

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES
SCOPE OF ASSESSMENT OF MJA



SCOPE OF ASSESSMENT of MJA 07/17

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Field of activity: Market surveillance testing, Official batch release testing, Post-registration testing

Name of the OMCL: NATIONAL MEDICINES INSTITUTE

OMCL code PL_NIL

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History of assessments:

- MJA 07/17 Date: 6th to 8th June 2017
- MJA 06/13 Date: 25th to 27th June 2013
- MJA 03/09 Date: 30th June to 2nd July 2009

SCOPE OF ASSESSMENT		
Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Chemicals Active Pharmaceutical Ingredients (API) <input checked="" type="checkbox"/> Pharmaceutical finished dosage forms <input checked="" type="checkbox"/> Pharmaceutical excipients <input checked="" type="checkbox"/> Herbals <input checked="" type="checkbox"/>	Physico-chemical	Degree of coloration of liquids Ph. Eur.2.2.2
		Potentiometric determination of pH Ph. Eur.2.2.3
		Relative density Ph. Eur.2.2.5
		Refractive index Ph. Eur.2.2.6
		Optical rotation Ph. Eur.2.2.7

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Others <input checked="" type="checkbox"/> Chemical substances Dietary supplements Medical device Chemicals Active Pharmaceutical Ingredients (API) <input checked="" type="checkbox"/> Pharmaceutical finished dosage forms <input checked="" type="checkbox"/> Pharmaceutical excipients <input checked="" type="checkbox"/> Herbals <input checked="" type="checkbox"/> Others <input checked="" type="checkbox"/> Chemical substances Dietary supplements Medical device	Physico-chemical	Capillary viscometer method Ph. Eur.2.2.8 Ph. Eur.2.2.9
		Melting point – instrumental method Ph. Eur.2.2.60
		Potentiometric titration Ph. Eur.2.2.20
		Potentiometric determination of ionic concentration using ion- selective electrodes Ph. Eur.2.2.36
		Complexometric titrations Ph. Eur.2.5.11
		Atomic emission spectrometry (AES) Ph. Eur. 2.2.22
		Atomic absorption spectrometry (AAS) Ph. Eur.2.2.23
		Absorption spectrophotometry, infrared (IR) Ph. Eur.2.2.24
		Absorption spectrophotometry, ultraviolet and visible (UV-VIS) Ph. Eur.2.2.25
		Thin – layer chromatography (TLC) Ph. Eur.2.2.27

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
<p>Chemicals</p> <p>Active Pharmaceutical Ingredients (API) <input checked="" type="checkbox"/></p> <p>Pharmaceutical finished dosage forms <input checked="" type="checkbox"/></p> <p>Pharmaceutical excipients <input checked="" type="checkbox"/></p> <p>Herbals <input checked="" type="checkbox"/></p> <p>Others <input checked="" type="checkbox"/></p> <p>Chemical substances</p> <p>Dietary supplements</p> <p>Medical device</p>	Physico-chemical	<p>Gas chromatography (GC)</p> <p>Ph. Eur.2.2.28</p>
		<p>Liquid chromatography (HPLC)</p> <p>Ph. Eur.2.2.29</p>
		<p>Size-exclusion chromatography</p> <p>Ph. Eur.2.2.30</p>
		<p>Molecular mass distribution in dextrans</p> <p>Ph. Eur.2.2.39</p>
		<p>Loss on drying</p> <p>Ph. Eur.2.2.32</p>
		<p>Nuclear magnetic resonance spectrometry (NMR)</p> <p>Ph. Eur. 2.2.33</p>
		<p>Osmolality</p> <p>Ph. Eur.2.2.35</p>
		<p>Mass spectrometry (LC-MS/MS)</p> <p>Ph. Eur.2.2.43</p>
		<p>Capillary electrophoresis</p> <p>Ph. Eur.2.2.47</p>
		<p>Amino acid analysis</p> <p>method 4 or 5</p> <p>Ph. Eur.2.2.56</p>

