

GUIDELINES ON REGISTRATION REQUIREMENTS TO ESTABLISH INTERCHANGEABILITY (TRS 1052 – Annex 8)

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Overview

This document provides recommendations for authorities on defining requirements for the approval of generic (multisource) pharmaceutical products in their respective countries. These guidelines establish criteria to ensure the interchangeability of these products while maintaining their safety, quality, and efficacy.

Specifically, the document details methods for categorizing and assessing these products to confirm interchangeability, requiring that the product be therapeutically equivalent to the (innovative product) comparator. This serves as a guide to facilitate product matching and allow interchangeability.

Link to Document

[TRS 1052 - ANNEX 8: MULTISOURCE \(GENERIC\) PHARMACEUTICAL PRODUCTS: GUIDELINES ON REGISTRATION REQUIREMENTS TO ESTABLISH INTERCHANGEABILITY](#)