EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 05/21

## General Information

| | |
|---|---|
| **Laboratory audited** | Austrian Federal Office for Safety in Health Care OMCL (Chemicals & Pharmaceuticals) |
| **OMCL code** *(if applicable)* | OMCL-AT_BASG-C |
| **GEON Membership Status** | Full member |
| **Lab Address 1** | Spargelfeldstrasse 191 |
| **Lab Address 2** | (Traisengasse 5, 1200 Wien: Head of OMCL, QM) |
| **Postal Code** | 1220 |
| **City** | Vienna |
| **Country** | Austria |
| **Head of OMCL** | Gerhard Beck |
| **QA Manager** | Klaus Stüwe |
| **Contact person for the MJA** | Klaus Stüwe |
| **Contact e-mail** | klaus.stuewe@ages.at |
| **Date of MJA 05/21** | 17-21 May 2021 |
| **History of Assessments** | MJA 14/17 Date: 5-7 September 2017<br>MJA 11/12 Date: 4-7 December 2012<br>MJA 08/07 Date: 11-14 December 2007 |

## Field of Activity

As main activities, CPAA is involved in:

1) Activities related to the national market
   - Legal Supply Chain: Authorised Medicines (MRP/DCP, CAP, MSS, quality defects, national testing programme) and Suspected Samples
   - Illegal Supply Chain (Counterfeit and suspicious samples)
   - Sampling: on risk-based approach in relation with the risk signals from all parts of the Austrian Medicines and Medical Devices Agency (mainly Inspection, OMCL and Marketing Authorisation).
   - Coordination of Austrian Medicines Enforcement Group (AMEG) combating illegalities in the medical market and the prevention of illegal activities.

2) Activities related to the Network
   - CAP, MRP/DCP, MSS, establishment of Ph. Eur. CRS and participation in PTSs
   - Member of the "OMCL Communication Group", Counterfeit WG and "API Group"
   - Auditors in the MJA/MJV system
   - Scientific Advisor: MSSIP004 „ Suspected Illegal Products Medicines in Disguise"
   - Member of Ph. Eur. Commission and Expert Groups 10B and P4

3) National Pharmacopoeia ÖAB (Österreichisches Arzneibuch):
- Membership (Chair) in ÖAB-Expert Group, elaboration of monographs and analytical methods
- Membership in ÖAB-Commission
- Member of "Task Force for Dosage Recommendation for Finished Products".

## Scope of Assessment

### Samples tested:

Chemicals
- ☑ Active Pharmaceutical Ingredients (API)
- ☑ Pharmaceutical finished dosage forms
- ☑ Pharmaceutical excipients
- ☑ Herbals

Biologicals
- ☐ Vaccines
  - ☐ a) Bacterial
  - ☐ b) Viral
- ☐ Blood/plasma derivatives
- ☐ Biotechnology products
- ☐ VIMP (veterinary immunological medicinal
- ☐ Other biological products (please specify)

Others (please specify)

Animal housing ☐ Yes ☑ No

| Test item*/Test methods | Ph.Eur. Chapter/ Monograph# | Additional references / comments |
|---|---|---|
| Clarity and degree of opalescence of liquids, Visual | 2.2.1. | included under Appearance (PV_339) |
| Degree of coloration of liquids | 2.2.2. | included under Appearance (PV_339) |
| Potentiometric determination of pH | 2.2.3. | |
| Relative density | 2.2.5. | |
| Refractive index | 2.2.6. | |
| Optical rotation | 2.2.7. | |
| Melting point-capillary method | 2.2.14. | |
| Potentiometric titration | 2.2.20. | |
| Absorption spectrophotometry infrared | 2.2.24. | |
| Absorption spectrophotometry ultraviolet and visible | 2.2.25. | |
| Thin-layer chromatography | 2.2.27. | |
| Gas chromatography, Flame ionisation (FID) | 2.2.28. | |
| Gas chromatography, Mass spectrometry (MS) | 2.2.28. | Including PV_702 "Identification of active substances in unknown products by GC-MS" |
| Liquid chromatography, Diode array (DAD) | 2.2.29. | |

| Test item*/Test methods | Ph.Eur. Chapter/ Monograph# | Additional references / comments |
|---|---|---|
| Liquid chromatography, Mass spectrometry (MS) | 2.2.29. | |
| Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength) | 2.2.29. | |
| Loss on drying | 2.2.32. | |
| Mass spectrometry, Electron ionisation (EI) | 2.2.43. | |
| Mass spectrometry, Electrospray ionisation (ESI) | 2.2.43. | |
| Mass spectrometry, Quadrupol | 2.2.43. | |
| Mass spectrometry, Time of flight (TOF) | 2.2.43. | |
| Identification reactions of ions and functional groups | 2.3.1. | |
| Sulfated ash | 2.4.14. | |
| Total ash | 2.4.16. | |
| Acid value | 2.5.1. | |
| Iodine value | 2.5.4. | |
| Peroxide value | 2.5.5. | |
| Water- semi-micro determination | 2.5.12. | |
| Water- micro determination | 2.5.32. | |
| Foreign matter | 2.8.2. | |
| Essential oils in herbal drugs | 2.8.12. | |
| High-performance thin-layer chromatography of herbal drugs and herbal drug preparations | 2.8.25. | |
| Disintegration of tablets and capsules | 2.9.1. | |
| Dissolution test for solid dosage forms (Basket apparatus, Apparatus 1) | 2.9.3. | |
| Dissolution test for solid dosage forms (Paddle apparatus, Apparatus 2) | 2.9.3. | |
| Dissolution test for transdermal patches (Disk assembly method, Method 1) | 2.9.4. | |
| Dissolution test for transdermal patches (Rotating cylinder method, Method 3) | 2.9.4. | |
| Uniformity of mass of single-dose preparations | 2.9.5. | |
| Uniformity of content of single-dose preparations | 2.9.6. | |
| Friability of uncoated tablets | 2.9.7. | |
| Resistance to crushing of tablets | 2.9.8. | |
| Test for extractable volume of parenteral preparations | 2.9.17. | |
| Uniformity of dosage units | 2.9.40. | |

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| Test item*/Test methods | Ph.Eur. Chapter/ Monograph# | Additional references / comments |
|---|---|---|
| Appearance | | PV_339 (incl. opalescence + colour) |
| Volumetric titration by visual end-point | | PV_603 |
| Herbal Drugs / Identification | 1433 | PV_601 includes microscopy and macroscopy of herbals and suspected falsifications |
| Herbal Teas / Identification | 1435 | included under PV_601 above |
| Subdivision of tablets | 0478 | |

* - whenever applicable

# - Chapter/Monograph in force at the moment of the Audit

## Remarks

None