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
<p>Chemicals</p> <p>Active Pharmaceutical Ingredients (API) <input checked="" type="checkbox"/></p> <p>Pharmaceutical finished dosage forms <input checked="" type="checkbox"/></p> <p>Pharmaceutical excipients <input checked="" type="checkbox"/></p>	Physico-chemical	<p>Inductively coupled plasma - mass spectrometry (ICP MS) Ph. Eur.2.2.58</p>
		<p>Sulfated ash Ph. Eur.2.4.14</p>
		<p>Total ash Ph. Eur.2.4.16</p>
		<p>Determination of nitrogen by sulphuric acid digestion Ph. Eur.2.5.9</p>
		<p>Water semi-micro determination Ph. Eur.2.5.12</p>
		<p>Total protein Ph. Eur.2.5.33</p>
		<p>Determination of essential oils in herbal drugs Ph. Eur.2.8.12</p>
		<p>Disintegration of tablets and capsules Ph. Eur.2.9.1</p>
		<p>Dissolution test for solid dosage forms Ph. Eur.2.9.3</p>
		<p>Uniformity of mass of single-dose preparations Ph. Eur.2.9.5</p>
<p>Uniformity of content of single-dose preparations Ph. Eur.2.9.6</p>		

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Herbals <input checked="" type="checkbox"/> Others <input checked="" type="checkbox"/> Chemical substances Dietary supplements Medical device		Friability of uncoated tablets Ph. Eur.2.9.7
		Resistance to crushing of tablets Ph. Eur.2.9.8
		Ethanol content Ph. Eur.2.9.10
		Preparation for inhalation: aerodynamic assessment of fine particles Ph. Eur.2.9.18
		Particulate contamination sub-visible particles Ph. Eur.2.9.19
		Softening time determination of lipophilic suppositories Ph. Eur.2.9.22
		Uniformity of mass of delivered doses from multidose containers Ph. Eur.2.9.27
		Particle size analysis by laser light diffraction Ph. Eur.2.9.31

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
		<p>Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD) Ph. Eur.2.9.33</p> <p>Uniformity of dosage units Ph. Eur.2.9.40</p>
<p>Biologicals Vaccines <input checked="" type="checkbox"/> a) Bacterial <input checked="" type="checkbox"/> Blood/plasma derivatives <input checked="" type="checkbox"/> Chemicals <input checked="" type="checkbox"/> Pharmaceutical finished dosage forms <input checked="" type="checkbox"/> Other products <input checked="" type="checkbox"/> (please specify) Medical devices Chemical substances</p>	Biological	<p>Bacterial endotoxins (LAL) Ph. Eur.2.6.14 method A and B</p> <p>Cytotoxicity PN-EN ISO 10993-5 USP / NF Extraction test Direct contact test Agar test Filter test</p> <p>Genotoxicity PN-EN ISO 10993-3 Ames test Micronucleus test <i>in vitro</i></p>
<p>Chemicals <input checked="" type="checkbox"/> Biologicals <input checked="" type="checkbox"/> Others <input checked="" type="checkbox"/></p>	Microbiological	<p>Sterility Ph. Eur.2.6.1</p> <p>Microbiological examination of non-sterile products: microbial enumeration tests Ph. Eur.2.6.12</p>

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Medical devices Biocidal products Disinfectants and antiseptics Dietary supplements		Microbiological examination of non-sterile products: test for specified micro-organisms Ph.Eur.2.6.13
		Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation Ph.Eur.2.6.31
		Microbiological assay of antibiotics Ph.Eur.2.7.2
		Efficacy of antimicrobial preservation Ph.Eur.5.1.3
		Determination of bactericidal, fungicidal or yeasticidal activity PN-EN 1040; PN-EN 1275; PN-EN 14347; PN-EN 13727; PN-EN 1276; PN-EN 1650; PN-EN 1656; PN-EN 1657; PN-EN 13624; PN-EN 14348; PN-EN 13697; PN-EN 14561; PN-EN 14562; PN-EN 14563; PN-EN 14204; PN-EN 13704; PN-EN 14349, PN-EN 16438; Ph.Eur.5.1.11 planning

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Products/materials to be tested	Type of test	Test methods (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Others <input checked="" type="checkbox"/> (please specify) Materials used for the manufacture of containers	Physico-chemical	Polyolefins Ph. Eur.3.1.3
		Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations Ph. Eur.3.1.4
		Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations Ph. Eur.3.1.5
Others <input checked="" type="checkbox"/> (please specify) Containers	Physico-chemical	Glass containers for pharmaceutical use Ph. Eur.3.2.1
		Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders Ph. Eur.3.2.9
Animal housing YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>		

Remarks: /