

PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride tablet

InvaTech Pharma Solutions LLC

Phenylephrine Hydrochloride

<u>PHENYLEPHRINE HYDROCHLORIDE TABLETS USP</u>		
<u>10 MG</u>		
Each film coated tablet contains: Phenylephrine hydrochloride USP 10 mg		
Batch No. :	Mfg. Date :	
Unit No. :	Exp. Date :	
NDC No. : 57631-018-00	Quantity :	
WARNING : KEEP OUT OF THE REACH OF CHILDREN		
Store At USP Controlled Room Temperature of 59° to 86° F (15° C to 30° C). Protect from Light, Moisture and Freezing.		HANDLE WITH CARE
This is a Bulk Shipment Intended for Further Processing Only. Contents Should Be Approved, Repackaged Immediately (9 Months From MFG. Date) and Labelled in strict conformance with The FD&C Act and Regulations Thereunder.		“S08” Debossed
Manufactured By: ELYSIUM PHARMACEUTICALS LIMITED At & Post – Dabhasa, Tal.: Padra, Dist.: Vadodara, Gujarat – 391440, INDIA Manufacturer Code No.: Guj/Drugs/G/25/2258 Labeler Code #14803		Manufactured For: InvaTech Pharma Solutions LLC 40 C Cotters Lane, Suite # A, East Brunswick, NJ 08816 PH # 732-307-7926 FAX # 732-307-7931
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”		
CAUTION : “REMOVE SILICA GEL BAG BEFORE USE”		
QJAD1021928-00		

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57631-018
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	S08	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57631-018-00	30000 in 1 DRUM; Type 0: Not a Combination Product	01/13/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	01/13/2021		

Labeler - InvaTech Pharma Solutions LLC (078602180)

Establishment			
Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		915664486	manufacture(57631-018)