

Summary - Calculations of Residue Limits for Drug Product for Equipment Cleaning

This guideline provides equations and examples for calculating the Maximum Allowable Residue (MAR), and Residue Acceptability Limits (RAL) for Drug Products and Non-Therapeutics.

Examples are provided for determining the acceptable equipment cleaning residue limits for therapeutic drug products (MAR_T and RAL_T) and for non-therapeutic ingredients (MAR_N and RAL_N). For the therapeutic drug products both single product combination (Product A to B) and multiple products combination examples are given.

The attached Appendices give equations and example calculations for therapeutic drug product cleaning limits for a solid oral dosage form (tablet), creams/ointment and ophthalmic product. In Case-1 therapeutic example it is included the calculation of Maximum Allowable Residue (MAR) limits using two formulas; dose MAR_T and toxicity MAR. It also includes an example for determining the worst case limit for shared equipment using multiple products. Example for residue limits calculation of CIP® 100 detergent, a non-therapeutic ingredient is also given.

[Read More](#)