

### Azepur99<sup>®</sup> 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
1	Description	White to off-white, odorless, crystalline powder	visual
2	Identification	Reference sample	
3	Appearance of solution	Clear and not more intensily coloured than ref. solution	
4	Loss on drying, % w/w at 60-65 °C under 600 mm Hg vacuum	Max. 0,5	USP 731
5	Color and clarity solution transmission 440 nm transmission 550 nm 1% w/v solution in methanol	Min. 90% Min. 98% Should be clear	IH
6	Residue on ignition, % w/w	Max. 0,1	USP 281
7	Related substances (by GC) a) azelaic acid b) sebacic acid c) any unknown impurities, % d) total impurities	Min. 99,2 Max. 0,5 Max. 0,1 Max. 0,8	IH IH IH IH
8	Assay by titration (on anhydrous basis)	NLT 99.0 NMT 101.0 w/w	
9	Residual solvents (by GC) a) methanol, ppm b) ethyl acetate, ppm	Max. 3000 Max. 5000	IH 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 TYMC Enterobacteria Pseudomonas Staphylococcus E.Coil	NMT 100 cfu/g NMT 10 cfu/g Absent/g Absent/g Absent/g Absent/g	IH

Shelf life time minimum 3 years, if stored properly.

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