

Epinephrine bitartrate

Synonym	Adrenalin bitartrate, Epinephrin-/Adrenalin hydrogentartrate / (2R,3R)-2,3-dihydroxybutanedioic acid / 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]benzene-1,2-diol				
CAS. No.	51-42-3				
Quality	EP / USP				
CMO / Manufacturer	SYN-TECH CHEM. & PHARM. CO. LTD., No. 168 Kai Yuan Rd., Hsin Ying Tainan City 73055, Taiwan				
Pharmacological Group	Mydriatics / Adrenergic alpha & beta-agonists / Bronchodilator Agents / Sympathomimetics/ Vasoconstrictor Agents / dental anesthesia				
Application	Injection, solution				
Manufacturing / Extraction	<i>Synthetic</i>	<i>Semi-Synthetic</i>	<i>Fermentation</i>	<i>Extractive</i>	
	■	-	-	-	
Project status	<i>Lab</i>	<i>Up-Scale</i>	<i>Validation</i>	<i>Commercial</i>	
	-	-	-	■	
Regulatory documentation	<i>CEP</i>	<i>EU-AP (Open Part)</i>	<i>US-TDP</i>	<i>J-DMF</i>	<i>Other</i>
	■	■	■	-	-
Technical product specification	<i>Samples</i>	<i>Batch size</i>	<i>Retest Period</i>	<i>Stability Data</i>	<i>Packaging</i>
	■	50-55 kg	5 years	■	1 kg polybottle
	<i>Lead Time</i>		<i>Shipping & Storage Conditions</i>		<i>Other</i>
	1 week		no special		-
GMP status / Audit	<ul style="list-style-type: none"> • EU-GMP & local GMP • Third Party audit report available • US-FDA / EDQM / PMDA approved manufacturing site 				
Unique features	<ul style="list-style-type: none"> • Originators proces (BI) transferred 1:1 to Taiwan • Identical API with identical impurity profile • fully integrated process at Syn-Tech (including starting material & intermediate to the final API) 				
Other information	<ul style="list-style-type: none"> • comparison study (Boehringer Ingelheim / Syn-Tech) available on key intermediate and final API basis • worldwide approvals 				
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