

**Statement regarding stability and compatibility comparison between Soluvit N and Soluvit N  
(without Metagin)**

Issuer Karin Petersson	Document owner Jannica Grundstrom	Valid from 2021-07-27
Signatures Karin Petersson, Godkännare, 2021-07-27 14:44:13 (UTC+01.00) (This is an electronic signature) Karin Petersson, Utfärdare, 2021-07-27 14:40:23 (UTC+01.00) (This is an electronic signature)		

To whom it may concern,

The Design Responsible for Soluvit N was contacted by ELAMA Regulatory Affairs to provide a statement regarding compatibility for Soluvit N and Soluvit N (without Metagin) due to drug shortage in many European countries. The request was to issue a statement confirming that the compatibility for the two products is the same.

### INDICATION AND BATCH FORMULA

Soluvit N and Soluvit N (without Metagin) are both freeze-dried powders for solution for infusion and used as additives in parenteral nutrition. However, the formula for one vial of each product differs slightly, as can be seen in table 1. The main difference is that Soluvit N contains Metagin, which is a stabiliser, whereas Soluvit N (without Metagin) does not, as the name implies.

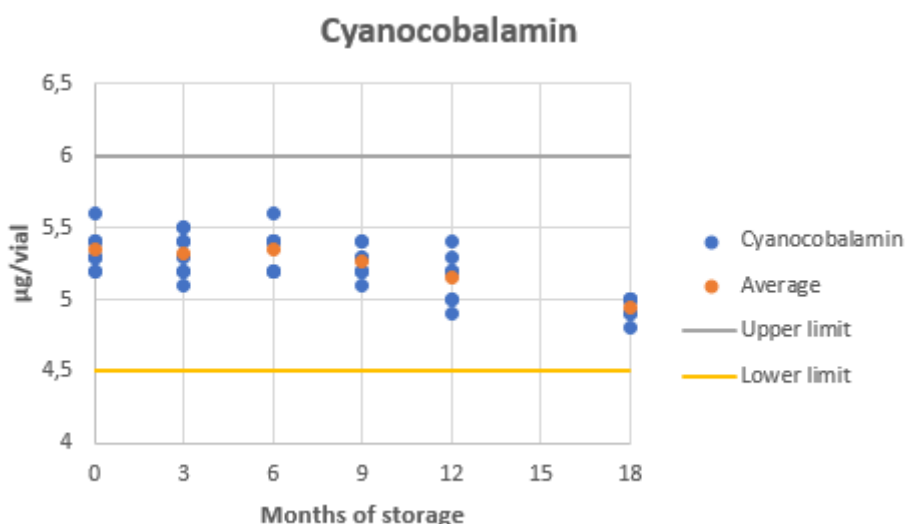
**Table 1.** Composition in one vial of Soluvit N and Soluvit N (without Metagin).

<b>Ingredient</b>	<b>Soluvit N</b>	<b>Soluvit N (without Metagin)</b>
Thiamine mononitrate	3.1 mg (corresponding to vitamin B1, 2.5 mg)	3.1 mg (corresponding to vitamin B1 hydrochloride, 3.2 mg)
Riboflavin sodium phosphate	4.9 mg (corresponding to vitamin B2, 3.6 mg)	4.9 mg (corresponding to vitamin B2, 3.6 mg)
Nicotinamide	40 mg	40 mg
Pyridoxine hydrochloride	4.9 mg (corresponding to vitamin B6, 4.0 mg)	4.9 mg (corresponding to vitamin B6, 4.0 mg)
Sodium pantothenate	16.5 mg (corresponding to pantothenic acid, 15.0 mg)	16.5 mg (corresponding to pantothenic acid, 15.0 mg)
Sodium ascorbate	113 mg (corresponding to vitamin C, 100 mg)	113 mg (corresponding to vitamin C, 100 mg)
Biotin	60 µg	60 µg
Folic acid	0.40 mg	0.40 mg
Cyanocobalamin	5.0 µg	5.0 µg
Glycine (aminoacetic acid)	300 mg	300 mg
Methyl parahydroxybenzoate	0.5 mg	-
Disodium edetate	0.5 mg	0.5 mg
Nitrogen	-	-

