



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 241536**

|                   |   |
|-------------------|---|
| Product:          | TRIMETOPRIM   |
| Lot:              | 241536  |
| Expiry date:      | 30/12/2027  |
| Reference:        | Cumple PhEur11.5  |
| Synonyms:         | Trimetoprima.   |
| Formula:          | C <sub>14</sub> H <sub>18</sub> N <sub>4</sub> O <sub>3</sub> |
| Molecular weight: | 290,3 g/mol   |

| Assay                     | Result      | Specification  |   |
|---------------------------|-------------|----------------|---|
| Identification            | Conform (C) | Test PhEur (C) |   |
| Organoleptic properties   | Conform     | PhEur          |   |
| Appearance of solution    | Conform     |                |   |
| Related substances (HPLC) | Conform     |                |   |
| Elemental impurities      | Conform     | Test PhEur     | # |
| Impurity K                | 1 ppm       | <= 5 ppm       | # |
| Loss on drying            | 0,02%       | <= 1,0 %       |   |
| Sulphated ashes           | 0,01%       | <= 0,1%        |   |
| Assay                     | 99,6 %      | 99,0 - 101,0 % |   |
| Unspecified Impurities    | 0,08%       | <= 0,10 %      |   |
| Total impurities          | 0,08 %      | <= 0,2 %       |   |
| Residual solvents         | Conform     | Test PhEur     | # |
| Nitrosamine impurities    | Conform     | Test PhEur     | # |

Organoleptic characteristics: White or yellowish-white powder. Very slightly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 31/07/2024

Judgement:  
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00182 SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

Manufacturer batch: A-20112301026

| Product | Name        | Capacity | Batch      |
|---------|-------------|----------|------------|
| 1100070 | TRIMETOPRIM | 25 kg    | 241536-T-1 |
| 1187056 | TRIMETOPRIM | 1 kg     | 241536-P-1 |
| 1200279 | TRIMETOPRIM | 100 g    | 241536-J-1 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.  
Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer  
(=) UE certificate

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