

INFORMATION

Quality / Regulatory Affairs



EIP-5014

Revision 13

Date of issue: 12.09.2023

1/1

Residual Solvents

Ph. Eur. General Texts 5.4; USP-NF General Chapter <467>; JP General Tests 2.46, ICH Guideline Q3C (R8)

MEGGLE Product:

Co-processed Excipient: RetaLac®

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing

- 50 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and

- 50 % Hypromellose (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 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 (i.e.: < 100 ppm) of class 2 solvent methanol.

RetaLac®:

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.

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 acetic acid is typically < 50 ppm and does not exceed the 3000 ppm Option 1 limit.

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