

PRODUCT SUBMISSION FORM

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

Journal Date: 25/02/2023 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-00010 Quantity Submitted: 10000

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

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

MS Analysis: APCI Type Of Compound: Impurity

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

No Of Steps of Final Route: 2 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 : Unstable

Any of last 3 step NMR done ?: No

Any of last 2 step crystallization done? : No

Purification By: Preparative HPLC