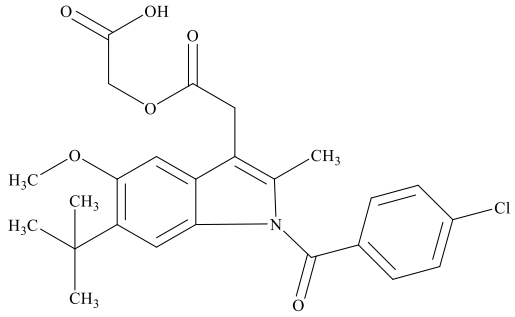


Certificate of Analysis

Certificate No.: 20200709007

Date: July 9, 2020

Retest date: July 6, 2023

Compound Name:	Acemetacin EP Impurity D	
Synonyms:	2-(2-(6-(<i>tert</i> -butyl)-1-(4-chlorobenzoyl)-5-methoxy-2-methyl-1 <i>H</i> -indol-3-yl)acetoxy)acetic acid	
TLC Catalogue Number:	A-445	
CAS Number:	76812-64-1	
Molecular Weight:	471.93	
Molecular Formula:	C ₂₅ H ₂₆ ClNO ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3905-095A2	
Storage Conditions:	Store at 2-8 °C	
Solubility:	DMSO, Acetonitrile	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.0%
Impurity (HPLC)	RT 5.58, 0.96%	
Water Content (KF)	N/A	1.6%
Residual Solvents (NMR)	0.4% <i>n</i> -hexane and 0.4% ethyl acetate	
Assay (%)	Not less than 90.0%	96.6%
Recommendation:	Released. The compound contains 1.0% Acemetacin Impurity 7 (RT 5.58, TLC No. A-4414) according to HPLC. The compound is unstable in methanol.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.