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CERTIFICATE OF ANALYSIS

TR0422_22796401/1

Product Tris-(hydroxymethyl)-aminomethane, Pharmpur®, Ph Eur, BP

Batch 22796401

TR0422

Quality release date 16/05/2022

Expiry date

05/2027

Analysis	Batch value	Specifications
Assay (Acidimetric, referred to dried sample)	99,18 %	99,0 - 100,5
Identification A (EP)	passes test	passes test
Identification D (EP)	passes test	passes test
Identification IR	passes test	passes test
Melting point	169,10 °C	168 - 174
pH (5 %, H2O)	10,84	10,0 - 11,5
Appearance of solution	clear and colourless	clear and colourless
Chlorides (CI)	< 1 ppm	≤ 100
Iron (Fe)	< 1 ppm	≤ 10
Related Substances	passes test	passes test
Residue on ignition	0,030 %	≤ 0,1
Loss on drying (105 °C)	0,03 %	≤ 0,5

This product is intended to be suitable for the manufacture of pharmaceuticals, medical devices, cosmetics and food products, but is entirely under the user's responsibility.