



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 23.07.2021
Page 1/1
Doc.-No. EIP-6014
Revision 8

Residual Solvents

ICH Q3C (R8) (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: CombiLac®

The product is a co-processed, directly compressible spray agglomerate comprising 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). 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 Microcrystalline (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 of class 3 solvent is acetic acid (i.e.: < 20 ppm).

CombiLac®:

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.

Due to starting material Maize Starch Ph. Eur. / USP-NF: 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.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller