

Technical Information

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Ludipress®

® = Registered trademark of
BASF Aktiengesellschaft

Direct tableting aid based on lactose.

pharma
SOLUTIONS

- Excipients
- Actives
- Contract Manufacturing
- Value Added

 **BASF**
The Chemical Company

Nature

White, free-flowing granules that are odourless and tasteless.

Specification

Lactose monohydrate	Ph. Eur.	93.0% ± 2%
Kollidon® 30	USP	3.5% ± 0.5%
Kollidon CL	USP	3.5% ± 0.5%

Total water content (Karl Fischer) ≤ 6.0%

Bulk density 500 ± 50 g/l
Tapped bulk density 600 ± 50 g/l

The lactose assay is polarimetric; Kollidon CL is determined gravimetrically and Kollidon 30 is determined photometrically. Exact 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.

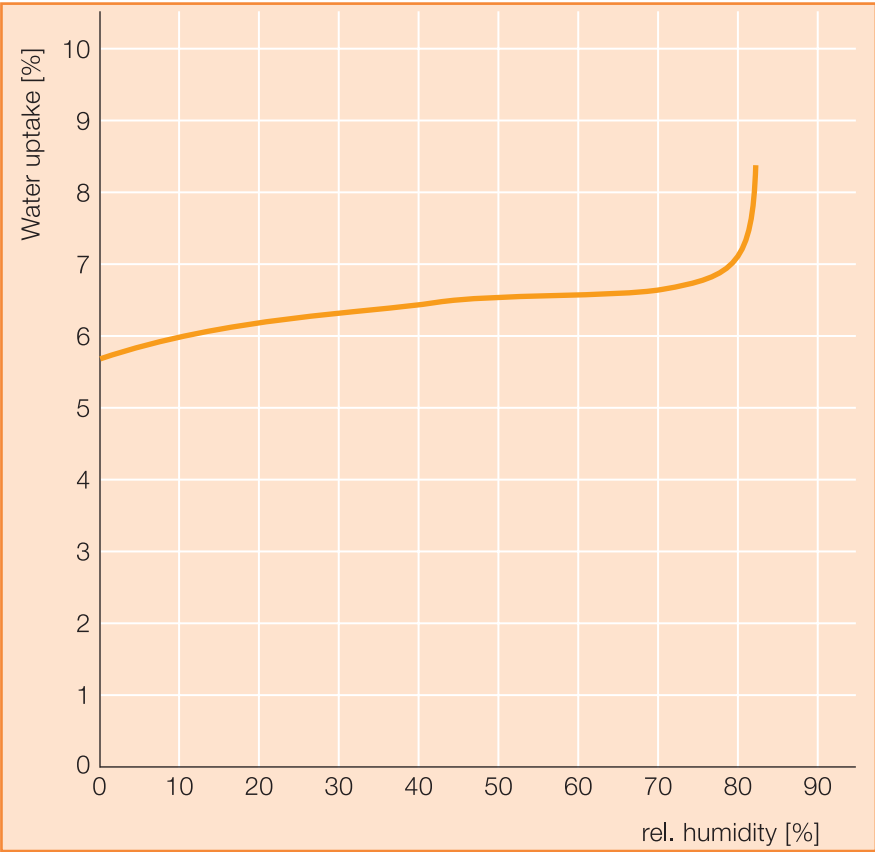


Fig. 1: Sorption isotherm of Ludipress at 30°C

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.

