

ANALYTICAL SPECIFICATIONS

AMLODIPINE BESILATE, USP

(Cod.: 70450)

Doc.: ASP70450-01CAT

Revision:1

EFFECTIVE DATE: 21/04/2017

PREPARED BY:

REVIEWED BY:

APPROVED BY:

 21/04/2017
QC Documentation and LIMS

 21.04.17
QUALITY ASSURANCE

 21/04/17
TECHNICAL MANAGER

ANALYSIS

SPECIFICATIONS

CHARACTERS

Characters

Conforms to USP

IDENTIFICATION

IR Spectrum

Conforms to Std.

HPLC

Conforms to Std.

SPECIFIC TESTS

Water (KF)

Maximum 0,5%

Optical rotation

-0,10° to +0,10°

ORGANIC IMPURITIES

Related Substances (HPLC)

Imp.D (Ph.Eur.) = Imp.A (USP)

Maximum 0,30%

Impurity A (Ph.Eur.)

Maximum 0,15%

Impurity E (Ph.Eur.)

Maximum 0,15%

Imp.F (Ph.Eur.) (Dimethyl com)

Maximum 0,15%

Impurity B (Ph.Eur.)

Maximum 0,10%

Imp.G (Ph.Eur.) (Dicrotonate)

Maximum 0,10%

Unspecified impurities (biggest)

Maximum 0,10%

Total impurities

Maximum 0,50%

INORGANIC IMPURITIES

Heavy Metals

Maximum 10 ppm

Residue on ignition

Maximum 0,2%

ASSAY

Assay (HPLC) on anhydrous subs.

97,0% to 102,0%

ADDITIONAL TESTS

Besilate counter-ion content

27,0% to 28,4%

RESIDUAL SOLVENTS

Isopropyl alcohol

Maximum 500 ppm

Acetone

Maximum 500 ppm

Ethyl acetate

Maximum 100 ppm

Class 3 solvents (LoD)

Maximum 0,5%

PLAN DE INSPECCIÓN

PRODUCTO

AMLODIPINE BESILATE, USPCODIGO PRODUCTO :
70450(01)CODIGO DOCUMENTO :
ASP70450-01CATFECHA EMISIÓN:
21/04/2017**HISTORICO**

Rev.	Fecha	Descripción
1	21/04/2017	Initial version in Starlims, from version 4 in dBase (Doc. 112-1BESD1 - 04/05/2010)