

Epidemiologic cutoff values, abbreviated ECV (CLSI) or ECOFF (Eucast) , are measures of a drug MIC distribution that separate bacterial populations into those representative of a wild type population, and those with acquired or mutational resistance to the drug.

A **breakpoint** is a chosen concentration (mg/L) of an **antibiotic** which defines whether a species of bacteria is susceptible or resistant to the **antibiotic**. If the MIC is less than or equal to the susceptibility **breakpoint** the bacteria is considered susceptible to the **antibiotic**.

Breakpoints are used to predict whether an AM product will be clinically effective against a particular bacteria isolate. **They are based on a combination of MIC values, pharmacokinetic/pharmacodynamic values, and clinical outcome data.**

When the only piece of data available is the MIC distribution, a breakpoint cannot be determined and an ECV is the only available tool that may provide some guidance for treatment

An ECV is not a predictor of clinical success. The usefulness of an ECV lies in its ability to predict for an isolate possible resistance to an AM product that has known activity against the species but for which there are not enough data to establish breakpoints.

A breakpoint, by definition, is a predictor of the clinical success of a particular AM/ Bacteria combination. In creating a breakpoint, the MIC distribution and the PK/PD data of the product in play are important, but perhaps most critical is the addition of outcome data, especially from a clinical trial. The outcome for a patient treated with a given AM is compared to the PK/PD values of the product, the MIC of the isolate, and any known resistance mechanisms that are present..