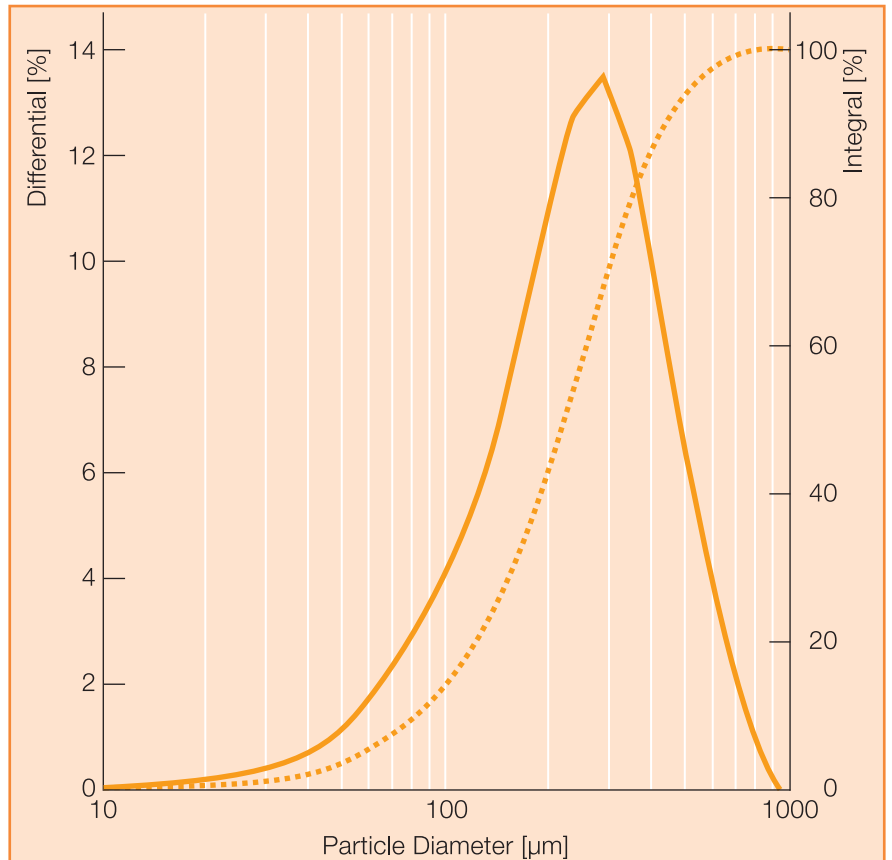
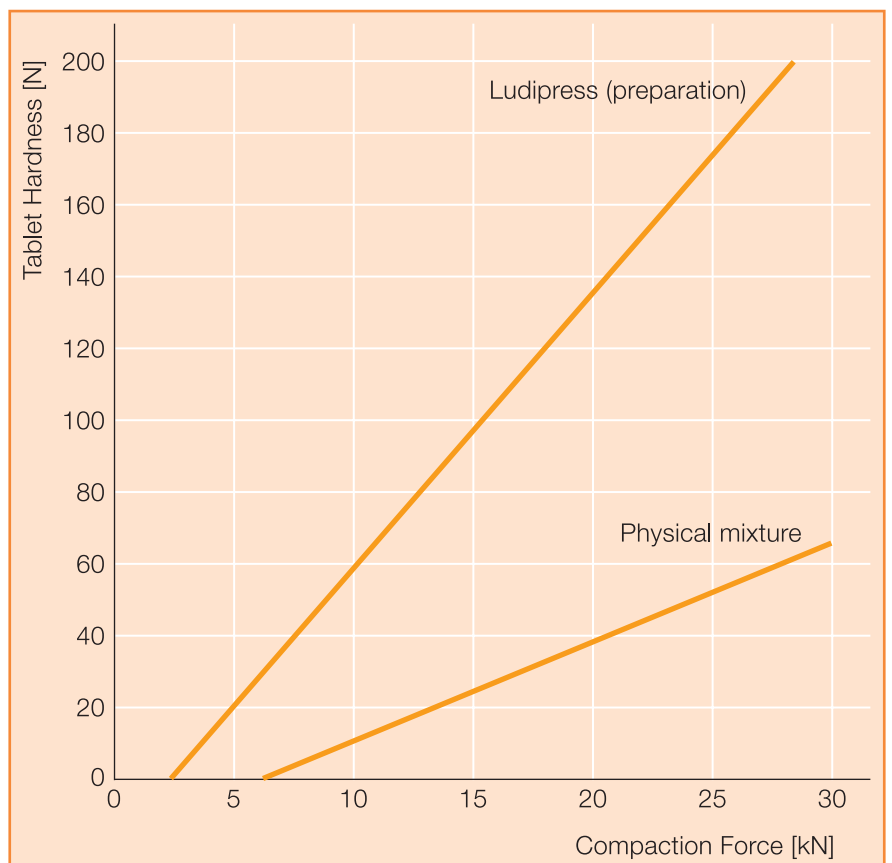


Fig. 2: Ludipress particle size distribution as measured by laser diffraction techniques

Tabletting properties

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



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%

Packaging	20-kg cardboard boxes with liner
Storage	Keep containers tightly closed in a cool place
Storage stability	The shelf life of the product in original unopened containers is at least two years if they are properly stored.
PBG-Number	10086160
Note	The data contained in this publication are based on our current knowledge and experience. In view of the many factors that may affect processing and application of our product, these data do not relieve processors from carrying out their own investigations and tests; neither do these data imply any guarantee of certain properties, nor the suitability of the product for a specific purpose. Any descriptions, drawings, photographs, data, proportions, weights etc. given herein may change without prior information and do not constitute the agreed contractual quality of the product. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing laws and legislation are observed. May 2005

