TECHNICAL DATA SHEET

Product	**Annurtrofil® - Annurca apple fruit dry extract**
Botanical Name	*Malus pumila Miller cv Annurca*
CAS Number	-------
Product Code	SSDMPMAC0500900A Date 22/11/2023
Production Site	Italy
Extraction Solvent	Water
Excipients	Maltodextrin 30%
Auxiliary Substances	---
Particle size	>= 90% - goes through sieve nr.500 (sieve method Eur.Ph.)
Other information	Recommended dosage: 800 mg/die** - Control is made on raw material with following limits: <5ppb aflatoxine B1 <10ppb total aflatoxin (sum of B1,B2, G1 and G2) - Residual pesticides comply to Reg.(EC) No.396/2005 and subs. amendments and updates - product gluten free and not irradiated - Product does not contain and it is not manufactured from GMO components (EEC Reg. 1829/2003 and 1830/2003) - Storage in cool, dark and dry place The product complies to Reg.(EC) No. 1933/2015

TEST	LIMITS	METHODS
Characters	Brownish, brown-yellowish fine powder	Inspection
Identification	Positive (may be performed on the extract or on the half-processed product or on the drug)	TLC and/or botanical identification
Content	60-90 µg/g procyanidin B2	HPLC
	4000- 6000 µg/g total polyphenols exp. as gallic acid	Internal method
Composition	Dry Annurca apple extract powder 70%, Maltodextrin 30%	
Drug extract ratio (DER)	10:1 (indicative)	
Tapped Density	about 0.5 g/ml	
Loss on drying	<= 5%	105° C - 3 hours
Residual Solvents	---	Gas Chromatography
Heavy Metals	<= 10 ppm (Pb <3 ppm; Cd <1 ppm; Hg <0.1 ppm)	Atomic absorption
Antimicrobial Preservatives	Absent	
Microbial contamination		
Aerobic microrganism *	<= 10000 c.f.u./g	as per Eur.Ph
Moulds-Yeasts *	<= 100 c.f.u./g	as per Eur.Ph
Enterobacteriaceae	<= 100 c.f.u./g	as per Eur.Ph
E.Coli (1 g)	Absent	as per Eur.Ph
Salmonella (10g)	Absent	as per Eur.Ph
*	all indicated limits have to be interpreted as 5X according to Eur.Ph	
**	De Biasio, F., et al. 2023. Journal of Applied Cosmetology. 41,2. DOI: https://doi.org/10.56609/jac.v41i2.276.	

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