

ANALYSIS CERTIFICATE

CODE: 142050

BATCH: 0002670442

PRODUCT: Tween ® 80 (USP-NF, BP, Ph. Eur.) pharma grade, BioChemica

ISSUE DATE: 12/03/2025

RETEST DATE: 03/2031

SPECIFICATIONS

Identity according to Pharmacopoeias:

Density 25/25

Viscosity 25°C

Maximum limit of impurities

Residue on ignition (as SO₄)

Acidity value

Hydroxyl value

Iodine value

Peroxide value

Saponification value

Composition of fatty acids:

Total ashes

Residual solvents (Ph.Eur/USP)

Myristic acid

Palmitic Acid

Palmitoleic acid

Stearic acid

Oleic acid

Linoleic acid

Linolenic acid

Dioxan

Ethylene Oxide

Reducing impurities

Water (H₂O)

Heavy metals (as Pb)

Elemental impurities (ICH Q3D):

Class 1

Cd

Pb

As

Hg

Class 2A

Co

V

Ni

Class 2B

Tl

Au

Pd

Ir

Os

Rh

Ru

Se

Ag

Pt

Class 3

Li

Sb

Ba

Mo

Cu

Sn

Cr

GUARANTEE VALUE

passes test

1.06-1.09

300-500 cSt

0,2 %

2,0

65-80

18-24

10,0

45-55

0,25%

passes test

5,0 %

16,0 %

8,0 %

6,0 %

58,0 - 85,0 %

18,0 %

4,0 %

0,001%

0,0001%

passes test

3,0 %

0,001%

0,5 ppm

0,5 ppm

1,5 ppm

1,5 ppm

5 ppm

10 ppm

20 ppm

5 ppm

10 ppm

10 ppm

10 ppm

10 ppm

10 ppm

10 ppm

15 ppm

15 ppm

10 ppm

55 ppm

120 ppm

140 ppm

25 ppm

250 ppm

600 ppm

25 ppm

ACTUAL VALUE

passes test

1,06

437 cSt

0,2 %

0,6

75

19

0,0

48

0,18%

passes test

0,4 %

5,1 %

0,1 %

1,8 %

79,6 %

<18,0 %

2,8 %

<0,001%

<0,0001%

passes test

2,6 %

<0,001%

<0,5 ppm

<0,5 ppm

<1,5 ppm

<1,5 ppm

<5 ppm

<10 ppm

<20 ppm

<5 ppm

<10 ppm

<10 ppm

<10 ppm

<10 ppm

<10 ppm

<10 ppm

<15 ppm

<15 ppm

<10 ppm

<55 ppm

<120 ppm

<140 ppm

<25 ppm

<250 ppm

<600 ppm

<25 ppm



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

12 MAY 2025

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