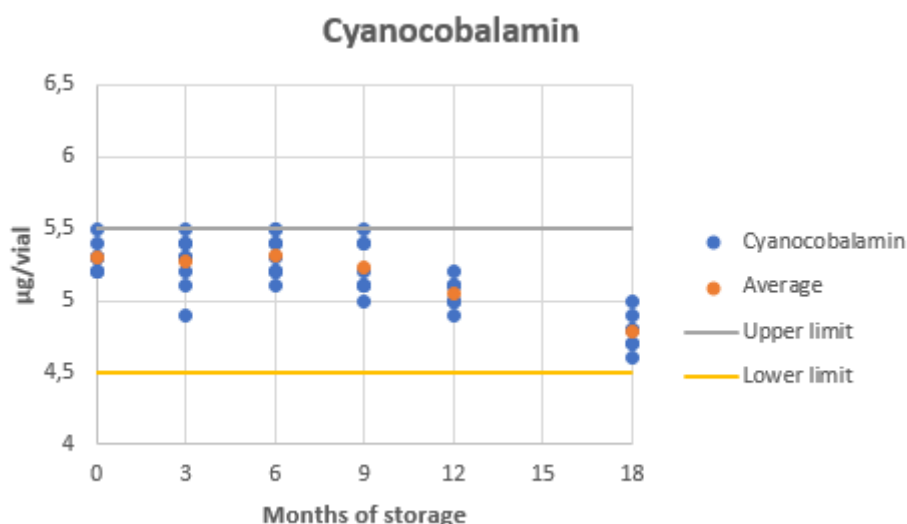
**Statement regarding stability and compatibility comparison between Soluvit N and Soluvit N (without Metagin)**

**STABILITY**

The products have similar stability profile where the only parameter changing over time is cyanocobalamin, which decreases, see figures 1 and 2.



**Figure 1.** Stability trend of cyanocobalamin in Soluvit N. The trend is based on stability data from studies conducted from 2012 to 2020.



**Figure 2.** Stability trend of cyanocobalamin in Soluvit N (without Metagin). The trend is based on stability data from studies conducted from 2012 to 2020.

A compilation of the average values of stability data from stability studies conducted from 2012 to 2020 for cyanocobalamin has been performed, see table 2. It is shown that the degradation of cyanocobalamin is slightly more pronounced in Soluvit N (without Metagin) than in Soluvit N. However, both products fulfil the shelf life specification at 18 months, which is the shelf life of the products.

**Statement regarding stability and compatibility comparison between Soluvit N and Soluvit N (without Metagin)**

**Table 2.** Comparison of average amount of cyanocobalamin ( $\mu\text{g}/\text{vial}$ ) in Soluvit N and Soluvit N (without Metagin).

Months of storage	Average amount of cyanocobalamin ( $\mu\text{g}/\text{vial}$ )	
	Solvit N	Solvit N (without Metagin)
<b>0</b>	5.34	5.30
<b>3</b>	5.33	5.27
<b>6</b>	5.35	5.31
<b>9</b>	5.26	5.23
<b>12</b>	5.15	5.05
<b>18</b>	4.94	4.79

## COMPATIBILITY

When it comes to compatibility with other products, there are some differences in the product SmPCs, see comparison made in table 3. In particular, the compatibility differs for Intralipid and Glucose solutions.

**Table 3.** Compatibility for Soluvit N and Soluvit N (without Metagin), according to respective SmPC.

	Solvit N	Solvit N (without Metagin)
Adults and children age 11 years and above	Vitalipid N Adult	Vitalipid N Adult
	Intralipid 10%, Intralipid 20%, Intralipid 30%	Intralipid 20%
	Water for Injections	Water for Injections
	Glucose solution for infusion (5%-50%)	Glucose solution (electrolyte free)
	-	Structolipid
Children below 11 years of age	Vitalipid N Infant (for children above 10 kg/bw)	Vitalipid N Infant (for children above 10 kg/bw)
	Intralipid 10%, Intralipid 20%	Intralipid 20%
	Water for Injections	Water for Injections
	Glucose solution for infusion (5%-50%)	Glucose solution (electrolyte free)

## CONCLUSION

There are no comparative studies, where compatibility similarities have been tested and evaluated for both products (Solvit N and Soluvit N (without Metagin)). Hence, it cannot be confirmed that the compatibility for Soluvit N and Soluvit N (without Metagin) is the same. However, when used according to the information provided in the respective SmPC, no patient risk is seen with the differences of the products.

Karin Petersson  
Design Responsible  
QA Product Maintenance  
Fresenius Kabi AB, Uppsala, Sweden