

**PRODUCT CODE: 142060****Gelatine 80-100 Blooms (USP-NF, BP, Ph. Eur.) pure, pharma grade**

CAS [9000-70-8]

EINECS 232-554-6

TARIC 3503 00 10 00

PHYSICAL DATA: powder, Small granules, Yellowish, Slightly soluble in cold water. Soluble in hot water. pH(1% sol.) 3,8 - 7,6 •

BIBLIOGRAPHY: Merck Index **14**, BP.**2018** • USP -**NF 36** • Ph. Eur. **8.0** (2014) **9.0** (2017) 6.3 • F.C.C **10 11** • Royal Decree I1017 • BOE **667527**(17-3-84) • AFNOR NF U59-001 •

HAZARDOUS: RTECS: LX 8580000 •

SPECIFICATIONS:

Identity :

Identity according to Pharmacopoeias:

pH sol. 1% at 55°C

passes test

3,8-7,6

T.L.C. (phenolic preservatives)

passes test

Maximum limit of impurities

Appearance of solution

passes test

Loss on drying at 105°C

15,0%

Peroxides (as H₂O₂)

0,0010%

Conductivity sol. 1.0% at 30±1.0°C

1 mS/cm

Residual solvents (Ph.Eur/USP)

passes test

Sulfur dioxide

0,005%

Contamination Total combined yeast and moulds (TYMC)

100 cfu /g

Total aerobic microbial count (TAMC)	1000 cfu/g
Salmonella	absence/10g
Escherichia coli	absence/g
Cr	0,001 %
Fe	0,003 %
Zn	0,003 %
Elemental impurities (ICH Q3D):	
Class 1	
Cd	0,5 ppm
Pb	0,5 ppm
As	1,5 ppm
Hg	1,5 ppm
Class 2A	
Co	5 ppm
V	10 ppm
Ni	20 ppm
Class 2B	
Tl	0,8 ppm
Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Se	15 ppm
Ag	15 ppm
Pt	10 ppm
Class 3	
Li	55 ppm
Sb	120 ppm
Ba	140 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	10 ppm