Technical information
Technische Information

1.02440 Parteck® Mg DC

Content

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1. General

Parteck® Mg DC is a superior directly compressible Magnesium salt for solid dosage preparations. It comprises of just one single component Magnesium Carbonate without any additional binder. Its unique and very large surface area creates a very good compressibility and can adsorb a quantity of additional excipients. This can help the formulator reducing tablet size while maintaining high contents of Magnesium. This will be advantageous in producing antacida or mineral supplements where large quantities of Magnesium are relevant.

Parteck® is the brand name for a range of products under Merck's Functional Particle Engineering concept which allows us to offer specialty excipients with outstanding functionalities especially for the design of solid dosage forms. Further products in this context are **Parteck® delta M** (delta mannitol), **Parteck® M** (directly compressible mannitols), **Parteck® SI** (directly compressible sorbitols), **Parteck® ODT** and **Parteck® LUB** (various lubricants).

Parteck® Mg DC is produced using a unique synthesis technology which offers distinct advantages in direct compression to the pharmaceutical formulator. It is particularly developed to ensure a robust dosage form containing a high amount of mineral content at the same time.

2. Chemical composition

Parteck® Mg DC is a pure compound consisting of Magnesium carbonate conforming with all relevant regulations and pharmacopeias. Its unique characteristics solely result from its physical structure and particle morphology.

Magnesium Carbonate heavy (Ph. Eur., BP, USP, E 504)	CAS Registry	12125-28-9

3. Appearance and Properties

Parteck® Mg DC is a white, colorless and slightly hygroscopic powder showing unique particle morphology and properties.

• Bulk density	0,5 g/ml
• Tapped density	0.7 g/ml
• Mean particle size distribution (measured by laser diffraction, D 0.50)	27 µm
• Angle of repose	43°
• BET Pore volume	0,2 cm^3/g
• BET surface area (measured by nitrogen adsorption)	46 m^2/g
• Assay, complexometric, calculated as MgO	41%

The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: www.merck4pharma.com.

4. Particle size distribution

Figure 1. Particle size distribution with laser light scattering for **Parteck® Mg DC**

laser light scattering: Method 102440 (wet dispersion in deionised water, pump speed: 2000 rpm, stirrer speed: 2000 rpm, disperser pressure: 0 bar, feed rate: 0%, ultrasonic duration: 1 sec., ultrasonic level: 100 %, tray type: general purpose, background time: 7500 msec., measurement time: 7500 msec., obscuration limits: 10,0 - 20,0 %)

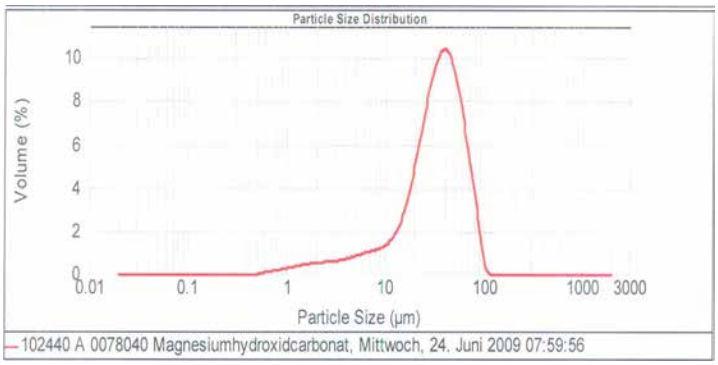


Table 1. Particle size distribution with laser light scattering for **Parteck® Mg DC**

	D(0,05)	D(0,10)	D(0,25)	D(0,30)	D(0,50)
Parteck® Mg DC, #102440, average from 3 batches	3,40	7,05	16,48	18,76	27,34

	D(0,75)	D(0,90)	D(0,95)	D(0,99)	D(1,00)
Parteck® Mg DC, #102440, average from 3 batches	40,74	55,20	64,37	79,36	96,58

