



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260414

| | |
|-------------------|----------------------------|
| Product: | BISMUTH SUBSALICYLATE |
| Lot: | 260414 |
| Expiry date: | 22/11/2030 |
| Reference: | Cumple PhEur12.1 |
| Synonyms: | Bismuto salicilato básico. |
| Formula: | C7H5BiO4 |
| Molecular weight: | 362,11 g/mol |

| Assay | Result | Specification | |
|---------------------------|---------------|------------------|---|
| Identification | Conform (A,B) | Test PhEur (A,B) | |
| Organoleptic properties | Conform | PhEur | |
| Acidity | Conform | | |
| Chlorides | < = 200 ppm | <= 200 ppm | |
| Nitrates | <= 0,4 % | <= 0,4% | |
| Soluble Bismuth | < 0,7 ppm | <= 40 ppm | # |
| Loss on drying | 0,11 % | <= 1,0 % | |
| Assay | 58,0 % Bi | 56,0 - 59,4 % Bi | |
| Organic solvents residues | Conform | | # |
| Elemental impurities | Conform | Test PhEur | # |
| Nitrosamine impurities | Conform | Test PhEur | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/03/2026

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00251 OCB PHARMACEUTICAL, S.R.L.

Manufacturer batch: C25244149

| Product | Name | Capacity | Batch |
|---------|------|----------|-------|
|---------|------|----------|-------|

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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