

HIDROCORTISONA ACETATO (EUR. PH.)

| | | |
|----------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 1083 | CAS Nº: 50-03-3 | ANALYSIS Nº: 218/21 |
| MANUFACTURER BATCH: K06M20210605 | CERTIFICATE ID: 32.554 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 24/06/2021 | |
| METAPH BATCH: 0050921 | RETEST DATE: 30/05/2026 | |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------------|---|--------------------------|
| Appearance | White or almost white crystalline powder | White crystalline powder |
| Solubility | Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride | Complies |
| Identification A | Complies | Complies |
| Identification B | Complies | Complies |
| Specific optical rotation | +158 / +167 | +164 |
| Related substances | | |
| Impurity C | =< 0.6 % | 0.34 % |
| Impurity A | =< 0.5 % | 0.16 % |
| Impurity B | =< 0.3 % | < 0.05 % |
| Impurity D | =< 0.3 % | < 0.05 % |
| Impurity E | =< 0.3 % | Not Detected |
| Impurity G | =< 0.15 % | Not Detected |
| Unspecified impurities | =< 0.10 % | 0.05 % (RT = 3.92 min) |
| Total of impurities | =< 1.5 % | 0.55 % |
| Loss on drying | =< 0.5 % | 0.06 % |
| Assay | 97.0 - 102.0 % | 99.0 % |
| Residual solvents [In-house] | | (*) (**) |
| Acetone | =< 5000 ppm | 549 ppm |
| Methanol | =< 3000 ppm | Not Detected |
| Methylene chloride | =< 600 ppm | Not Detected |
| Particle size | | (*) |
| =< 30 µm | 85 % | < 30 µm |

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Hydrocortisone Acetate is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Analysis date: 19/10/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000493

HENAN LIHUA Ph. Co., Ltd.

Middle Of Huanghe Street, Hi-Tech Industry

Development Zone

455000 Anyang





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Keep the containers in a cool and well-ventilated place.

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