



To whom it may concern

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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: RetaLac®

RetaLac® is a co-processed, directly compressible spray agglomerate comprising 50 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and 50 % Hypromellose (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 Hypromellose (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 2 solvent methanol (i.e.: < 100 ppm).

RetaLac®:

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 Hypromellose Ph. Eur. / USP-NF / JP: As mentioned above, the only class 2 solvent likely to be present is methanol. The total amount of methanol is typically < 50 ppm and does not exceed the 3000 ppm Option 1 limit.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller