

METFORMINA HCL (EUR. PH.)

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|---------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 1278 | CAS Nº: 1115-70-4 | ANALYSIS Nº: 219/24 |
| MANUFACTURER BATCH: MET06590724 | CERTIFICATE ID: 43.307 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 01/07/2024 | |
| METAPH BATCH: 0020924 | EXPIRY DATE: 30/06/2029 | |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------|---|----------------------|
| Appearance | White or almost white crystals | White crystals |
| Solubility | Freely soluble in water, slightly soluble in ethanol (96 %), practically insoluble in acetone and in methylene chloride | Complies (*) |
| Identification B | Complies | Complies |
| Identification E | Complies | Complies |
| Appearance of solution | Clear and colourless | Clear and colourless |
| Impurity F | =< 0.05 % | 0.02 % |
| Related substances | | |
| Impurity A | =< 0.02 % | < 0.01 % |
| Unspecified impurities | =< 0.05 % | < 0.05 % (#) |
| Total impurities | =< 0.2 % | 0.1 % |
| Loss on drying | =< 0.5 % | 0.1 % |
| Sulfated ash | =< 0.1 % | 0.04 % |
| Assay | 98.5 - 101.0 % | 99.5 % |

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Unspecified impurities detailed underneath:
 RT (22.54 min) = 0.03 %
 RT (26.20 min) = 0.03 %

Metformine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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.

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

Store in a dry, cool and well-ventilated place. Keep away from sources of heat.

Analysis date: 01/10/2024
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001502