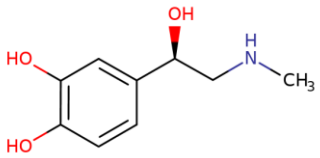
TRANSO-PHARM THE CONNECTING LINK

Revision No. 1.1 08/03/2021

Epinephrine Base

Synonym	Adrenaline / L-Adrenaline / (R)-1-(3,4-Dihydroxyphenyl)-2-(N-methylamino)ethanol
CAS. No.	51-43-4
Quality	EP / USP / JP
CMO / Manufacturer	SYN-TECH CHEM. & PHARM. CO. LTD, No. 168 Kai Yuan Rd, Hsin Ying Tainan City 73055, Taiwan
Pharmacologigal group	Catecholamines / andrenergic
Application	injection / auto-injector / inhaler / prefilled syringe / nasal spray / sublingual tablets



Manufacturing / Extraction	*Synthetic*	*Semi-Synthetic*	*Fermentation*	*Extractive*	
	■	–	–	–	
Project status	*Lab*	*Up-Scale*	*Validation*	*Commercial*	
	–	–	–	■	
Regulatory documentation	*CEP*	*EU-AP (Open Part)*	*US-TDP*	*J-DMF*	*Other*
	■	■	■	■	■
Technical product specification	*Samples*	*Batch size*	*Retest Period*	*Stability Data*	*Packaging*
	■	approx. 50-55 kg	5 years	■	100 g / 500 g
	Lead Time		*Shipping & Storage Conditions*		*Other*
	1 week		no special		–

GMP status / Audit	• EU-GMP & local GMP • third party audit available • US-FDA / EDQM / PMDA approved manufacturing site
Unique features	• Originators process (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	• comparison study (Boehringer/Syn-Tech) available • worldwide approvals
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