

FARMADENT d.o.o.  
 Minarikova ul.6  
 2000 Maribor  
 Pregled: FUJS DRAGO  
 Zcu: *[Signature]*  
 Datum prejeta: *7.11.14*  
 Pregledal: MAMOLT Robert, mag. farm., spec.  
 Datum pregleda: *7.11.2014*



Date: 25.04.2014

TTAB 70 A2

Delivery-No.: 414158

Man.Date: YEAR 2014 WEEK 15

Exp.Date: YEAR 2017 WEEK 14

Lot-No.: L1415 A 4034 ✓

	Method / Specification	Unit	Result
Loss on drying	USP/NF <731>/NMT 0.5	%	0,1
Sulphated ash	Ph.Eur.2.4.14/NMT 0.1	%	conforms*
Particle size distribution	< 63 µm NMT 6	%	conforms
Mechanical shaker	<200 µm 30-70	%	conforms
	<500 µm NLT 98	%	conforms
Angle of repose	ISO 4324 NMT 34	°	conforms

### MICROBIAL CONTAMINATION

Total aerobic microbial count(TAMC)	Ph.Eur.2.6.12/USP<61>/JP4.05 NMT 10 <sup>2</sup>	/g	4
Total combined yeast and mould count (TYMC)	Ph.Eur.2.6.12/USP<61>/JP4.05 NMT 50	/g	conforms
Escherichia coli	Ph.Eur.2.6.13/USP<62>/JP4.05 negative	/10g	conforms*
Salmonella spp.	Ph.Eur.2.6.13/USP<62>/JP4.05 negative	/10g	conforms

\* The conformity to specification is assured by periodical testing.

### STORAGE

In well-closed containers, under dry and odourfree conditions.

**Production site:** Molkerei MEGGLE Wasserburg GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany

**Release site:** Molkerei MEGGLE Wasserburg GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany

This document is valid without signature.

Quality Assurance

Dr. G. Müller

The above data does not release purchaser from performing an incoming control. A legally binding assurance for the suitability of the product for a defined application purpose cannot be derived from the above.



**CERTIFICATE OF ANALYSIS** (Spec. 3034/07)

Product: **TABLETTOSE 70**

Delivery-No.: 414158

Man.Date: YEAR 2014 WEEK 15

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**DEFINITION**

Tabletose 70 is the brandname for an agglomerated lactose.  
Tabletose 70 conforms with the monograph "lactose monohydrate" in the European Pharmacopoeia (Ph.Eur.). This monograph is harmonized between Ph.Eur., USP/NF and JP.

**CHARACTERS**

Tabletose 70 is a direct compressible lactose.  
Tabletose 70 is a white or almost white, odourless, free flowing powder.  
It is freely but slowly soluble in water, practically insoluble in alcohol.

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**IDENTIFICATION**

	<b>Method / Specification</b>	<b>Unit</b>	<b>Result</b>
Identification	Ph.Eur./A IR S.2.2.24/conforms Ph.Eur./D Water2.5.12/conforms		conforms*

**TEST**

Appearance of solution	Ph.Eur./Solution is clear, not more coloured than reference solution BY 7		conforms
Acidity or alkalinity	Ph.Eur. 0187/NMT 0.4 0.1 n NaOH	ml	0,20
Spec. optical rotation	Ph.Eur.2.2.7/+54.4 - +55.9	°	55,4
Absorbance 400 nm	Ph.Eur.2.2.25/NMT 0.04		0,00
Absorbance 210-220 nm	Ph.Eur.2.2.25/NMT 0.25		0,05
Absorbance 270-300 nm	Ph.Eur.2.2.25/NMT 0.07		0,03
Heavy metals	Ph.Eur.2.4.8meth.A/NMT 5	ppm	conforms*
Water	Ph.Eur.2.5.12/4.5-5.5	%	5,16