



SODIO CROMOGLICATO (EUR. PH.)

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|--------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 007903 | CAS Nº: 15826-37-6 | ANALYSIS Nº: 195/20 |
| MANUFACTURER BATCH: 2050002201 | CERTIFICATE ID: 29.459 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 03/08/2020 | |
| METAPH BATCH: 0100920 | RETEST DATE: 02/08/2025 | |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------------|--|---------------------------------------|
| Appearance | White or almost white, hygroscopic, crystalline powder | White crystalline powder, hygroscopic |
| Solubility | Soluble in water, practically insoluble in ethanol (96 %) | Complies (*) |
| Identification B | Complies | Complies |
| Identification D | Complies | Complies |
| Appearance of solution | Not more opalescent than ref. sus. II and not more intensely coloured than ref. sol. BY5 | Complies |
| Acidity or alkalinity | Complies | Complies |
| Related substances | | |
| Impurity C | =< 0.3 % | < 0.05 % |
| Unspecified impurities | =< 0.10 % | 0.05 % (TR = 8.00 min) |
| Total impurities | =< 0.5 % | 0.05 % |
| Oxalates | =< 0.35 % | < 0.35 % |
| Loss on drying | =< 10.0 % | 6.1 % |
| Assay | 98.0 - 101.0 % | 99.4 % |
| Residual solvents [In-house] | | (*) (**) |
| Methanol | =< 200 ppm | 60 ppm |
| Dimethylformamide | =< 200 ppm | 7 ppm |

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Sodiu, Cromoglicate 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

Store in a cool and well-ventilated place, away from heat, flames, sparks and other sources of ignition.

Analysis date: 21/09/2020

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000353

OLON s.p.a.

Stabilimento di Garbagnate Milanese

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