

## PRODUCT SUBMISSION FORM

Submission Date: 27/01/2023 Scientist Name: Tarang Kaneria

Journal Date: 21/01/2023 Team Leader Name: Tarang Kaneria

Chemist:

Catelogue No. : SZ-F005010

Project Name : Formoterol

Formoterol Fumarate

**Product Name :** Dihydrate EP Impurity I (R,S-

isomer) ((R,S)-Formoterol)

**CAS No.:** 67346-51-4

Mole. Weight: 344.4

Mole. Formula: C19H24N2O4

Batch Code: TEST-004 Quantity Submitted: 9630

Ref. 1H/HPLC/MS Code : 1H Status : SER Pending

**HPLC/GC/ELSD Date**: 26/01/2023 **Chromatography**: 798465 %

MS Analysis: APCI Type Of Compound: Impurity

State Of Compound: Pink If Salt Mention the Name: Salt

No Of Steps of Final Route: 6 Earlier Synthesized: Yes

Temp Sensitive

IR, Mass, HPLC/GC/ELSD, NM

Additional Analysis: R,APCI Mass,NMR Remark: ,

Interpretaion

Stability Related Comment : Stability :

Physical State: Sticky Solid

Stability data in solution form after 7 days: Unstable

Stability data in solid form after 7 days : Stable

Any of last 3 step NMR done?: No

Any of last 2 step crystallization done? : No

Purification By: Trituration