



EGIS PHARMACEUTICALS PLC  
1106 Budapest, Keresztúri út 30-38. - Hungary  
Phone: 36-1-803-5554    Telefax: 36-1-803-5556

CERTIFICATE OF ANALYSIS  
N°.: A1294/4311392/2023

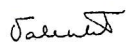
Name of the Product:	Promethazine hydrochloride	Manufacturing date:	04 2023
Batch N°.: 95231C0423		Retest date:	04 2028
Control N°.: ALA/2023/2700			
Date of analysis:	26 06 2023		
Batch size:	648.46 kg		
Manufacturer:	EGIS Pharmaceuticals PLC.		

<u>Test</u>	<u>Results</u>	<u>Requirements</u>
Appearance:	complies	A white or faintly yellowish, crystalline powder.
Identification:		
A: IR	complies	Concordant with that of reference standard.
B: Reaction of chloride	complies	Pass the test.
C: HPLC	complies	To conform.
Assay (HPLC): (dried substance)	100.4 %	97.0 - 101.5 %
Residue on ignition:	0.05 %	NMT 0.1 %
Organic impurities (HPLC):		
Promethazine sulfoxide	LT 0.05 %	NMT 0.1 %
Desmethyl promethazine	LT 0.05 %	NMT 0.2 %
Promethazine related compound B	LT 0.05 %	NMT 0.8 %
Phenothiazine	LT 0.05 %	NMT 0.1 %
Any individual unspecified impurity (each)	LT 0.05 %	NMT 0.10 %
Total impurities	LT 0.05 %	NMT 1.2 %
pH:	4.2	4.0 - 5.0
Loss on drying:	0.11 %	NMT 0.5 %

I certify hereby that the above product corresponds to the specifications of **current USP**.

We, EGIS Pharmaceuticals PLC Hungary, certify that the above product has been manufactured including packaging and quality control in full compliance with the current GMP regulations.

Budapest, 20 07 2023

  
Head of Quality Assurance

**KalChem**™  
INTERNATIONAL  
Compounding Chemicals You Can Trust

EGIS PHARMACEUTICALS PLC  
Budapest - Hungary



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