GUINAMA
ABSOLUTA CALIDAD

# Certificate of Analysis

## Dexamethasone

| | |
|---|---|
| **CODE ARTICLE:** 94155 | **BATCH:** 0117743 **Active pharmaceutical ingredient** |
| **TEST DATE:** 28/06/2022 | **TEST:** QC-00244153 |
| **EXPIRY DATE:** 30/03/2026 **FABRICATION DATE:** 30/04/2022 | **MR:** 392,50 |
| **CAS:** [50-02-2] | **FORMULA:** C22H29FO5 |
| **SYNONYMS / BOTANICAL NAME:** Hexadecadrol | |
| **STORAGE:** Store in tightly closed containers in a cool, dry place. | |

| TEST | RESULTS | Units | MIN | MAX | METHOD |
|---|---|---|---|---|---|
| APPEARANCE | POWDER | | | | PH.EUR.* |
| COLOUR | WHITE | | | | PH.EUR.* |
| *SOLUBILITY* | | | | | |
| SOLUBLE | SPARINGLY SOLUBLE IN ABSOLUT ETHANOL | | | | PH.EUR.* |
| SOLUBLE | SLIGHTLY SOLUBLE IN DICHLOROMETHANE | | | | PH.EUR.* |
| INSOLUBLE | WATER | | | | PH.EUR.* |
| *IDENTIFICATION* | | | | | |
| IR IDENTIFICATION | CONFORM | | | | PH.EUR.* |
| TLC | CONFORM | | | | PH.EUR.* |
| SPECIFIC ROTATION | 90 | DEGREES | 86 | 92 | PH.EUR.* |
| *RELATED SUBSTANCES* | | | | | |
| TOTAL IMPURITIES | 0,1% (PASS) | - | | <= 0.5% (<5xArea RS b) | PH.EUR.* |
| UNSPECIFIED IMPURITIES | 0,07% (PASS) | - | | <= 0.10% (<area RS b) | PH.EUR.* |
| IMPURITY G | N.D. | - | | <= 0.3% (<3xArea RS b) | PH.EUR.* |
| IMPURITY B | N.D. | - | | <= 0.15% (<1.5xarea rs b) | PH.EUR.* |
| IMPURITY F | N.D. | - | | <= 0.15% (<1.5xarea rs b) | PH.EUR.* |
| IMPURITY J | N.D. | - | | <= 0.15% (<1.5xarea rs b) | PH.EUR.* |
| IMPURITY K | N.D. | - | | <= 0.15% (<1.5xarea rs b) | PH.EUR.* |
| LOSS ON DRYING | 0,3 | % | 0,0 | 0,5 | PH.EUR.* |
| ASSAY (DRY SUBSTANCE) | 97,42 | % | 97 | 103 | PH.EUR.* |
| *RESIDUAL SOLVENTS* | | | | | |
| METHANOL | 74 | ppm | - | 3.000 | Manufacture's Standard |
| DICHLOROMETHANE | 212 | ppm | - | 600 | Manufacture's Standard |
| N,N-DIMETHYL FORMAMIDE | N.D. | ppm | - | 880 | Manufacture's Standard |
| DI ISOPROPYL ETHER | N.D. | MG/KG | - | 5000 | Manufacture's Standard |
| PARTICLE SIZE | CONFORM | | | 99% <30um | Manufacture's Standard |
| CORRECT BATCH | YES | | | | Manufacture's Standard |

**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: 53686 M. P. C. PVT. LTD. (India) Manufacturer Batch: DXMFE22004 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
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| TEST | RESULTS | Units | MIN | MAX | METHOD |
|---|---|---|---|---|---|
| SAMPLING | COLLECT | | | | Manufacture's Standard |
| SPECIFICATION | PH.EUR 10 | | | | PH.EUR. |
| Elemental Impurities ICHQ3D | CONFORM | | | | |
| Risk Assessment Evaluation for Nitrosamines | CONFORM | | | | |

***This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.***

**This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.**

**Silvia Sancho-Tello Ripoll**
**Technical Director.**

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