STOCK PRODUCTION OF INTRAVITREAL SYRINGES OF BEVACIZUMAB, RANIBIZUMAB AND AFLIBERCEPT

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What was done?

We established a production process to repackage intravitreal anti-vascular endothelial growth factor (anti-VEGF) drugs, specifically bevacizumab, ranibizumab, and aflibercept, for use in ophthalmic treatments such as age-related macular degeneration (AMD), retinal vein occlusion (RVO), and diabetic macular edema (DME).

Why was it done?

To optimize preparation and ensure efficient use of vials.

We implemented a system to repackage pre-filled syringes, taking advantage of the drugs\' physico-chemical stability for up to 28 days.

This centralized process, handled by the hospital pharmacy, follows Good Manufacturing Practices (GMP) for sterile medicines, ensuring quality and efficiency.

How was it done?

The preparation process for intravitreal injections was reviewed to improve batch traceability.

A literature review was conducted on the physicochemical and microbiological stability of bevacizumab, ranibizumab, and aflibercept.

Based on the GMP risk matrix, intravitreal injections were classified as high-risk.

Batch preparation protocols were developed for these three drugs, and microbiological control measures were put in place to ensure aseptic handling and product quality.

All processes were validated according to regulatory standards, including environmental, instrumental, and maintenance controls.

What has been achieved?

By standardizing batch protocols for bevacizumab, ranibizumab, and aflibercept, we have significantly reduced the weekly workload and optimized the use of anti-VEGF vials.

We strictly follow national guidelines for validating aseptic techniques in intravitreal preparation and have thoroughly trained our technical staff.

What next?

This practice is recommended for broader implementation in hospital settings, as it provides significant cost savings while maintaining high-quality and safe treatments for patients.

Looking forward, we aim to expand this approach to include emerging therapies such as faricimab, ensuring that our repackaging protocols can adapt to new treatments as they become available, maintaining both efficiency and patient safety in line with evolving clinical practices.

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