**INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE**

# Explanatory Memorandum

EDQM Terminologies for Dose Forms and Routes of Administration as Part of ISO/IDMP Standards for ICH Use in Individual Case Safety Reports Created in E2B(R3) Format

## *Step 5* Release E2B(R3)

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The purpose of this explanatory memorandum is to document the decision of the ICH E2B EWG/IWG to use Dose Forms (DF) and Routes of Administration (RoA) specified in ISO standard 11239:2012[1], as used in electronic exchange of Individual Case Safety Reports according to the ICH E2B(R3) Implementation Guide. ICH and the E2B(R3) IWG/EWG prefer to use established Standards Development Organizations to provide most terminologies and code lists for use in conjunction with ICH work products. Standard Terms for DF and RoA used by ICH in E2B(R3) messages will be excerpted from those published by the European Directorate for the Quality of Medicines and Healthcare (EDQM). These terms will be periodically published by ICH on the ESTRI website. Maintenance will be per EDQM established process, with needed change requests submitted to EDQM by ICH regulators. The ICH excerpt will be in the English language only. Consult the ESTRI website and each regulatory authority for additional details.

[1] ISO 11239:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging



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