Epinephrine Base and Bitartarte

Impurity Profile

Process transfer from Boehringer to Transo-Pharm's CMO, Syn-Tech, guarantees same Impurity Profile

Comparison Study

Comparability study available; Boehringer versus Transo-Pharm Quality

Stability Study

Stability studies for smaller packing sizes running (100 g); EDQM granted re-test period of 5 years - US FDA accepted 4 years !

EDQM & FDA Approval

EDQM approved second starting material and Intermediate producer under the existing CEP (no CEP revision)

Enantiomeric Purity

Approximately 99%

Supply Continuity

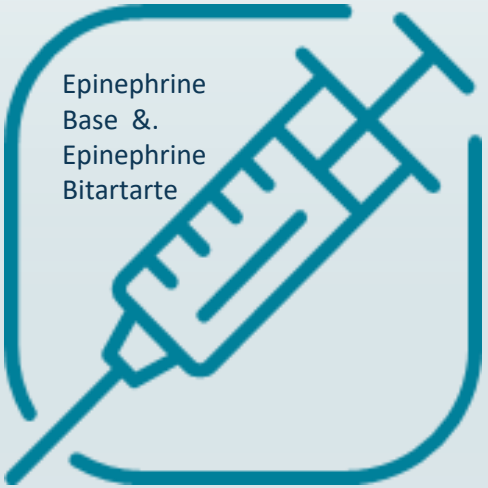
Safety stock for our customers available for APIs and key intermediate

Full Regulatory Support

State of the art documentation; additional testing parameters (Bioburden, Endotoxins);
Epinephrine Base conforms to current USP 43.1 monograph

Inspections / Audits

Manufacturing site FDA inspected; last FDA inspection on Epinephrine in March 19; TFDA performed GMP inspection in March 2018;
GMP certificate and WC available; Shared audit reports available (Concept Heidelberg / Intertek / blue inspection)



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