



PHARMAGAL spol.s r.o., Murgašova 5, Nitra, Slovak Republic

PROTOCOL ON CONTROL

CERTIFICATE

Product:	TYMPANOL emulsio a.u.v.	Batch size:	50 l
Batch:	50 01 21	Manufacture date:	01/2021
Examination according to:	ZAP-02-067/09-02	Expiry date:	01/2024
Destination country	Hungary, Republic of Latvia, Romania		

Parameter		Requirements	Results
Appearance		White to cream, easy-mixed emulsio.	complies
Identity of polydimethylsiloxan		Brown-purple colour is formed.	positive
Residue after drying (%)		7,65 – 9-35	7,96
Microbiological purity	TAMC (CFU/ml)	$\leq 10^2$	$< 10^2$
	TYMC (CFU/ml)	$\leq 10^1$	$< 10^1$
	E. coli (in 1 ml)	0	0
Extractable weight	25 ml	$25,0 \pm 2$	25
	50 ml	$50,0 \pm 2$	---
	500 ml	$500,0 \pm 10$	---

c o m p l i e s

PHARMAGAL s.r.o.
Murgašova 5
940 01 NITRA ④

Certification declaration:

This is to certify that the presented data are valid and precise. This batch was manufactured in the company PHARMAGAL, s.r.o. Nitra in accordance with the requirements of the GMP. The manufacturing process, as well as the relevant analyses are carried out in accordance with the GMP.

The Qualified Person responsible for batch release: PharmDr. Milan Dubaj

Deputy: Ing. Viera Zátoková

Person responsible for batch release	PharmDr. Milan Dubaj
Date and signature: 4.2 2021	