

INFORMATION

Quality / Regulatory Affairs



EIP-3014

Revision 15

Date of issue: 22.05.2025

1/1

Residual Solvents

ICH Guideline Q3C (R9) / Ph. Eur. General Texts 5.4 / USP-NF General Chapter (467) / JP General Tests 2.46

MEGGLE Product:

Co-processed Excipient: MicroceLac® 100

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

- 75 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and

- 25 % Microcrystalline Cellulose (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 Microcrystalline Cellulose (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.

Product MicroceLac® 100:

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 and are therefore "not likely to be present".

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