Residual Solvents

ICH Guideline Q3C (R9) / Ph. Eur. General Texts 5.4 / USP-NF General Chapter ⟨467⟩ / JP General Tests 2.46
MEGGLE Product:
Co-processed Excipient: Cellactose® 80

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing
- 75 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and
- 25 % Cellulose, Powdered (Ph. Eur. / USP-NF / JP).

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 Cellulose, Powdered (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.

Product Cellactose® 80:
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 and are therefore “not likely to be present”.

This MEGGLE Information was electronically released and is valid without signature.

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