

Release notes for version 8.2 of the EU eCTD M1 Validation Criteria (minor update)

June 2025

Comparison of the new minor version (8.2) with the current version (8.1)

Criterion number in 8.1	Criterion number in 8.2	Change
14.BP5, 14.BP7	14.BP5, 14.BP7	Clarifications added for Super-grouping
15.11, 15.12	15.11, 15.12	added clarification that the tracking table is not needed to EDQM Submissions
16.6	16.6	Added more details on how to identify electronic application forms created with the PLM Portal and the ones created with the interactive PDF
-	16.7	New rule to check there are no attachments in the interactive pdf eAF