Table 2. Particle size distribution with dry sieving for **Parteck® Mg DC**

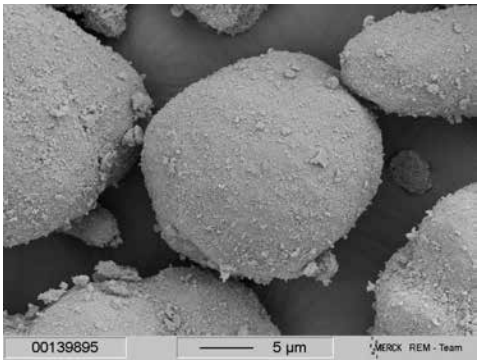
dry sieving: sieve machine Retsch AS 200 control, time: 30 min., interval: 5 sec., intensity: 1,0 mm

	< 32µm	32 – 50µm	50 – 75µm	75 – 100µm	100 – 150µm	150 – 200µm	200 – 250µm
Parteck® Mg DC, #102440, average from 3 batches	12,8%	65,7%	16,9%	2,9%	0,3%	0,2%	0,1%

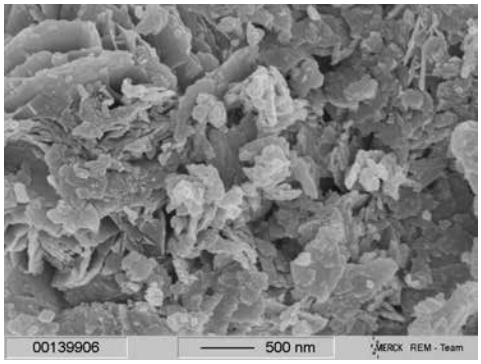
	250 – 300µm	300 – 355µm	355 – 400µm	400 - 500µm	500 – 600µm	600 – 710µm	> 710µm
Parteck® Mg DC, #102440, average from 3 batches	0,1%	0,2%	0,4%	0,1%	0,1%	0,1%	0,1%

5. Morphology (SEM)

SEM 1. (magnification 2500x)



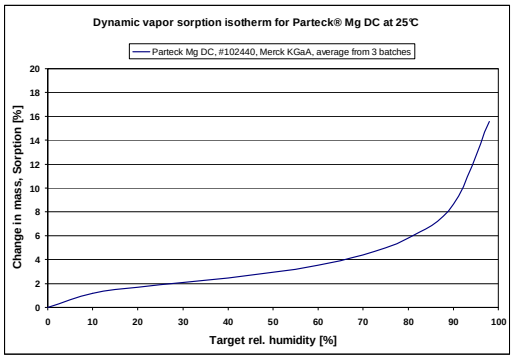
SEM 2. (magnification 25000x)



This micro structure of **Parteck® Mg DC** explains the great surface area and its good compression behavior

6. Hygroscopicity (Dynamic Vapor Sorption, DVS)

Figure 1. Dynamic Vapor Sorption isotherm for **Parteck® Mg DC** at 25 °C



Parteck® Mg DC exhibits slight hygroscopicity, which allows handling the component without special precaution measures as long as the ambient humidity is in regular ranges below 60%.

7. Direct Compression Properties

Parteck® Mg DC placebo formulation

Parteck® Mg DC, Merck KGaA, Cat. No. 1.02440	495 mg	99 %
Parteck® LUB MST Magnesium stearate, Merck KGaA, Cat. No. 1.00663	5 mg	1 %

Parteck® LUB MST Magnesium stearate is sieved through a 250 µm sieve onto the Parteck® Mg DC and than blended for 5 minutes in a turbula mixer (Willy A. Bachofen, Basel, Switzerland). After that, the tabletting mixture is compressed on a Korsch EK 0 single punch instrumented tablet press with a total tablet weight of 500 mg into 11 mm tablets, flat, facetted at 52 rpm.

