

CERTIFICATE OF ANALYSIS

PL. NO. 04000 / 4301

PRODUCT NAME: MAX-COAT 4405TM (USP-40, BP-2018, Ph., Eur., B.B)			
	Titanium Dioxide (Pharmaceutical Grade)		T.R. NO. 147000638
Lot. NO.	TD-31448520	Analysis Date	19-09-2024
Mfg. Date	Sep 2024	Sample Receiving Date	20-09-2024
Exp. Date	Sep 2028	Manufacturer / Party	HSN Chemie GmbH

TEST RESULTS

ITEM	TEST PERFORMED	LIMIT	RESULTS
1	Description	White, amorphous, odorless, and tasteless nonhygroscopic Powder	Conforms
2	Solubility	Practically insoluble in dilute sulfuric acid, hydrochloric acid, nitric acid, organic solvents, and water. Soluble in hydrofluoric acid and hot concentrated sulfuric acid	Conforms
3	Identification (A,B,C)	To Be confirm	Conforms
4	Appearance of solution	To Be confirm	Conforms
5	Acidity or Alkalinity	To Be confirm	Conforms
6	Assay – Dried Basis	99.0 – 100.5 %	99.4 %
7	Loss on Drying (105 °C)	≤ 0.5 %	0.15 %
8	Loss on Ignition (800 °C)	≤ 0.5 %	0.22 %
9	Water Soluble substances	≤ 0.25 %	0.18 %
10	Acid Soluble substances	≤ 0.5 %	0.35 %
11	Barium	To Be confirm	Conforms
12	Heavy Metals	≤ 20 mg/kg	< 2 mg/kg
13	Iron	≤ 200 mg/kg	< 50 mg/kg
14	Arsenic	≤ 1 mg/kg	< 1 mg/kg
15	Antimony	≤ 100 mg/kg	< 7 mg/kg


Dr. Jim Andersen (QC Lab)


Dr. Stephen M. Kearney (QA Supervisor)

ISO 9001:2000 Certified Quality System

This product is manufactured in accordance to GMP as detailed in IPEC GMP guide for bulk excipients.

HSN Chemie Warrants MAX-COAT 4405™ to meet Current USP/NF and BP Requirements for Titanium Dioxide.

This product meets the requirements for residual solvents USP < 467 > and ICH Guide Q3C.

We certify that as of the date of shipment the product conforms with the current USP/NF, BP Specifications on the date of manufacture.

Manufacturer guarantees complies based on process knowledge and audit testing.