



CERTIFICAT D'ANALYSE/CERTIFICATE OF ANALYSIS

Nom/Name **TILDREN**
Présentation/Pres. 10 Vials powder+ 10solvents
Code liste/Code list **83841U**

N° lot/Batch N° **344A2**
Date fab. /Mfg date **SEP 2014**
Date pér. /Expiry date **SEP 2017**

Contrôles /Tests	Specifications	Résultats / Results
Caractères - Characters		
Aspect / Appearance	Lyophilisat compact blanc / Compact freeze dried white powder	CONFORME / COMPLIES
Teneur en eau/ Water content	≤ 4.0 %	1.6
Uniformité de masse / Uniformity of mass	Conforme aux exigences Ph. Eur. / According to Ph. Eur.	CONFORME / COMPLIES
Volume extractible / Extractable volume	≥ 99.0 %	99.1
Identification		
Acide tiludronite / Tiludronic acid (HPLC)	Tr identique au standard / RT identical to standard	CONFORME / COMPLIES
Dosage / Assays		
Acide tiludronate / Tiludronic acid (HPLC)	47.5 – 52.5 mg / vial	49.7
Stérilité / Sterility		
CF Ph. Eur. / According to Ph. Eur.	Stérile / Sterile	CONFORME / COMPLIES
Solution injectable / Injectable solution		
Solubilisation / Solubilization	La dissolution est instantanée (pas plus de 10 s) / The dissolution is instantaneous (not more than 10S)	CONFORME / COMPLIES
Aspect / Appearance	Soluté limpide incolore, exempt de particules en suspension / Clear, colourless, free from visible suspended particles	CONFORME / COMPLIES
pH/pH	4.0 – 5.0	4.7

Ce lot a été fabriqué en accord avec les BPF et les spécifications correspondent au dossier en vigueur /
This batch has been tested in reference to the dossier in force and has been found to meet the specification
requirements

COMPLIES / NOT COMPLIES

Batch Release number 358932
Batch Release date 27-OCT-2014

ACCEPTÉ par
ACCEPTED by

Stéphanie ZEBST
Quality Assurance Manager

Le soussigné certifie que ceci est une copie exacte des résultats de dosages et d'analyses/
The undersigned certifies this is a true copy of the results of tests and assays