Table 1. Physical data of **Parteck® Mg DC** placebo tablets (excenter press), average from 3 batches

Compaction force [kN]	5	10	20	30
Tablet thickness[1] [mm]	5,4	4,9	4,1	3,8
Tablet weight[2] [mg]	501,8	509,8	500,9	497,9
Weight variation [% RSD[3]]	1,0	1,2	1,3	1,0
Tablet hardness[1] [N]	53,0	122,2	266,8	407,2
Friability[4] [%]	0,89	0,10	< 0,10	< 0,10

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation
4 : measured with ERWEKA TA420

Figure 1. **Parteck® Mg DC** placebo compression profile (excenter press)

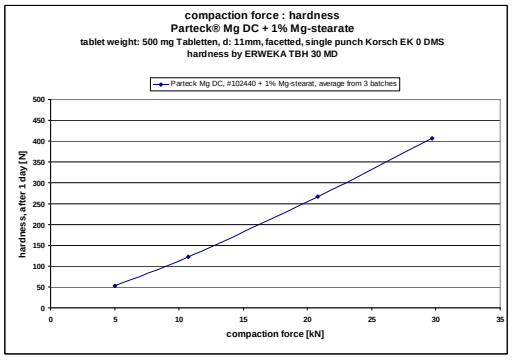
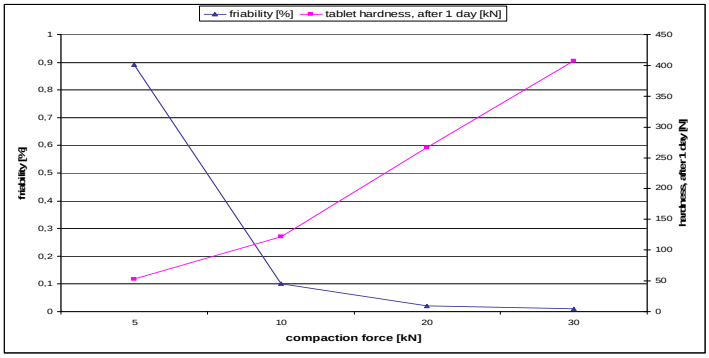


Figure 2. **Parteck® Mg DC** placebo compression profile (excenter press)



Good tablet quality can be achieved with very low compaction forces as it is otherwise only possible to achieve with combinations of Mg-hydroxide-carbonate with a binder (like starch).

8. Drug Formulations with Parteck® Mg DC by Direct Compression

Parteck® Mg DC formulation with Starch 1500®, sample 1:

Parteck® Mg DC, Merck KGaA, item No. 1.02440	280 mg	80%
Starch 1500®, Colorcon	63 mg	18%
Silicon dioxide, highly dispersed, Merck KGaA, item No. 1.13126	3,5 mg	1%
Parteck® LUB MST, Merck KGaA, item No. 1.00663	3,5 mg	1%

Parteck® Mg DC, Starch 1500® and Silicon dioxide, highly dispersed are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, Parteck® LUB MST is sieved through a 250 µm sieve onto the mixture and than again all components are blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 350 mg into 11 mm tablets, flat and facetted.

Table 1. Physical data of **Parteck® Mg DC** with Starch 1500®, tablets (rotary press), rotation speed: 30 Upm, sample 1

Compaction force [kN]	10	15	20	25
Tablet thickness[1] [mm]	3,25	3,06	2,82	2,69
Tablet weight[2] [mg]	355,9	356,8	356,5	356,3
Weight variation [% RSD[3]]	1,2	1,1	1,0	1,1
Tablet hardness[1] [N]	33,1	64,4	100,5	141,8
Friability[4] [%]	0,79	< 0,10	< 0,10	< 0,10
Disintegration[5] [sec.]	34 - 50	32 - 44	30 - 42	20 - 32

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation
4 : measured with ERWEKA TA420
5 : measured with Biomation disi 4

Figure 1. **Parteck® Mg DC** tablet with Starch 1500®, sample 1, compaction force 20 kN, Ø 11 mm, flat, facetted

Parteck® Mg DC formulation with Parteck® M 200, sample 2:

Parteck® Mg DC, Merck KGaA, item No. 1.02440	280,0 mg	80%
Parteck® M 200, Merck KGaA, item No. 1.00419	59,8 mg	17,1%
Ac-Di-Sol®, FMC BioPolymer	3,2 mg	0,9%
Silicon dioxide, highly dispersed, Merck KGaA, item No. 1.13126	3,5 mg	1%
Parteck® LUB MST, Merck KGaA, item No. 1.00663	3,5 mg	1%

Parteck® Mg DC, Parteck® M200, Ac-Di-Sol and Silicon dioxide, highly dispersed are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, Parteck® LUB MST is sieved through a 250 µm sieve onto the mixture and than again all components are blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 350 mg into 11 mm tablets, flat and facetted.

