



Trecale, 15 May 2025

CERTIFICATE OF ANALYSIS n° 162

Product: **INOSINE PRANOBEX (METHISOPRINOL)**

Batch: **MTP250225** ✓

Formula: **C₅₂H₇₈N₁₀O₁₇**

Molecular weight: **1115.25**

Manufacturing date: **04/2025** ✓

Expiry date: **04/2028** ✓

Characters Crystalline powder, white/almost white colour, with weak odour
Freely soluble in water (230g/l-25°C), very slightly soluble in methanol,
practically insoluble in acetone and *n*-hexane

TESTS	SPECIFICATIONS	RESULTS
IR Identification ✓	Conforms to standard	Conforms
HPLC Identification	Conforms to standard	Conforms
Related substance HPLC ✓		
- Hypoxanthine	≤ 0.05% (on Methisoprinol)	0.01 %
- Guanosine	≤ 0.15% (on Methisoprinol)	0.03 %
- 4-amino-benzoic acid	≤ 0.15 % (on Methisoprinol)	0.03 %
- Adenosine	≤ 0.05% (on Methisoprinol)	0.00 %
- each other impurity	≤ 0.05 %	Conforms
- sum of impurities	≤ 0.5 %	0.1 %
Clarity	Solution should be clear with colour not more intense than standard B5	Conforms
10% w/v aqueous sol. ✓		
pH		
10% w/v aqueous sol. ✓	6.00 - 7.00	6.64
Water Content ✓	≤ 0.50%	0.18%
Assay by HPLC		
- Inosine (<i>theoretical 24.05%</i>) ✓	95.0 - 105.0 %	102.4 %
- 4 acet. Benzoic acid salt with 1-dimethyl amino-2-propanol (<i>theoretical 75.95%</i>) ✓	95.0 - 105.0 %	98.4 %
- sum of active components (<i>theoretical 100.00%</i>)	97.0 - 102.0%	99.4 %
Potentiometric assay		
N,N dimethylamino-2 prop. (<i>theoric 27.75%</i>)	95.0% - 105.0%	99.6 %
Residual solvent		
- Acetone	less than 1000 ppm	28 ppm
- Isopropanol	less than 5000 ppm	215 ppm
TAMC ✓	Not more than 500 ufc/g	0 ufc/g
TYMC ✓	Not more than 50 ufc/g	0 ufc/g
Escherichia Coli ✓	Absent / 1g	Absent

Qualified Person
Sara Michele

ABC FARMACEUTICI S.p.A. DIVISIONE UNIBIOS

Sede Legale: C.so Vittorio Emanuele II, 72 - 10121 Torino - Italy
Cap. Soc. € 4.000.000,00 - Cod. Fisc. / P.IVA: IT 08028050014
www.unibios.it - E-mail: info@unibios.it

Stabilimento di IVREA: Canton Moretti, 29
Località San Bernardo - 10015 Ivrea (TO)
Centr. Tel. ++39 0125 240111 - Fax ++39 0125 240176

Stabilimento di TRECALE: Via S. Pellico, 3 - 28069 TRECALE (NO)
Tel. ++39 0321 784311