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DRUG MANUFACTURERS PRACTICE ON MEETING REGULATORY REQUIREMENTS FOR RELEASE OF DRUG THE FIRST BATCH ON THE MARKET IN THE REPUBLIC OF SERBIA

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The first batch is a medicinal product batch manufactured or imported after the marketing authorization issuance, for the purpose of placing on the market (approved size). Agency for Medicines and Medical Devices of Serbia (ALIMS) performs laboratory quality control in accordance with approved the specification during the drug „shelf life“ and analytical procedures during drug license issuing. Submitted to the ALIMS also: samples, certificate of analysis (CoA) for analyzed batch, reference standards with appropriate certificates and other requested documentation. Manufacturers experience indicates few necessary things:

1. The outer packaging should contain the data approved in the formal completeness of the variation, and not the data initially approved registration document;
2. List CoA data from the „shelf life”, not from „release“ certificate;
3. Analysis request, CoA and Batch Release Certificate should have the same batch size;
4. Submit the placebo and appropriate documentation for the analyzed sample;
5. Submit an unused reference standard and evidence that the cold chain has been complied with as required;
6. The paper quality for printing drug instructions has to be 50 g/m^2 ± 2% (GMP guidelines);
7. If additional samples are submitted at the ALIMS request, the batch size has to be corrected on the Request for Analysis, CoA and Batch Release Certificate

Quantities of drug samples for laboratory control provided by the client are given on the ALIMS website. Sample size and delivery of immunological drugs (vaccines, serums, toxins, allergens, blood and plasma drugs) are not the subject of this summary.

References

1. https://www.alims.gov.rs/wp-content/uploads/2022/02/p-kontrola-64-2011-1.pdf Last accession date: 10.06.2022.
2. Reiner Gnibl, EU-Compliant Batch Release of Medicinal Products: How to Meet the GMP Requirements of Annex 16 EU GMP Guide. 1st edition 2018 https://www.fdanews.com/products/57880-eu-compliant-batch-release-of-medicinal-products-how-to-meet-the-requirements-of-annex-16-of-the-eu-gmp-guide Last accession date: 10.06.2022.

PRAKSA PROIZVOĐAČA LEKOVA O ISPUNJENJU REGULATORNIH ZAHTEVA ZA PUŠTANJE PRVE SERIJE LEKA U PROMET U REPUBLICI SRBIJI

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Prva serija je serija leka proizvedena ili uvezena posle izdavanja dozvole za lek, radi stavljanja u promet, a čija je veličina odobrena u postupku izdavanja dozvole za lek. Agencija za lekova i medicinska sredstva Srbije (ALIMS) obavlja laboratorijsku kontrolu kvaliteta prve serije leka. Laboratorijska kontrola kvaliteta leka, vrši se u skladu sa specifikacijom u roku trajanja leka („*shelf life*") i analitičkim postupcima odobrenim u postupku izdavanja dozvole za lek, postupku izmene/dopune dozvole za lek (varijacije), odnosno obnove dozvole za lek. Uz zahtev za laboratorijsku kontrolu kvaliteta leka dostaviti ALIMS-u: uzorak serije leka, sertifikat analize (CoA) za tu seriju leka, referentni standardi sa sertifikatima i druga dokumentacija, na zahtev ALIMS. Praksa proizvođača ukazuje da je potrebno:

1. Na kutiji navesti podate sa formalne kompletnosti, a ne inicijalno odobrene pri registracij;
2. Na CoA navesi podatke iz „shelf life", a ne „release"sertiikata;
3. Zahtev za analizu, CoA i *batch release* sertifikatu treba da imaju istu veličinu serije;
4. Dostavi i placebo za analizirani uzorak kao i odgovarajuću dokumentacija za placebo;
5. Dostaviti nekorišćen referentni standard i dokaz da je ispoštovan hladni lanac po potrebi;
6. Kvalitet papira za štampanje uputstava za lek mora biti 50 g/m^2 ± 2% (GMP smernice);
7. Ukoliko se dostavljaju dodatni uzorci na zahtev ALIMS mora se korigovati veličina serije na Zahtevu za analizu, CoA i batch release sertifikatu.

Količine uzoraka lekova za laboratorijsku kontrolu koje dostavlja klijent date su na sajtu ALIMS. Veličina i dostavljanje uzorka imunoloških lekova (vakcine, serumi, toksini, alergeni) nije predmet ovog sažetka.

Literatura

1. https://www.alims.gov.rs/wp-content/uploads/2022/02/p-kontrola-64-2011-1.pdf
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