# Test Report N°: 22/05678



## Description of the Sample

| | |
|---|---|
| Laboratory No. | 22-003182 |
| Type of the sample | Pharmaceutical raw materials, drugs and auxiliary materials |
| Name of the sample / Product | Oxitriptanum |
| Strength / Dosage form | - |
| Batch No. | 22A17-B03 |

## Test Results

**Physico-chemical testing: INTERNAL Oxitriptanum**

| Test / parameter | Test method | Unit of measurement | Limit value | Result | Statement of Compliance | Start of the Test |
|---|---|---|---|---|---|---|
| Identification A (infrared absorption) | IR | - | Compliance | Compliance ✓ | Compliance | 30.03.2022 |
| Identification B (related substances) | HPLC | - | The main peak in the chromatogram obtained with the test solution is equivalent to the main peak in the chromatogram obtained with the standard solution. | The main peak in the chromatogram obtained with the test solution was equivalent to the main peak in the chromatogram obtained with the standard solution. ✓ | Compliance | 17.03.2022 |
| Specific rotation (anhydrous material) | Polar | ° | -38 to -30 | -32 ✓ | Compliance | 05.04.2022 |
| pH | Potent. | - | 4.0-7.0 | 5.7 ✓ | Compliance | 05.04.2022 |
| Arsenic | ICP-MS | ppm | ≤1.5 | <0.1 ✓ | Compliance | 24.03.2022 |
| Heavy metals | Test | ppm | ≤15 | <15 ✓ | Compliance | 07.04.2022 |
| Water | PotTitr | % | ≤2.0 | 0.31 ✓ | Compliance | 22.03.2022 |
| Sulfated ashes | GA | % | ≤0.1 | 0.05 ✓ | Compliance | 05.04.2022 |
| Related substances : | | | | | | |
| L-tryptophan | HPLC | % | - | 0.11 | - | 17.03.2022 |
| any other impurity RRT= 1.06 | HPLC | % | - | 0.06 | - | 17.03.2022 |
| any other impurity RRT= 1.13 | HPLC | % | - | 0.03 | - | 17.03.2022 |
| any other impurity RRT= 1.77 | HPLC | % | - | 0.04 | - | 17.03.2022 |
| any other impurity RRT= 2.10 | HPLC | % | - | 0.01 | - | 17.03.2022 |
| any other impurity RRT= 2.23 | HPLC | % | - | 0.02 | - | 17.03.2022 |
| total impurities | HPLC | % | ≤0.5 | 0.29 ✓ | Compliance | 17.03.2022 |
| Assay of Oxitriptanum (anhydrous substance) | PotTitr | % | 98.0 - 101.0 | 99.7 ✓ | Compliance | 05.04.2022 |
| Residual solvents: | | | | | | |
| methanol | GC/FID | ppm | ≤1000 | 76 ✓ | Compliance | 04.04.2022 |
| terz-butylmethylether | GC/FID | ppm | ≤100 | <2 ✓ | Compliance | 04.04.2022 |

**Person responsible for results:** Ing. Eva Pjaláková Palenčárová, PhD., Head of LFOA

**EL spol. s r.o.,** Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia
Accredited Testing Laboratory according to ISO/IEC 17025: 2017
Holder of the Certificate of GMP Compliance No. SK/033V/2020

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## Customer

| | | | |
|---|---|---|---|
| **Customer:** ( name and address ) | Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków | **Date of sample receipt :** | 21.02.2022 |
| **Division:** | Fagron Kraków | **Date of testing from:** | 21.02.2022 |
| **Contract / order:** | 2022 19/0033/SLP/F | **to:** | 14.04.2022 |
| **Order No.:** | 22-01439 | **Date of Test Report Issue:** | 14.04.2022 |

## Description of the Sample

| | |
|---|---|
| **Laboratory No.** | **22-003182** |
| **Type of the sample** | **Pharmaceutical raw materials, drugs and auxiliary materials** |
| **Name of the sample / Product** | **Oxitriptanum** ✓ |
| **Strength / Dosage form** | - |
| **Batch No.** | 22A17-B03 ✓ |
| **Expiry date** | 10.07.2024 ✓ |
| **Description of package** | plastic cup |
| **Size of package / Quantity** | 1 unit -12 g ✓ |
| **Manufacturer / Trader** | Fagron |
| **Sampling / Delivery** | Sample delivered by Customer |
| **Purpose of testing** | Batch release – Assessment of conformity with specification No.: INTERNAL Oxitriptanum ✓ |
| **Specification / Test procedure** | External documentation with specification No.: INTERNAL Oxitriptanum |
| **Appearance of the sample** | creme to brown powder, hygroscopic ✓ |

## Statement of Compliance / Non-compliance with the requirements / specifications

**Test sample:** Oxitriptanum **Batch:** 22A17-B03 **Manufacturer / Trader:** Fagron

**Tested sample in performed tests**
**is in compliance with**
**the specifications presented in INTERNAL Oxitriptanum.**

- Statement of compliance / noncompliance is presented according to customer requirements.
- Statement of compliance / noncompliance of the results with requirements is based on comparison of the test results presented in this Test Report with values presented in external document No.: INTERNAL Oxitriptanum.

**Statements:**

- **EL spol. s r.o. performs pharmaceutical quality control testing on the basis of the Manufacturer's Authorisation No. V-23/2020, issued by the State Institute for Drug Control (ŠÚKL).**
- This Cerificate of Analysis shall not be reproduced except in full without approval of the Laboratory.
- Laboratory is not responsible for sampling, the results apply to the sample as received.
- Test results relate only to the sample tested and do not substitute the approval of the test item by the competent authority.
- Test equipment and instruments have been calibrated and verified in accordance with applicable metrological regulations.
- Test results can be claimed within 30 days of their sending to the customer. Claims delivered in written form only are accepted and executed.
- Return of sample remains - samples will be returned to the customer upon his written request and at his expense. In other cases, the remaining samples are discarded at the customer's expense after the expiration of the storage period (which is at least until the end of the claim period, or as agreed in the contract with a specific customer).

**Test Report issued by and for Statement of Compliance is responsible:** Ing. Eva Pjatáková Palenčárová, PhD., Head of LFOA

**Test Report will be delivered to:** Fagron Kraków

**Date:** 14.04.2022 **Approved by:** Ing. Mária Gaviáková, Qualified Person

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**Test Methods**

| Abbreviation | Method |
|---|---|
| GA | Gravimetric analysis |
| GC/FID | Gas chromatography with flame ionization detector |
| HPLC | High-performance liquid chromatography |
| ICP-MS | Inductively coupled plasma mass spectrometry |
| IR | Infrared spectrometry |
| Polar | Polarimetry |
| PotTitr | Potentiometric titration |
| Potenl. | Potentiometry |
| Test | Test |

**Date:** 14.04.2022
**Approved by:** Ing. Mária Gavláková, Qualified Person