Table 1. Physical data of **Parteck® Mg DC** with Parteck® M 200 tablets (rotary press), rotation speed: 30 Upm

Compaction force [kN]	10	15	20	25
Tablet thickness[1] [mm]	3,03	2,77	2,62	2,51
Tablet weight[2] [mg]	338,4	338,0	339,9	334,8
Weight variation [% RSD[3]]	1,62	1,49	1,54	2,00
Tablet hardness[1] [N]	70,6	125,8	165,7	204,7
Friability[4] [%]	< 0,10	< 0,10	< 0,10	< 0,10
Disintegration[5] [sec.]	32 - 48	24 - 38	30 - 40	38 - 44

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation
4 : measured with ERWEKA TA420
5 : measured with Biomation disi 4

Figure 2. Effect of tablet hardness on compaction force, sample 1 using Starch 1500® (single punch vs. rotary press), Ø 11 mm, flat, facetted

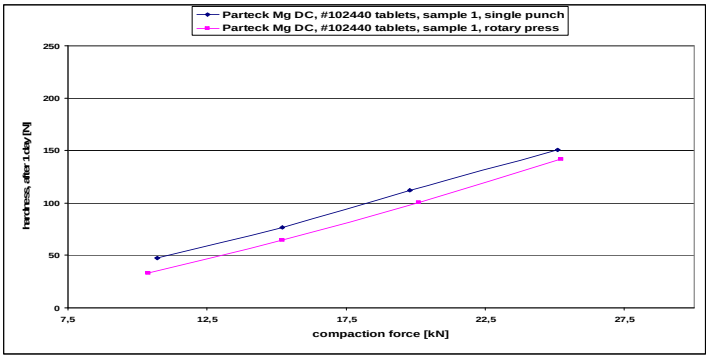
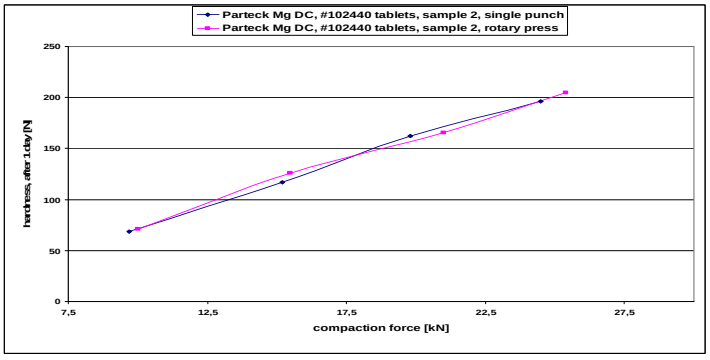


Figure 3. Effect of tablet hardness on compaction force, sample 2 using Parteck® M200 (single punch vs. rotary press), Ø 11 mm, flat, facetted



Parteck® Mg DC formulation chewable tablets with Parteck® SI 150, sample 1:

Parteck® Mg DC, Merck KGaA, item No. 1.02440	400 mg	40,0%
Parteck SI 150, Merck KGaA, item No. 1.03583	540 mg	54,0%
Sucralose, granule, Merck KGaA, item No. 1.00894	2,5 mg	0,25%
Orange flavour Permaseal, Givaudan	5,0 mg	0,50%
Lemon flavour Permaseal, Givaudan	7,5 mg	0,75%
Methocel K4M, Dow Chemicals	25,0 mg	2,5%
Silicon dioxide, highly dispersed, Merck KGaA, item No. 1.13126	10 mg	1%
Parteck® LUB MST, Merck KGaA, item No. 1.00663	10 mg	1%

All components are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, Parteck® LUB MST is sieved through a 250 µm sieve onto the mixture and than again all components are blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 1000 mg into 15 mm tablets, flat and facetted.

