

SPECIAL SERVICES TO SHORTEN AND SIMPLIFY BATCH RELEASE

Parallel Application

The applicant can first hand in samples and later on the batch protocol when testing is completed. Batch release is usually performed within one working day. Suggestions for further optimizing our release times are welcome.

e-Submission of Applications

Protocols can be simply submitted by e-mail or fax.

Certificates for Auxiliaries & Excipients

Protocols for excipients can be handed in without samples for testing. Certificates are granted free of charge.

e-Transmission of Release Certificates

Certificates are sent by e-mail or fax before they are sent postal to shorten the time to marketing for the applicants.

Export Certificates

Export certificates are granted for products intended for marketing outside the EU.

Meetings with Applicants

Periodical Meetings concerning process improvements are held upon request.

Fees

Description	Fee
Notifications of batch releases	100,00 €
Evaluation of plasma pools	200,00 €
Human albumin	1.330,00 €
Immunoglobulins	1.330,00 €
Coagulation concentrates, tissue adhesives, plasmas	2.000,00 €
Batch testing of vaccines without animal trials	1.330,00 €
Batch testing of vaccines with animal trials	5.000,00 €
Batch testing of medicinal products with a blood product as excipient	600,00 €

Contact

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Published by

AGES – Austrian Agency for Health and Food Safety
Spargelfeldstraße 191 | 1220 Vienna | Austria

photos: AGES / Peter Nemenz

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THE AGES OMCL

The principal task of the AGES OMCL is the assessment of the quality of medicinal products pre-approval and post-marketing as well as to carry out the batch release procedure based on European and national legislation. The OMCL is part of the European OMCL network which was founded in the mid-1990s upon a decision of the Commission of the European Union and the Council of Europe under the umbrella of the EDQM (European Directorate for the Quality of Medicines & Healthcare).

The tests performed comprise immunochemical, molecular biological and virological methods as well as protein chemistry and coagulation tests. Beside plasma pools also human blood and plasma derived medicinal products and vaccines are released within the OCABR (Official control authority batch release) procedure by the AGES OMCL. Our certificates are accepted in the whole European Union and the European Economic Area.

OMCL Status

- ISO 17025 Accreditation since 2002
- Reaccreditation and Mutual Joint Audits (MJA) by the EDQM and the national accreditation body in 2007 and 2012
- ISO 9001 Certification since 2010

Product Portfolio and Capacity

Products	Release 2014	Capacity
Plasma Pools	3.005	5.000
SD Plasma	74	200
Human Albumin	802	1.400
Immunoglobulins	53	500
Coagulation Concentrates	398	800
Fibrin Sealants	480	700
Vaccines	196	300

Product Specific Release Times

Products	Average (d)
Plasma Pools	6,5
SD Plasma	7,9
Human Albumin	1,9
Immunoglobulins	6,5
Coagulation Concentrates	2,3
Fibrin Sealants	3,0
Vaccines w/o animal testing	1,7

Calendar days, parallel submission included

PLASMA DERIVED MEDICINAL PRODUCTS 2006 - 2014

