



To whom it may concern

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Date of issue: 02.02.2021
Page 1/1
Doc.-No. EIP-7066
Revision 2

Ph. Eur., General texts 5.1.7., Viral safety

MEGGLE Product: Reta M®

The product is a co-processed, directly compressible spray agglomerate comprising

- 50 % Mannitol (Ph. Eur. / USP-NF / JP) and
- 50 parts Hypromellose (Ph. Eur. / USP-NF / JP).

The necessity of virus validation studies is defined in Note for Guidance CPMP/BWP/268/95 and included the following products:

- products derived from in vitro cell lines of human and animal origin,
- products derived from in vivo culture of cell lines or from organs or tissues of human or animal origin,
- products derived from blood or urine or other biological fluids of human or animal origin.

The product is derived from material of vegetable origin.

Best regards

MEGGLE GmbH & Co. KG

represented by MEGGLE Verwaltungs GmbH


Dr. Stefan Dreiheller