Table 1. Physical data of **Parteck® Mg DC** chewable tablets (rotary press), rotation speed: 30 Upm, sample 1 using Parteck® SI 150

Compaction force [kN]	10	12,6
Tablet thickness[1] [mm]	5,45	5,18
Tablet weight[2] [mg]	995,7	991,9
Weight variation [% RSD[3]]	1,6	1,5
Tablet hardness[1] [N]	83,4	117,0
Friability[4] [%]	0,34	0,18

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation
4 : measured with ERWEKA TA420

Parteck® Mg DC formulation chewable tablets with Parteck® M 200, sample 2:

Parteck® Mg DC, Merck KGaA, item No. 1.02440	400 mg	40,0%
Parteck M 200, Merck KGaA, item No. 1.00419	540 mg	54,0%
Sucralose, granule, Merck KGaA, item No. 1.00894	2,5 mg	0,25%
Orange flavour Permaseal, Givaudan	5,0 mg	0,50%
Lemon flavour Permaseal, Givaudan	7,5 mg	0,75%
Methocel K4M, Dow Chemicals	25,0 mg	2,5%
Silicon dioxide, highly dispersed, Merck KGaA, item No. 1.13126	10 mg	1%
Parteck® LUB MST, Merck KGaA, item No. 1.00663	10 mg	1%

All components are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, Parteck® LUB MST is sieved through a 250 µm sieve onto the mixture and than again all components are blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 1000 mg into 15 mm tablets, flat and facetted.

Table 1. Physical data of **Parteck® Mg DC** chewable tablets (rotary press), rotation speed: 30 Upm, sample 2 using Parteck® M 200

Compaction force [kN]	10,1	12,3
Tablet thickness[1] [mm]	5,71	5,44
Tablet weight[2] [mg]	1006,9	995,3
Weight variation [% RSD[3]]	1,9	1,8
Tablet hardness[1] [N]	84,3	105,7
Friability[4] [%]	0,76	0,34

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation
4 : measured with ERWEKA TA420

Parteck® Mg DC formulation effervescent tablets, sample 1, tablet weight: 2200 mg (~ 275 mg Mg^{2+})

Parteck® Mg DC, Merck KGaA, item No. 1.02440	1100 mg	50,0%
Citric acid, anhydrous powder, Merck KGaA, item No. 1.00241	748 mg	34,0%
Sodium hydrogen carbonate, Merck KGaA, item No. 1.06323	154 mg	7,0%
Sucralose, granule, Merck KGaA, item No. 1.00894	11 mg	0,5%
Orange flavour Permaseal, Givaudan	22 mg	1,0%
Lemon flavour SBD, Symrise	33 mg	1,5%
Polyglycol 6000P, Clariant	132 mg	6,0%

All components are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, the mixture is blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 2200 mg into 18 mm tablets, flat and facetted without dry conditioning.

Table 1. Physical data of Parteck® Mg DC effervescent tablets (rotary press), rotation speed: 30 Upm, sample 1

Compaction force [kN]	30
Tablet thickness[1] [mm]	7,0
Tablet weight[2] [mg]	2222,3
Weight variation [% RSD[3]]	2,8
Tablet hardness[1] [N]	144,7

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation

Parteck® Mg DC formulation effervescent tablets with Parteck® SI 150, sample 2, tablet weight: 4200 mg (~ 315 mg Mg^{2+})

Parteck® Mg DC, Merck KGaA, item No. 1.02440	1260 mg	30,0%
Parteck SI 150, Merck KGaA, item No. 1.03583	798 mg	19,0%
Citric acid, anhydrous powder, Merck KGaA, item No. 1.00241	1449 mg	34,5%
Sodium hydrogen carbonate, Merck KGaA, item No. 1.06323	315 mg	7,5%
Sucralose, granule, Merck KGaA, item No. 1.00894	21 mg	0,5%
Orange flavour Permaseal, Givaudan	42 mg	1,0%
Lemon flavour SBD, Symrise	63 mg	1,5%
Polyglycol 6000P, Clariant	252 mg	6,0%

All components are blended for 10 minutes in a drum hoop mixer (J. Engelsmann AG, Germany) and passed through a 1 mm sieve. After that, the mixture is blended for 10 minutes again in a drum hoop mixer (J. Engelsmann AG, Germany). The tabletting mixture will be compressed on a Korsch PH230/14 high speed rotary press with a total tablet weight of 4200 mg into 25 mm tablets, flat and facetted without dry conditioning.

