

Celecoxib EP10.0

Batch no Mf date

111-20220507M

Retest

May 05 2022 May 04 2026

Molecular Structure

Molecular Formula $C_{17}H_{14}F_3N_3O_2S$

Molecular Weight 381.4

CAS Registry Number 169590-42-5

Nov 28 2022

<u>Tests</u>	Specifications		Results
Appearance	White or almost white crystalline or amorphous powder		White crystalline powder
Solubility	Practically insoluble in wate soluble in anhydrous ethanol soluble in methylene chlorid It shows polymorphism		Conforms
Identification	IR		Positive
Melting point	160 ~ 164°C		161 ~ 162°C
Related substances	Impurity A	≤ 0.4%	< 0.03%
	Impurity B	≤ 0.1%	< 0.03%
	Impurity C	≤ 0.1%	< 0.03%
	Impurity D	≤ 2.5 ppm	ND
	Impurity E	≤ 2.5 ppm	ND
	Impurity F	≤ 0.1%	< 0.03%
	Sum of impurity D & E	≤ 2.5 ppm	ND
	Max individual unknown impuri	ty ≤ 0.1%	< 0.03%
	Total impurities	≤ 0.5%	0.0%
Water	≤ 0.5%		0.0%
Sulfated ash	≤ 0.2%		0.0%
Residual solvents	Ethanol ≤ 5000 ppm		41 ppm
	Toluene ≤ 890 ppm .		4 ppm
	· Benzene ≤ 2 ppm		ND
Assay	98.0 ~ 102.0%		99.5%



