

Certificate of Analysis

Anastrozole API

Lot Number : 18BL000748
Item Number : 214236 Date of Manufacture : 18-Oct-2018
Retest Date : 18-Oct-2023
Manufacturing Site : Synthon, s.r.o.

Tests	Results	Acceptance Criteria
Appearance	Complies	White or almost white powder
Identification		
IR spectrum	Complies	The same as Ref. Std.
Water content	0.0 %	≤ 0.3 %
Sulphated ash	0.0 %	≤ 0.1 %
Residual solvents (GC)		
Methanol	≤ 0.030 %	≤ 0.3 %
Impurities (HPLC)		
Largest unspecified impurity	≤ 0.05 %	≤ 0.10 %
Total impurities	≤ 0.05 %	≤ 0.2 %
Assay (anhydrous basis, HPLC)	99.7 %	98.0 - 102.0 %
Residual solvents GC (Not routinely carried out. 1 out of 10 batches, but at least 1 yearly unless no batches are produced)		
Benzene	≤ 0.00006 %	if tested: ≤ 0.0002 %

This batch complies with the specification set in CASS.NUS.61317 (1.0).

Issued by : Michaela Matejková
QA manager

Date of Issue : 18/Nov/2020
This is an electronic signature