Table 1. Physical data of **Parteck® Mg DC** effervescent tablets (rotary press), rotation speed: 30 Upm, sample 2 with Parteck SI 150.

Compaction force [kN]	25	30
Tablet thickness[1] [mm]	8,0	7,7
Tablet weight[2] [mg]	4247,4	4286,6
Weight variation [% RSD[3]]	2,1	1,7
Tablet hardness[1] [N]	71,4	103,2

1 : measured with ERWEKA TBH 30MD, after 1 day
2 : measured with Mettler AT201
3 : relative standard deviation

9. Main Benefits of Parteck® Mg DC

- **Direct compressibility:** facilitates formulation work and reduces production costs
- **High compactibility even at low compression forces:** reduces stress on tabletting presses and tooling
- **No need for extra binder:** simplifies formulation work and the regulatory effort
- **High mineral content:** due to lack of binder allows for smaller tablet sizes and/or more additional formulation components
- **No license agreement or payment required:** saves time

10. Specification

The currently valid specification can be retrieved from the website: www.merck4pharma.com

11. Storage and Shelf Life

Storage in tightly closed packs protected from moisture. The storage temperature should be kept around 25°C. Minimum 2 years shelf life when stored in unopened original packs in this way.

12. Packaging and Ordering Information

40 kg PE bag in carton box Cat. No. 1.02440.9040

13. Certificate of Analysis

Certificate of Analysis

http://certificates.merck.de

Date of print: 27.07.2010

1.02440.9040	Parteck® Mg DC (Magnesium hydroxide carbonate) heavy Ph Eur,BP,USP,E 504
Batch	A0078040

	Spec. Values		Batch Values	
Assay (complexometric calculated as Magnesiumoxide)	40.0 - 43.5	%	41.5	%
Assay USP (alkalimetric calculated as Magnesiumoxide)	40.0 - 43.5	%	41.3	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Substances soluble in water	≤ 1.0	%	≤ 1.0	%
soluble salts	≤ 1.0	%	≤ 1.0	%
Substances insoluble in acetic acid	≤ 0.05	%	≤ 0.05	%
Substances insoluble in acid	≤ 0.05	%	≤ 0.05	%
Chloride (Cl)	≤ 0.02	%	≤ 0.02	%
Nitrate (NO_3)	≤ 0.015	%	≤ 0.015	%
Nitrite (NO_2)	≤ 0.015	%	≤ 0.015	%
Sulphate (SO_4)	≤ 0.3	%	≤ 0.3	%
Heavy metals (as Pb)	≤ 0.001	%	≤ 0.001	%
As (Arsenic)	≤ 0.0002	%	≤ 0.0002	%
Ca (Calcium)	≤ 0.4	%	≤ 0.4	%
Fe (Iron)	≤ 0.005	%	≤ 0.005	%
Hg (Mercury)	≤ 0.0001	%	≤ 0.0001	%
Na (Sodium)	≤ 0.4	%	≤ 0.4	%
Pb (Lead)	≤ 0.0002	%	≤ 0.0002	%
Residual solvents (Ph.Eur./USP/ICH)	excluded by manufacturing process		excluded by manufacturing process	
Bulk density	≥ 0.25	g/ml	≥ 0.25	g/ml
E.coli (absent in 1 g)	passes test		passes test	

Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt (Germany): +49 6151 72- 0 Page 1 of 2

Certificate of Analysis

1.02440.9040	Parteck® Mg DC (Magnesium hydroxide carbonate) heavy Ph Eur,BP,USP,E 504
Batch	A0078040

Date of examination (DD.MM.YYYY): *16.03.2010*
Minimum shelf life (DD.MM.YYYY): *30.06.2014*

Dr.Matthias Ohm

responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature

14. Safety Data Sheet

The currently valid safety data sheet can be retrieved from the website: www.merck4pharma.com

15. Legal Disclaimer

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

Latest update: July 2, 2010