Annex III

Conditions for lifting the suspension of the marketing authorisation(s)

Conditions for lifting the suspension of the marketing authorisation(s)

The National Competent Authorities, coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the marketing authorisation holders:

Bioequivalence between the generic medicinal product and the reference medicinal product shall be demonstrated for all criteria (90% confidence interval: 80.00 – 125.00% for AUC0-t and C_{max}; comparable median (≤ 20% difference, 80.00–125.00%) and range for T_{max}), in line with the guidance.