

CERTIFICATE OF COMPLIANCE

BATCH	E2001803	Article number	270001
Your reference		Sample code	2020060113
Product	TF765 x0.30 mm 3222 SETA TRANSFUFOL	Quality system	ISO13485
Compound	3222	Approval date	20200610

We confirm that batch E2001803 fulfills the agreed specification.

Test	Lower limit	Upper limit	Result	Unit
Acidity	-	1.5	PASS	ml NaOH
Alkalinity	-	1.0	PASS	ml HCl
Reducing substances	0.0	2.0	PASS	ml KMnO4
UV abs 220-340nm	0.00	0.20	PASS	abs
Aluminum	0.00	0.05	PASS	ppm
Calcium	0.0	2.0	PASS	ppm
Zinc	0.0	2.0	PASS	ppm
Cytotoxicity	0	2+	PASS	-
Physical tests			PASS	

Test methods:

Sample preparation chemical tests	European Pharmacopoeia 3.1.14. Solution S2 (= 3.3.2.), performed on compound
Acidity and alkalinity	European Pharmacopoeia 3.3.2. (pH; Internal method)
Reducing substances	European Pharmacopoeia 3.3.2.
UV	European Pharmacopoeia 3.1.7.
Metals	ICP-AES (European Pharmacopoeia 3.3.2. / 2.2.57.)
Cytotoxicity test	ISO 10993-5, performed on compound
Physical tests	Internal method

The current edition of the test methods at the approval date is used.

The employed test methods and/or specifications will usually be at least equivalent to the corresponding methods from the following references:

- European Pharmacopoeia 3.3.3.
- ISO 15747 section 4.2.2
- ISO 3826-1 section 6.3.2
- FDA 21 CFR, 201.323
- USP <87>
- USP <661>

APPROVED



Q&HSE manager

This certificate has been made by electronic data processing.

We herewith represent that, at the time of delivery to customer, the material will conform to the specifications in our brochure and datasheets, and that the material had been tested in accordance with the methods set forth on this Certificate of Compliance, and had achieved the results disclosed herein. We make no other warranties, express or implied, and we hereby disclaim any warranty that the material: (i) is fit for any particular purpose or intended use by customer, or (ii) is in compliance with any applicable law, regulation or ordinance.