

Budesonide

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|---|---|---|
| CODE ARTICLE: 11761 | BATCH: 0127363 | Active pharmaceutical ingredient |
| TEST DATE: 19/04/2024 | TEST: QC-00263484 | |
| EXPIRY DATE: 01/12/2026 | FABRICATION DATE: 02/12/2023 | MR: 430,50 |
| CAS: [51333-22-3] | FORMULA: C ₂₅ H ₃₄ O ₆ | |
| STORAGE: Store in tightly closed containers in a cool, dry place. | | |

| TEST | RESULTS | Units | MIN | MAX | METHOD |
|--------------------------------|---------------------------------------|-------|-----|--|------------------------|
| APPEARANCE | CONFORM | - | | ALMOST WHITE CRYSTALLINE POWDER | PH.EUR.* |
| SOLUBILITY | | | | | |
| SOLUBLE | FREELY SOLUBLE IN DICHLOROMETHANE | | | | PH.EUR.* |
| SOLUBLE | MODERATELY SOLUBLE IN ETHANOL 96 | | | | PH.EUR.* |
| SOLUBLE | FREELY SOLUBLE IN TRICHLOROMETHANE | | | | Manufacture's Standard |
| INSOLUBLE | PRACTICALLY INSOLUBLE IN WATER | | | | PH.EUR.* |
| IDENTIFICATION | | | | | |
| IDENTIFICACION POR IR [A] | CONFORM | | | | PH.EUR.* |
| LOSS ON DRYING | 0,1 % | | - | 0,5 | PH.EUR.* |
| SUSTANCIAS RELACIONADAS | | | | | |
| IMPURITY A | <DL=0,05% (CONFORM) | % | | <=0.2% (<=2xSum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |
| IMPURITY D | <DL=0,05% (CONFORM) | - | | <=0.2% (<=2xSum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |
| IMPURITY L | 0,1% (PASS) | - | | <=0.2% (<=2xSum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |
| IMPURITY K | <DL=0,05% (CONFORM) | - | | <=0.2% (<=2xSum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |
| UNSPECIFIED IMPURITIES | <DL=0,05% (CONFORM) | - | | <=0,10% (=<Sum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 43240 H. G. PHARMACEUTICAL CO., LTD. (China) Manufacturer Batch: BD231202M1 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
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| EXPIRY DATE: 01/12/2026 | FABRICATION DATE: 02/12/2023 | MR: 430,50 |
| CAS: [51333-22-3] | FORMULA: C25H34O6 | |
| STORAGE: Store in tightly closed containers in a cool, dry place. | | |

| TEST | RESULTS | Units | MIN | MAX | METHOD |
|---|---------------|-------|------|--|------------------------|
| TOTAL IMPURITIES | 0,1% (PASS) - | | | <=0,5% (<=5xSum of the areas of the two peaks due to Budesonide Ref A) | PH.EUR.* |
| EPIMERO A | 42 % | | 40 | 51 | PH.EUR.* |
| ASSAY (DRY SUBSTANCE) | 100,8 % | | 97,5 | 102 | PH.EUR.* |
| RESIDUAL SOLVENTS | | | | | |
| ETHANOL | 951 MG/KG | | | <=5000 | Manufacture's Standard |
| PARTICLE SIZE | CONFORM - | | | 100%<=10um ; 95%<=5um | Manufacture's Standard |
| SAMPLING | COLLECT | | | | Manufacture's Standard |
| CORRECT BATCH | YES | | | | Manufacture's Standard |
| SPECIFICATION | PH.EUR 11 | | | | Manufacture's Standard |
| Risk Assessment Evaluation for Nitrosamines | PASS | | | | |
| Elemental Impurities ICHQ3D | CONFORM | | | | |



Silvia Sancho-Tello Ripoll
Technical Director.

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