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> **Outcome Details**

Outcome Details

Variation type IA
Reference: EMA/VR/0000244623

Outcome Details

Opinion outcome

Positive

Approved Scope

B.III.2.b – Change in the specifications for the pharmacopeial grade excipients used in the manufacturing of Grasustek, to remove the copies of the current version of Standard Analytical

Refused Scope

—

Annexed document

No

Annex A

☒ No ☐ Yes

Annex I

☒ No ☐ Yes

Precise scope (case)

—

Annex II

☒ No ☐ Yes

Grounds for refusal

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Annex IIIA

☒ No ☐ Yes

Annex IIIB

☒ No ☐ Yes

Scopes (Case)

Search



Scope (validation) ↑	Scope (outcome)	Scope outcome
B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	Accepted

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