



To whom it may concern

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Date of issue: 01.07.2020
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Doc.-No. EIP-2014
Revision 8

Residual Solvents

ICH Q3C (R7) (EMA/CHMP/ICH/82260/2006); Ph. Eur. Chapter 5.4; USP-NF Chapter <467>; JP XVII
Chapter 2.46; EMEA/CVMP/423/01-Final

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


Dr. Stefan Dreiheller