

PRODUCT SUBMISSION FORM

SER Pending

Impurity

Submission Date: 07/02/2023 **Scientist Name:** Tarang Kaneria

Journal Date: 25/02/2023 **Team Leader Name:** Tarang Kaneria

Chemist:

SZ-F005010 Catelogue No.:

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

Ref. 1H/HPLC/MS Code:

MS Analysis:

Mole. Formula: C19H24N2O4

Quantity Submitted: Batch Code: **TEST-009** 7788

HPLC/GC/ELSD Date: 465312 % 28/02/2023

1H Status:

Type Of Compound:

Chromatography:

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

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

IR, Mass, HPLC/GC/ELSD, NM

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

Interpretaion

APCI

Stability Related Comment: Stability:

Physical State: Semi Solid

Stability data in solution form after 7 days : Stable

Stability data in solid form after 7 days: Unstable

Any of last 3 step NMR done?: No

Any of last 2 step crystallization done? : No

Purification By: Precipitation