Reference SOP NO :SOP-000476520

Certificate for cGMP Conformity

Product Name, Strength and Dosage Form	Trental® 400 mg Extended – Release Tablets
Batch N°	4P1344A
Packaging Form	Blister(6X10's Pack)GMID:941280
Marketing Authorization Holder	Sotex Pharm firm
Manufacturing Authorisation number/Code Number	GUJ/DRUGS/G/25/2386, [MA No.: П N014747/01]
Manufacturing Site	Pharmaceuticals, Ankleshwar, INDIA
Batch size	0.4 Mio.
Destination country	Russia
Manufacturing Date	05/2024
Expiration Date	04/2028
Specification / Version number / Effective date	ANP-FPS-000073/Version 2.0/ 08.12.2022
Batch Manufacturing Record number / Version number / Effective date	ANP-BMR-000076, Version 4.0 / 01.05.2024
Batch Packaging Record number / Version number / Effective date	ANP-BPR-000019-A06, Version 2.0/ 02.03.2024
Batch Packaging Record Appendix version number / Effective date	ANP-CPM-000019-A06, Version 2.0 / 05.03.2024

QC / In Process Control Results (According to the Manufacturing Formula):

Parameter	Reported Result	Acceptance criteria	Parameter	Reported Result	Acceptance criteria
Assay	99.8 %	95.0-105.0 %	Dissolution Test-Avg. (After 8 hours)	63 %	55 - 75%
Compression Yield	100.71 %	90.00-102.00%	Coating Yield	100.27 %	90.00-102.00%
Batch Yield	100.71 %	89.00-103.00%	Source of Pentoxifylline : Zentiva Private Limited Chemistry Site, Plot No.3501 to 3515,6301 to 6313 & 16.00 meter road/c. GIDC Estate, Ankleshwar 393002, Dist. Bharuch, Gujarat, India (API CONTROL NO. 4A01306)		
Number of Finished Packs	6693 Cartons				

Have Quality Relevant observation / deviation occurred during Manufacture : Yes [] No [√]
(If yes see attachment or comment): Not Applicable
Have Quality Relevant observation / deviation occurred during Packaging : Yes [] No [√]
(If yes see attachment or comment): Not Applicable
All in-process controls have been performed with results within specification? : Yes [√] No []
I hereby to certify that the manufacturing, packaging & controlling of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorization (s) of the destination country.

Name of the Site Quality Person certifying the batch Abhilash Gupta

Signature of Site Quality Person certifying the batch _____ Date of signature 22/07/2024

Передан через Диадок 28.10.2026 16:38 GMT+03:00;
d12060a0-e335-40c7-9bfd-ecd3fd4aa011
Страница 1 из 2

Документ подписан и передан через оператора ЭДО АО «ПФ «СКБ Контур»

	Организация, сотрудник	Доверенность: рег. номер, период действия и статус	Сертификат: серийный номер, период действия	Дата и время подписания
Подписи отправителя:	Закрытое акционерное общество "Фармфирма "Сотекс" Вострикова Татьяна Васильевна Доверитель: Закрытое акционерное общество «ФармФирма «Сотекс»	c91c1f40-42ad-4e48-96f2-12f2922a2e58 с 17.04.2026 00:00 по 31.12.2026 23:59 GMT+03:00 Доверенность прошла проверку	3ED290993AA5598D4FC91BB7019E8234 с 01.06.2026 10:51 по 01.06.2027 11:01 GMT+03:00	28.10.2026 16:38 GMT+03:00 Подпись соответствует файлу документа