



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251030

| | |
|-------------------|--|
| Product: | ALLOPURINOL |
| Lot: | 251030 |
| Expiry date: | 30/07/2027 |
| Reference: | Cumple PhEur11.8 |
| Synonyms: | Allopurinol. |
| Formula: | C ₅ H ₄ N ₄ O |
| Molecular weight: | 136,11 g/mol |

| Assay | Result | Specification | |
|---|-------------|----------------|---|
| Identification | Conform (B) | Test PhEur (B) | |
| Organoleptic properties | Conform | PhEur | |
| Impurity F | Conform | Test PhEur | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Elemental impurities | Conform | Test PhEur | # |
| Loss on drying | 0,01 % | <= 0,5 % | |
| Sulphated ashes | 0,00 % | <= 0,1% | |
| Assay (HPLC) | 98,9 % | 97,0-102,0% | |
| Impurity A | < 0,05 % | <= 0,2 % | |
| Impurity B | 0,05 % | <= 0,1 % | |
| Impurity C | ND | <= 0,1 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Sum of impurities different from A, B and C | < 0,05 % | <= 0,3 % | |
| Impurity D | ND | <= 0,1 % | |
| Impurity E | ND | <= 0,1 % | |
| Residual solvent: formamide | < 220 ppm | <= 220 ppm | # |
| Residual solvent: Triethylamine | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Dimethylformamide | < 880 ppm | <= 880 ppm | # |
| Residual solvent: Dimethyl sulfate | < 1,7 ppm | <= 1,7 ppm | # |
| Nitrosamine impurities | Conform | | # |

Organoleptic characteristics: White or almost white powder. Very slightly soluble in water and in ethanol 96 (per cent). It dissolves in dilute solutions of alkali hydroxides.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/07/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00058 SMS LIFESCIENCES INDIA LIMITED

Manufacturer batch: ALP0050325

| Product | Name | Capacity | Batch |
|---------|------------------|----------|------------|
| 1103290 | ALOPURINOL | 10 g | 251030-F-1 |
| 1103290 | ALOPURINOL | 10 g | 251030-F-2 |
| 1103296 | ALOPURINOL | 100 g | 251030-J-1 |
| 1103296 | ALOPURINOL | 100 g | 251030-J-3 |
| 1103297 | ALOPURINOL | 5 kg | 251030-Q-1 |
| 1370100 | ALOPURINOL (FLB) | 100 g | 251030-J-2 |

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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