



To whom it may concern

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Quality Unit

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Residual Solvents

**Ph. Eur. General Texts 5.4; USP-NF General Chapter <467>; JP General Tests 2.26
ICH Guideline Q3C (R8)
MEGGLE Product: Cellactose® 80**

The product is a co-processed, directly compressible spray agglomerate comprising 75 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and 25 % Cellulose Powder (Ph. Eur. / USP-NF / JP). The monographs have undergone pharmacopoeial harmonisation.

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 Powder (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.

Cellactose® 80:

In the manufacturing process (spray-drying of suspension), only demineralized 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".

Best regards

MEGGLE GmbH & Co. KG

A handwritten signature in purple ink that reads "i. V. Stefan Dreiheller".

Dr. Stefan Dreiheller

Regulatory Affairs / Specification Management