



CERTIFICATE OF ANALYSIS (Spec. 3034/07)

Product: **TABLETTOSE 70**

Delivery-No.: 504462
Man.Date: YEAR 2014 WEEK 50
Exp.Date: YEAR 2017 WEEK 49

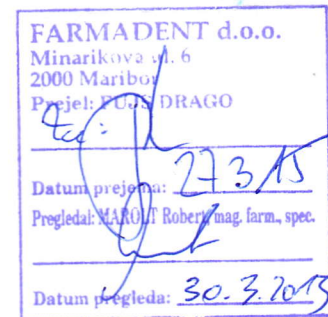
12.12.14 ✓

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.



Date: 23.12.2014
Lot-No.: **L1450** ✓ **A 4034**

TTAB 70 A2

IDENTIFICATION

Identification

Ph.Eur./A IR S.2.2.24/conforms
Ph.Eur./D Water 2.5.12/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

0,17

Spec. optical rotation

Ph.Eur. 2.2.7/+54.4 - +55.9

°

55,3

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

0,06

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

%

5,14



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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

Statement of Compliance: Product is produced and distributed under GMP and GDP according to EXCiPACT™ Standard.

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.