



CERTIFICATE OF ANALYSIS (Spec. 3034/07)
 Product: **TABLETTOSE 70**

Delivery-No.: 201692
 Man.Date: YEAR 2011 WEEK 40
 Exp.Date: YEAR 2014 WEEK 40

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.

FARMADENT d.o.o.
 Minarikova ul. 6
 2000 Maribor
 Prejel: FLIS DRAGO
Za: Pajec:
 Datum prejema: 20.4.2012
 Pregledal: MAROLT Robert, mag. farm., spec.
ic Bjele
 Datum pregleda: 20.4.2012

Date: 21.10.2011
 Lot-No.: L1140 ✓ A 4034
1.2014 ✓

TTAB 70 A2

IDENTIFICATION

Method / Specification	Unit	Result
Identification		
Ph.Eur./A IR S.2.2.24/conforms		conforms*
Ph.Eur./D Water 2.5.12/conforms		

TEST

Method / Specification	Unit	Result
Appearance of solution		conforms
Acidity or alkalinity		
Ph.Eur./Solution is clear, not more coloured than reference solution BY 7		
Ph.Eur. 0187/NMT 0.4	ml	0,18
0.1 n NaOH		
Spec. optical rotation		
Ph.Eur. 2.2.7/+54.4 - +55.9	°	55,2
Absorbance 400 nm		0,00
Ph.Eur. 2.2.25/NMT 0.04		
Absorbance 210-220 nm		0,05
Ph.Eur. 2.2.25/NMT 0.25		
Absorbance 270-300 nm		0,02
Ph.Eur. 2.2.25/NMT 0.07		
Heavy metals		
Ph.Eur. 2.4.8meth.A/NMT 5	ppm	conforms*
Water		
Ph.Eur. 2.5.12/4.5-5.5	%	5,15



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	Method / Specification	Unit	Result
Loss on drying	USP/NF <731>/NMT 0.5	%	0,2
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 ²	/g	1
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.