

MGF-400105
Bemotrizinol (BEMT)

3.2.S.2.6 Manufacturing Process Development

Batches of Bemotrizinol as described in Module 3.2.S were manufactured at production scale and were used to generate clinical and nonclinical safety data as described in Module 3.2.P for drug products, Module 4, and Module 5.

The sunscreen active is being used outside the USA since 2005 under the tradename Tinosorb[®] S (originally CIBA) and since 2014 under the tradename PARSOL[®] Shield from DSM globally. With reference to the ICH M4 Quality guideline, no significant changes have been made to the manufacturing process and the manufacturing sites of the drug substance being used as described above.

[Section 3.2.S.4.4](#) provides additional evidence that both commercial production processes for Tinosorb[®] S and PARSOL[®] Shield are resulting in equivalent quality including the respective impurity profiles as required by ICH Q3A.