

**Analysis Date:** 18-09-2025

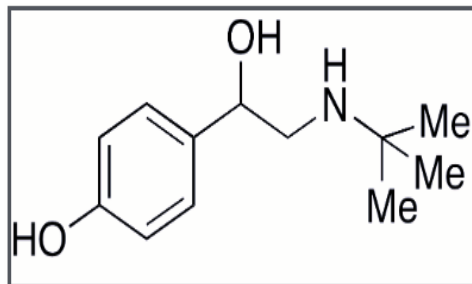
**Re-test Date:** 18-09-2028

**SALBUTAMOL EP IMPURITY B**
**Identification**
**Chemical Name** : 4-(2-(tert-butylamino)-1-hydroxyethyl)phenol

**CAT No** : ALL-S03604

**CAS No** : 96948-64-0

**Molecular Formula** : C<sub>13</sub>H<sub>21</sub>NO<sub>3</sub> : HCl

**Molecular Weight** : 209.3

**Analytical Information**

<b>Batch Code</b>	: ALL-S03604	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 96.49%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.704%	<b><sup>1</sup>H NMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.801%		

**Additional Information**

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (0.704+0.801) × 98.00]/100 = 96.49%

**Recommendation** : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

**Attachment** : HPLC, Mass, 1H NMR, IR, TGA

**Shipping Condition** : All Product are stable to be shipped at room temperature, unless otherwise specified

**Corporate Office**