

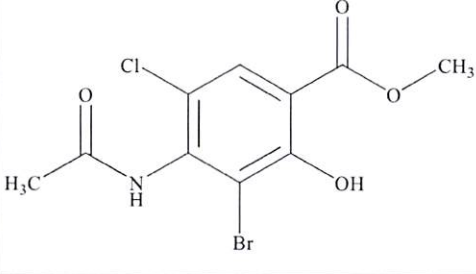


Certificate of Analysis



Certificate No.: 20240528501

Date: May 28, 2024

Retest date: May 24, 2027

Compound Name:	Prucalopride Impurity 38	
Synonyms:	Methyl 4-acetamido-3-bromo-5-chloro-2-hydroxybenzoate	
TLC Catalogue Number:	P-127044	
CAS Number:	232941-14-9	
Molecular Weight:	322.54	
Molecular Formula:	C ₁₀ H ₉ BrClNO ₄	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4910-019A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF, Acetonitrile	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.1%
Impurity (HPLC)	RT 16.64, 0.88%	
Water Content (KF)	N/A	0.1%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/29/2024
Approved by:	Quality Assurance		05/29/2024

Attachments: HPLC, IR, MS and NMR spectra.