

PHYTOR Ltd. Jerusalem Bio Park, 6th floor JERUSALEM 9112001 ISRAEL TEL: +972 2 6711911 FAX: +972 1532 6711911 phytor1@gmail.com

Jerusalem, Israel

May 28, 2019

Ref.: Babycalm Toxicological Evaluation and Clinical Trials

To whom it may concern,

- 1. I hereby confirm that I have conducted a toxicological evaluation of the "Babycalm" product of Hisunit Ltd., and that the product is safe for use icluding infants below the age of 6 months, in the dosage prescribed on the product, which has been sold to this target audience for over 20 years. The product has a wide safety margin and does not pose any risk of poisoning or side effects. All the ingredients are listed on the GRAS list of the FDA as safe for use, as they are also according to the Israeli Ministry of Health.
- 2. As per the request of the Ministry of Health, and in accordance with the instructions of Dr. Rina Versano and Dr. Tal Lavi, Hisunit Ltd. is conducting a clinical study on the "Babycalm" product in cooperation with the Maccabi Health Services. Hisunit Ltd. will conduct this research under the coordination of Dr. Gerard Korchia and Dr. Lilach Gavish.

At this stage, we have completed preparing the clinical study protocol, and after preliminary meetings with representatives of Maccabi Healthcare Services in their offices in Tel Aviv-Jaffa, we are due to submit it to the Ethics Committee for approval in the coming days. This study will include about 100 infants and will represent a continuation of a study conducted in 2002 on 20 infants whose results encouraged the company Hisunit Ltd. to conduct a more thorough study.

Date of Statement: 29 May, 2019

Signed:

PHYTOR LTD.

Dr. Yehoshua Maor (Ph.D, M.Sc., B.Pharm.)



PHYTOR Ltd.
Jerusalem Bio Park, 6th floor
JERUSALEM 9112001 ISRAEL **About my training:**

TEL: +972 2 6711911 FAX: +972 1532 6711911 phytor1@gmail.com

- Bachelor's degree in Pharmacy (B.Pharm, Brazil)
- Medicinal Chemistry degree (M.Sc., Hebrew University)
- PhD in Medicinal Chemistry and Molecular Biology (PhD, Hebrew University)
- Post Doctoral fellow at the Harvard Institutes of Medicine Division of Experimental Medicine. Harvard University, Boston, USA.
- Certificate of Environmental Health and Safety (EH&S) Training Harvard Institutes of Medicine, Boston USA.
- Coordinator of the Center of Excellence for Research in Agriculture and Environmental Health of the Hebrew University of Jerusalem (HU CEAEH) in the Rehovot campus and lecturer of Toxicology at the Faculty of Medicine in the Ein Kerem campus - Jerusalem.
- Lecturer of Toxicology, School of Pharmacy, Faculty of Medicine, The Hebrew University of Jerusalem
- GxP in Biomedicine Drug Regulatory Affair RFW Universität Bonn, Germany
- Chief Scientist at Phytor Ltd. Engaged in consulting in pharmacology, toxicology and regulatory aspects of new drugs and chemical substances of medicinal plants
- Full member of the Society of Toxicology (USA)