

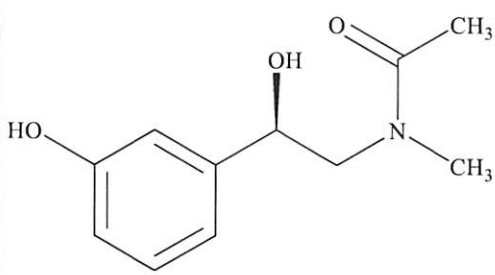
Certificate of Analysis

Certificate No.: 20241211505

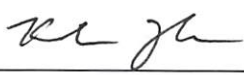

Date: December 11, 2024

Retest date: December 9, 2027

Compound Name: Phenylephrine Impurity 48 (<i>N</i> -Acetyl Phenylephrine)	
Synonyms:	(<i>R</i>)- <i>N</i> -(2-hydroxy-2-(3-hydroxyphenyl)ethyl)- <i>N</i> -methylacetamide
TLC Catalogue Number:	P-2629
CAS Number:	58952-80-0
Molecular Weight:	209.25
Molecular Formula:	C ₁₁ H ₁₅ NO ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3782-056A2
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Water



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
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.3%
Optical Rotation	N/A	[α] _D ^{20.0} (c=0.54, CH ₃ OH): -15.6°
Residual Solvents (NMR)	0.2% methanol	
Assay (%)	Not less than 90.0%	99.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12/12/2024
Approved by:	Quality Assurance		12/12/2024

Attachments: HPLC, IR, MS and NMR spectra.