



Emcompress® Premium

Dibasic Calcium Phosphate Dihydrate, USP; Calcium Hydrogen Phosphate Dihydrate, Ph. Eur.
Dibasic Calcium Phosphate, JP

CERTIFICATE OF ANALYSIS

Batch No.: C46073A

Manufacturing Site: Budenheim, Germany ✓

Re-evaluation date**: 11/2019

Manufacturing date: 11/2016

Description	
Appearance	White or almost white, crystalline powder
Solubility	practically insoluble in cold water and in ethanol. It dissolves in dilute hydrochloric acid and in dilute nitric acid

Characteristics	Specification	Lot Result	Test Reference
Identification I *	White precipitate	Conforms *	USP, Ph. Eur., JP
Identification II *	Yellow precipitate	Conforms *	USP, Ph. Eur., JP
Loss on ignition **	24.5 – 26.5 %	26.2 %	USP, Ph. Eur.
Carbonate *	No effervescence	Passes	USP, Ph. Eur., JP
Chloride *	Not more than 0.25 %	< 0.25 % *	USP, Ph. Eur., JP
Sulfate *	Not more than 0.160 %	< 0.160 % *	USP, Ph. Eur., JP
Arsenic *	Not more than 1 ppm	< 1 ppm *	USP, Ph. Eur., JP
Barium *	No turbidity	Passes *	USP, Ph. Eur., JP
Heavy metals *	Not more than 0.003 %	< 0.003 % *	USP, Ph. Eur., JP
Acid insoluble substances	Not more than 0.05 %	< 0.05 %	USP, Ph. Eur., JP
Fluoride *	Not more than 0.005 %	< 0.005 % *	USP, Ph. Eur.
Organic volatile impurities	Meets requirement	Conforms	USP
Assay **	98.0 – 105.0 %	99.5 %	USP, Ph. Eur., JP
Iron *	Not more than 400 ppm	< 400 ppm *	Ph. Eur.
Loss on drying (1g, 200°C, 3h)	19.5 – 22.0 %	Complies	JP
Lead	Not more than 2 ppm	0.17 ppm	JRS method
Particle size by Alpine®	Not more than 2 % retained on #40 mesh sieve (425 µm)	0.1 %	JRS method
	Not more than 15 % passes through #200 mesh sieve (75 µm)	4.2 %	

*) Results reported are expected results based on periodical testing

**) Dicalcium Phosphate Dihydrate has been known to dehydrate over time. As a precaution, we recommend re-evaluation of TYMC, Loss on Ignition and Assay before use.

The batch described by this certificate meets the requirements of Ph. Eur., NF, and JP monographs for "Dibasic Calcium Phosphate Dihydrate/Calcium Hydrogen Phosphate Dihydrate/Dibasic Calcium Phosphate" current edition, it complies with E 341 (ii) monograph (231/2012) and all relevant EU Food Regulations. The raw materials, manufacturing process and product do not contain any of the solvents listed in Organic Volatile Impurities (USP <467>) or Residual Solvents (Ph.Eur. <5.4>).

JRS PHARMA

GMBH & CO. KG

THE EXCIPIENT
FAMILYA Member of
the JRS Group

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Holzmühle 1

73494 Rosenberg (Germany) · www.jrspharma.de

Stefanie Henker

QUALITY ASSURANCE

Pharmaceutical and Food Excipients

JRS PHARMA LP

Worldwide headquarters

JRS PHARMA GMBH & CO. KG

Holzmühle 1 · 73494 Rosenberg (Germany)

Phone: + 49 (0) 7967 / 152 312

Fax: + 49 (0) 7967 / 152 345

info@jrspharma.de · www.jrspharma.de · www.jrsmile

Customer Service: + 49 (0) 7967 / 152 312

USA + Canada

2981 Route 22, Suite 1 · Patterson, NY 12563-2359 (USA)

Toll-Free: + 1 (800) 431 2457

Phone: + 1 (845) 878 3414 · Fax: + 1 (845) 878 3484

info@jrspharma.com · www.jrspharma.com

Customer Service: +1 (845) 878 3414