## PRODUCT DATA SHEET

**Azepur99®**

**Azelaic acid, pharma grade**

**Supplier**
AZELAIC PRODUCTS B.V., THE NETHERLANDS

**Producer**
TYCHE INDUSTRIES LIMITED on behalf of AZELAIC PRODUCTS B.V.

**EU-GMP Certificate No.**
DE_BE_01_GMP_2016_002 ; 5373/1-TYCHe/1

**Chemical description**
1,7-heptanedicarboxylic acid

**INCI name**
Azelaic acid

**CAS no.**
123-99-9

**EINECS no.**
204-669-1

**Reach no.**
01-2119557891-28-0001

### S.No. Item Specification Test Method
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1 Description White to off-white, odorless, crystalline powder visual
2 Identification Reference sample
3 Appearance of solution Clear and not more intensely coloured than ref. solution
4 Loss on drying, % w/w Max. 0,5 USP 731
at 60-65 °C under 600 mm Hg vacuum
5 Color and clarity solution
   transmission 440 nm Min. 90% IH
   transmission 550 nm Min. 98%
   1% w/v solution in methanol Should be clear IH
6 Residue on ignition, % w/w Max. 0,1 USP 281
7 Related substances (by GC)
   a) azelaic acid Min. 99,2 IH
   b) sebacic acid Max. 0,5 IH
   c) any unknown impurities, % Max. 0,1 IH
   d) total impurities Max. 0,8 IH
8 Assay by titration (on anhydrous basis) NLT 99.0 NMT 101.0 w/w
9 Residual solvents (by GC)
   a) methanol, ppm Max. 3000 IH
   b) ethyl acetate, ppm Max. 5000 IH
10 Particle size Min. 99.0 < 30 micron
11 Water content, % w/w Max. 0,5 IH
12 Melting range (°C) 103 - 110 IH
13 Heavy metals (ppm) less than 20 IH
14 Acid content (mgKOH/g) 585 - 610 IH
15 Microbial contamination
   - TAMC NMT 100 cfu/g
   - TYMNC NMT 10 cfu/g
   - Enterobacteria Absent/g
   - Pseudomonas Absent/g
   - Staphylococcus Absent/g
   - E.Coli Absent/g

**Shelf life time**
minimum 3 years, if stored properly.

**Version**
2018/01