

**Emcompress® Premium**

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

**CERTIFICATE OF ANALYSIS**

Batch No.: **17D/044-P2<sup>1)</sup>**  
Re-evaluation date\*\*: 03/2019  
Manufacturing date: 04/2017

Manufacturing Site: **Nandesari, India**  
Expiry date: **03/2022**

| 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., JP |
| Carbonate                            | No effervescence                                          | Passes     | USP, Ph. Eur., JP |
| Chloride                             | Not more than 0.25 %                                      | < 0.25 %   | USP, Ph. Eur., JP |
| Sulfate                              | Not more than 0.48 %                                      | < 0.48 %   | 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 0.2 %                                       | < 0.1 %    | USP, Ph. Eur., JP |
| Assay (Identification C)**           | 98.0 – 105.0 %                                            | %          | USP, Ph. Eur., JP |
| Iron                                 | Not more than 400 ppm                                     | < 400 ppm  | Ph. Eur.          |
| Aluminium*                           | Not more than 200 ppm                                     | < 200 ppm  | JRS method        |
| Arsenic*                             | Not more than 1 ppm                                       | < 1ppm     | USP, Ph. Eur., JP |
| Cadmium*                             | Not more than 1 ppm                                       | < 1ppm     | JRS method        |
| Fluoride*                            | Not more than 50 ppm                                      | < 50 ppm   | USP, Ph. Eur.     |
| Lead*                                | Not more than 1 ppm                                       | < 1ppm     | JRS method        |
| Mercury*                             | Not more than 1 ppm                                       | < 1ppm     | JRS method        |
| Particle size by Alpine <sup>3</sup> | 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) | 4.9 %      |                   |

\*) Results reported are expected results based on periodical testing

Zemcprp04

\*\* 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>).

1) Note: This sample is not intended for microbial testing and human consumption.

2017-07-05  
Ref: VA

APPROVED - PD

Stefanie Henker

QUALITY ASSURANCE

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