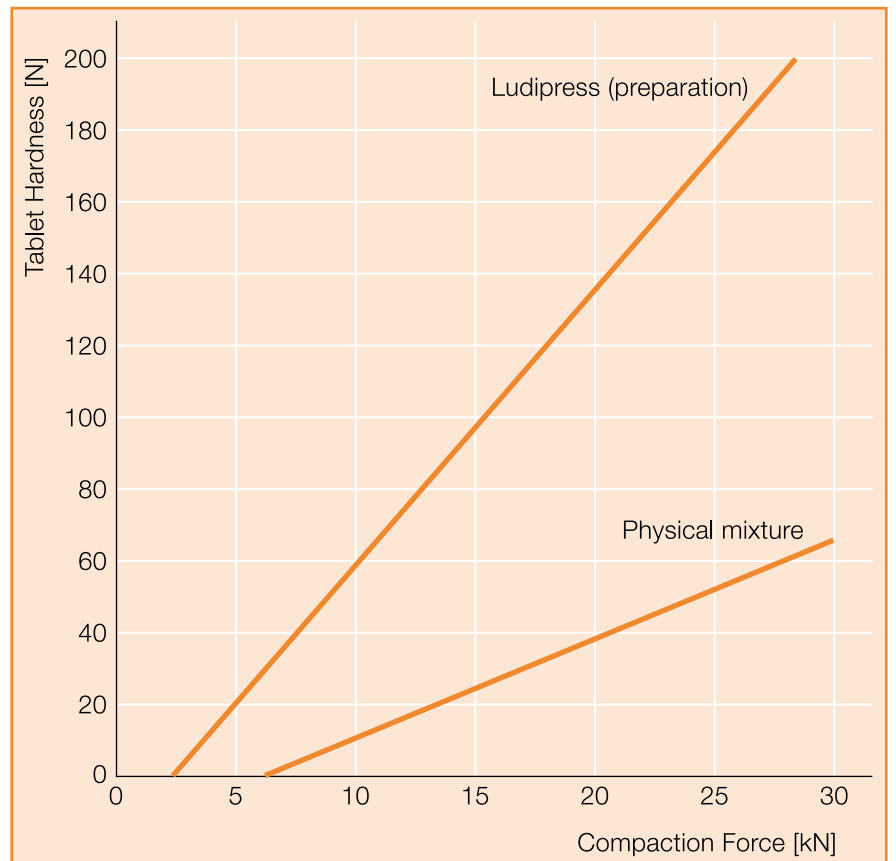


Fig. 2: Ludipress particle size distribution as measured by laser diffraction techniques

**Tabletting properties**

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



**Regulatory status**

No monographs exist.

**Microbiological status**

The microbiological status is determined according to Ph. Eur. 3, Category 3:

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 tableting, 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 or Kollidon 30 may improve tablet hardness in this case.

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

**Acetylsalicylic Acid Tablets (400 mg)**

Acetylsalicylic acid, crystalline	400 g
Ludipress	99 g
Stearic acid	1 g
Kollidon CL (BASF)	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	15 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%.

**β-Carotene Tablets (15 mg)**

β-Carotene dry powder BetaVit® 10% (BASF)	160.0 g
Ludipress	240.0 g
Kollidon CL (BASF)	6.0 g
Magnesium stearate	2.0 g

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

**Properties**

Weight	400 mg
Diameter	12 mm
Form	biplanar
Hardness	59 N
Disintegration	12 min
Friability	0.1%

**Chemical and physical stability (20-25°C)**

	6 Months	12 Months
Loss of beta carotene	3.5%	3.5%
Hardness	60 N	59 N
Disintegration	9 min	7 min
Friability	0.15%	0.16%

**Vitamin E Chewable Tablets (100 mg)**

## Formulations

Vitamin E acetate SD 50 (BASF)	200 g
Ludipress	493 g
Aerosil® 200 (Degussa)	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%

**Ibuprofen Tablets (400 mg)**

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

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

**Properties**

Weight	752 mg
Diameter	16 mm
Hardness	112 N
Disintegration	2-3 min
Friability	0.4%
Dissolution, 10 min	82%
15 min	91%

**4. 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%

**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

**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 (Formulation 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%

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

	No. 1	No. 2	No. 3
Propranolol hydrochloride (BASF)	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.

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

	No. 1	No. 2
Ascorbic acid, powder (BASF)	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%

### Vitamin B Complex + Vitamin C Tablets, Addition of Dry Binder Kollidon VA 64

	No. 1	No. 2
Thiamine mononitrate (BASF)	5.0 g	–
Thiamine hydrochloride (BASF)	–	15.0 g
Riboflavin (BASF)	5.0 g	2.0 g
Pyridoxine hydrochloride (BASF)	5.0 g	5.0 g
Folic acid	0.5 g	–
Choline bitartrate	–	25.0 g
Niacin	30.0 g	–
Nicotinamide	–	10.0 g
Biotin (Merck)	0.1 g	–
Calcium D-pantothenate (BASF)	10.0 g	–
Ascorbic acid, crystalline/powder (BASF)	150.0 g	100.0 g
Ludipress	172.4 g	220.0 g
Kollidon VA 64	20.0 g	–
Magnesium stearate	2.0 g	–
Stearic acid	–	8.0 g

Weigh all ingredients in, pass through a 0.8 mm-sieve and mix.  
Press the mixture with medium/low compression force.

#### Properties

	No. 1	No. 2
Weight	400 mg	411 mg
Diameter	10 mm	12 mm
Form	biplanar	biplanar
Hardness	95 N	69 N
Disintegration	3-4 min	5 min
Friability	0.1%	0.3%

#### Multivitamin Tablets

Vitamin A Acetate Dry Powder 500.00 I. U./g (BASF)	10.0 g
Thiaminmononitrate (BASF)	2.2 g
Riboflavin (BASF)	2.2 g
Nicotinamide (BASF)	16.5 g
Calcium D-pantothenate (BASF)	11.0 g
Pyridoxinhydrochloride (BASF)	2.2 g
Cyanocobalamine 0.1% SD (BASF)	6.0 g
Ascorbic Acid, Powder (BASF)	85.0 g
Vitamin E Acetate Dry Powder SD50 (BASF)	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.

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



<b>Packaging</b>	20-kg cardboard boxes with liner
<b>Storage</b>	Keep containers tightly closed in a cool place
<b>Storage stability</b>	Retest period of the product in original unopened containers is at least 24 months if they are properly stored.
<b>PBG-No.</b>	10086160
<b>PRD-No.</b>	30034982
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