

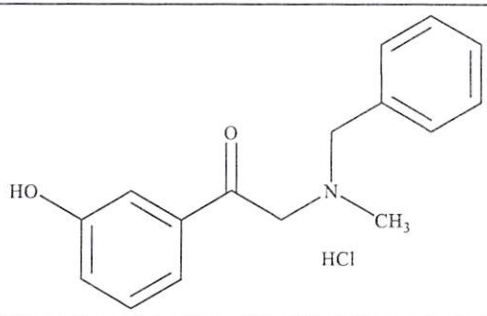
## Certificate of Analysis

Certificate No.: 20250129505


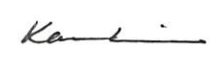
Date: January 29, 2025

Retest date: January 27, 2028

<b>Compound Name:</b> Phenylephrine EP Impurity E HCl (Phenylephrine USP Related Compound E)	
<b>Synonyms:</b>	2-(benzyl(methyl)amino)-1-(3-hydroxyphenyl)ethan-1-one, hydrochloride (1:1)
<b>TLC Catalogue Number:</b>	P-264
<b>CAS Number:</b>	71786-67-9
<b>Molecular Weight:</b>	255.32 36.46
<b>Molecular Formula:</b>	C <sub>16</sub> H <sub>17</sub> NO <sub>2</sub> . HCl
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	1292-017A1
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO



Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.1%</b>
<b>Impurity (HPLC)</b>	RT 1.28, 0.14%; RT 11.15, 0.20%; RT 13.85, 0.31%	
<b>Water Content (KF)</b>	N/A	<b>0.1%</b>
<b>Residual Solvents (NMR)</b>	0.1% acetone and 0.1% acetic acid	
<b>Assay (%)</b>	Not less than 90.0%	<b>98.8%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/29/2025
Approved by:	Quality Assurance		01/29/2025

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.