eurofins | BioPharma Product Testing

# *Certificate of Analysis*


Analytical Report: AAL39935
Eurofins Batch Number JJ20AA2914
Version: 1

Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: IOQ6PH19016847

General Method Reference: BP 93

| Eurofins Sample Number JJ20AA2914-1 | |
|---|---|
| **Original Received Date:** | 03-Nov-2020 |
| **Description:** | Secobarbitalum natricum; 520882 |
| **Lot Number:** | 20J27-F01 |
| **Containers Submitted:** | 1 container |

| Analysis/Sample | Specification | Result | Unit |
|---|---|---|---|
| **Appearance** | | | |
| JJ20AA2914-1 | White powder | Meets Requirements | ---- |
| Analysis Date 24-Nov-2020 to 24-Nov-2020 for JJ20AA2914-1 | | | |
| **Identification A** | | | |
| JJ20AA2914-1 | | | |
| about 96 | ---- | 100 | °C |
| Difference to mixture with reference | NMT 2 | 1 | °C |
| Analysis Date 25-Nov-2020 to 26-Nov-2020 for JJ20AA2914-1 | | | |
| **Identification B** | | | |
| JJ20AA2914-1 | The absorption maxima in the spectrum obtained with the test residue (see identification test A) correspond in position and relative intensity to those in the spectrum obtained with the reference residue prepared from secobarbital reference standard. | Meets Requirements | ---- |
| Analysis Date 25-Nov-2020 to 26-Nov-2020 for JJ20AA2914-1 | | | |
| **Identification E** | | | |
| JJ20AA2914-1 | The residue effervesces with acids, and responds to the test for sodium. | Meets Requirements | ---- |
| Analysis Date 26-Nov-2020 to 26-Nov-2020 for JJ20AA2914-1 | | | |

SPECIFICATIES GECONTROLEERD EN CONFORM

| DATUM | PARAAF |
|---|---|
| 09-12-20 | YS |

| Analysis/Sample | Specification | Result | Unit |
|---|---|---|---|
| **Appearance of solution** | | | |
| JJ20AA2914-1 | | | |
| Clarity | Clear | Meets Requirements - Clear | ---- |
| Colour | The solution is not more intensely coloured than reference solution $Y_7$ | < Y7 | ---- |
| Analysis Date 24-Nov-2020 to 24-Nov-2020 for JJ20AA2914-1 | | | |
| **Alkalinity** | | | |
| JJ20AA2914-1 | | | |
| pH of 10% w/v solution | max. 11.0 | 10.3 | ---- |
| Analysis Date 24-Nov-2020 to 24-Nov-2020 for JJ20AA2914-1 | | | |
| **Related substances** | | | |
| JJ20AA2914-1 | max. 0.5 | < 0.5 | % |
| Analysis Date 02-Dec-2020 to 02-Dec-2020 for JJ20AA2914-1 | | | |
| **Loss on drying** | | | |
| JJ20AA2914-1 | max. 3.0 | 0.5 | % |
| Analysis Date 24-Nov-2020 to 24-Nov-2020 for JJ20AA2914-1 | | | |
| **Assay** | | | |
| JJ20AA2914-1 | 98.5-102.0 | 101.4 | % |
| Analysis Date 27-Nov-2020 to 27-Nov-2020 for JJ20AA2914-1 | | | |
| **Impurity profile** | | | |
| JJ20AA2914-1 | | | |
| Single impurity | NMT 0.2 | 0.2 | % |
| Sum of impurities | NMT 1.0 | 0.3 | % |
| Analysis Date 02-Dec-2020 to 04-Dec-2020 for JJ20AA2914-1 | | | |
| **Residual Solvents** | | | |
| JJ20AA2914-1 | | | |
| Methanol | NMT 3000 | 2403 | ppm |
| Analysis Date 25-Nov-2020 to 27-Nov-2020 for JJ20AA2914-1 | | | |

| Sample Compliance Assessment |
|---|
| Samples JJ20AA2914-1 meet the requirement(s) for all listed test(s) where specifications were applied. |

**Contracted Company: PROXY Laboratories Chemistry and Biochemistry**
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*Questions about this report should be directed to your project manager or the general email listed above.*

Reviewed and electronically signed for Quality Assurance Approval by
Irina Pirog, Analytical Review Officer
for Eurofins PROXY Laboratories B.V., on 08-Dec-2020 09:12:37 UTC+01:00