Residual Solvents

Ph. Eur. General Texts 5.4; USP-NF General Chapter ⟨467⟩; JP General Tests 2.46, ICH Guideline Q3C (R8)
MEGGLE Product:
Co-processed Excipient: CombiLac®

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing
- 70 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP),
- 20 % Microcrystalline Cellulose (Ph. Eur. / USP-NF / JP) and
- 10 % Maize Starch (Ph. Eur. / USP-NF / JP) and

Starting material Lactose Monohydrate (Ph. Eur. / USP-NF / JP):
Raw materials, manufacturing process and product do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

Starting material Microcrystalline Cellulose (Ph. Eur. / USP-NF / JP):
According to the confirmation of the supplier, raw materials, manufacturing process and product do not contain Organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

Starting material Maize Starch (Ph. Eur. / USP-NF / JP):
According to the confirmation of the supplier, organic solvents listed as class 1, 2, 3 solvents in the mentioned documents are not used in the manufacturing process. The product may contain traces (i.e.: < 20 ppm). of class 3 solvent acetic acid.

CombiLac®:
In the manufacturing process (spray-drying of suspension), only demineralised water is used.

Organic solvents listed as Class 1, Class 2 or Class 3 solvents or any other solvents are not used.

Due to starting material Maize Starch (Ph. Eur. / USP-NF / JP): As mentioned above, the only class 3 solvent likely to be present is acetic acid. The total amount of acetic acid is typically < 2 ppm and does not exceed the 5000 ppm Option 1 limit.

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