

3.2.P.4. Control of Excipients [{Drug Product Name}, {Dosage Form}]

4. JUSTIFICATION OF SPECIFICATIONS [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Justification for the proposed non-compendial excipient specifications should be provided, where appropriate. Often manufacturer and/or vendor CoAs are submitted with this section.

Reference ICH guidances Q3C and Q6B.