

**BISACODYL USP - EP (micronized 50 microns)**

CAS N. 603-50-9

CODE 650M50

BATCH A170002

MAN. DATE 03/2017

RETEST DATE 03/2023

TEST FOR	SPECIFICATIONS	RESULTS
Description	white or almost white crystalline powder	Complies
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
Loss on drying	≤ 0.5 %	0.01
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.00
Heavy metals	NMT 10 ppm	Complies
Acidity or alkalinity	according to EP	Complies
Assay (volumetric, on dried basis)	≥ 98.0 ≤ 101.0 %	100.5
Related substances / Organic impurities (HPLC)		
· A) 4,4'-(pyridin-2-ylmethylene)diphenol (4,4'-Diphenol impurity)	≤ 0.1 % (USP spec.: NMT 0.15%)	Non quantifiable
· B) 2-[(RS)-(4-hydroxyphenyl)(pyridin-2-yl)methyl]phenol (2,4'-Diphenol impurity)	≤ 0.1 % (USP spec.: NMT 0.15%)	Non quantifiable
· C) 4-[(RS)-(4-hydroxyphenyl)(pyridin-2-yl)methyl]phenyl acetate (Monoacetyl Bisacodyl)	≤ 0.2 % (USP spec.: NMT 0.50%, EP spec.: NMT 0.5%)	Non quantifiable
· D) impurity at RRT ~ 0.8 (USP specified unidentified impurity 1)	≤ 0.20 % (EP spec.: NMT 0.2%)	Non quantifiable
· E) 2-[(RS)-[4-(acetyloxy)phenyl](pyridin-2-yl)methyl]phenyl acetate (2,4'-Bisacodyl analog)	≤ 0.50 % (EP spec.: NMT 0.5%)	Non quantifiable
· F) impurity at RRT ~ 2.6 (USP specified unidentified impurity 2)	≤ 0.1 % (USP spec.: NMT 0.30%, EP spec.: NMT 0.3%)	Non quantifiable
· any other impurity	NMT 0.10%	Complies
· total	≤ 0.8 % (USP - EP spec.: NMT 1.0 %)	Non quantifiable
Additional specifications		
Residual solvents (GC)		
· acetone	≤ 2000 ppm	706
Particle size (laser diffraction)		
· D(0,9)	≤ 50 µm	20.6

OBSERVATIONS:

Copies of this CoA are not valid

APPROVED

on Feb 21, 2018

QUALITY CONTROL

Dr. R. Roti

Apr 04, 2018