ATTACHMENT 10

PART V.

SPECIAL PARTICULARS

HUMET-R Syrup, 300 ml

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V.A. DOSAGE FORM

HORIZON-MULTIPLAN LTD.

ANNEX 2.

CARDBOARD BOX

ANNEX 3.

LABEL

HORIZON-MULTIPLAN LTD.

National Institute of Pharmacy
1051 Budapest, Zrinyi u.3.

Annex II to Amending Decision
No. 9689/51/95

B/Text of the bottle

HUMET®-R syrup

Roborating product for
macro- and microelement supplementation
300 ml

Active ingredients in 300 ml:

The product contains 2.25 g humic acid, 1.10 g potassium,450 mg magnesium, 420 mg iron, 300 mg zinc,90 mg manganase, 60 mg cuper, 15 mg vanadium, 6 mg cobalt, 5.2 mg molibdenum, 3.75 mg selenium in 300 ml flavored syrup.
A daily dose (10 ml syrup) contains 3.3 g carbohydrate

Shake well before use!

Manufactured by: Horizon-Multiplan Ltd.
1525 Budapest, P.O. Box 49

Shelf life:

Batch No:

Registration No: OGYI-430/1993

ANNEX 4.

PACKAGE INSERT

APPROVED IN THE STATE OF ORIGIN

HORIZON-MULTIPLAN LTD.

HUMET®-R syrup

Information for users

Roborating product for macro- and microelement supplementation

Active ingredients:
The product contains 2.25 g bottle acid, 1.10 g potassium, 450 mg magnesium, 420 mg iron, 300 mg zinc, 50 mg manganese, 40 mg copper, 15 mg vanadium, 6 mg cobalt, 5.2 mg molybdenum, 3.75 mg selenium in 300 ml flavored syrup.
A daily dose (10 ml syrup) contains 3.3 g carbohydrate

Indications:
- for general reduction in convalescence periods and for elderly,
- to help cross-element deficiency conditions,
- to strengthen resistance of the organism and to prevent diseases in epidemic periods,
- To improve mental and physical performance
  To cause iron deficiency, to supplement iron-requirement in conditions with blood loss (e.g. in wounds / periods)

Contraindications: *the first third of pregnancy, renal diseases.*

Dosage:

From well-shaken syrup, once daily, after a main meal, 10 ml is recommended for adults as dosed by the measuring device in the box, and one half of the adult dose is recommended for children below 40 kg.
Drink the syrup slowly, in drought, or mixed with 100 to 200 ml water or fruit juice.
Medical consultation is essential when the product is given to children younger than 3 years of age.

Shelf life:
use before the date indicated on the top of the box and the bottle.

Storage:
Store at 15 -25 °C.
Once opened, the bottle should be stored well-tight on a dark place, preferably in refrigerator. Broken product should be consumed within one month.

Warning:
If you are under medication, consultation with your physician about the use of HUMET-R is necessary.
Other drugs or parmendicated product used concomitantly with HUMET-R should be taken 3 hours before taking the product.
HUMET-R is not recommended to take in combination with other micro- or macroelement products
In diabetes, consider that each dose of the product contains 3.3 g carbohydrate.
Fiscal stools be coloured to dark brown in the period the product is consumed.

A parmendicated product!

Registration No: OGYI-430/1983

Manufactured by Humet Trading and Development Company
1525 Budapest P.O. Box 49

National Institute of Pharmacy
1051 Budapest, Zrinyi u.3.

Annex II to Amending Decision
No. 9689/51/95

Information for users

HUMET®-R syrup

Roborating product for macro- and microelement supplementation

Active ingredients:
The product contains 2.25 g humic acid, 1.10 g potassium,450 mg magnesium, 420 mg iron, 300 mg zinc,90 mg manganase, 60 mg cuper, 15 mg vanadium, 6 mg cobalt, 5.2 mg molibdenum, 3.75 mg selenium in 300 ml flavored syrup.
A daily dose (10 ml syrup) contains 3.3 g carbohydrate

Indications:
- for general roboration in convolascence periods and for elderly,
- to help trace element defficiency conditions,
- to strengthen resistance of the organism and to prevent diseases in epidemic periods,
- To improve mental and physical performance
- To cease iron defficiency, to supplementr iron-requirement in conditions with blood loss (e.g. in women's periods)

Contraindications: the first third of pregnancy, renal diseases.

Dosage: From well-shaken syrup, once daily, after a main meal, 10 ml is recommended for adults as dosed by the measuring device in the box, and one half of the adult dose is recommended for children below 40 kg.
Drink the syrup slowly, in draught, as mixed with 100 to 200 ml water or fruit juice.
Medical consultation is essential when the product is given to children younger than 3 years of age.

Shelf life: use before the date indicated on the top of the box and the bottle.

Storage: Store at 15 -25 °C.
Once opened, the bottle chould be stored well-thight on a dark place, preferably in refrigerator. Broken product should be consumed within one month.

Warning: If you are under medication, consultation with your physician about the use of HUMET-R is necessary.
Other drugs or paramedicinal product used concomitantly with HUMET-R should be taken 3 hours before taking the product.
HUMET-R is not recommended to take in combination with other micro- or macroelement products.
In diabetes, consider that each dose of the product contains 3.3 g carbohydrate.
Feces might be colored to dark brown in the period the product is consumed.

A paramedicinal product!

Registration No: OGYI-430/1993

Manufactured by Horizon-Multiplan Ltd
1525 Budapest P.O. Box 49.

ANNEX 5.

PACKAGE INSERT

HORIZON-MULTIPLAN LTD.

Warning: If you are under medication, consultation with your physician about the use of HUMET-R is necessary.
Other drugs or paramedicinal product used concomitantly with HUMET-R should be taken 3 hours before taking the product.
HUMET-R is not recommended to take in combination with other micro- or macroelement products.
In diabetes, consider that each dose of the product contains 3.3 g carbohydrate.
Feces might be colored to dark brown in the period the product is consumed.

A paramedicinal product!

Registration No: OGYI-430/1993

Manufactured by Horizon-Multiplan Ltd
1525 Budapest P.O. Box 49.

ANNEX 6.

INFORMATION FOR PROFESSIONALS

HORIZON-MULTIPLAN LTD.

National Institute of Pharmacy
1051 Budapest, Zrinyi u. 3.

Annex III. to Amending Decision
No. 9689/51/95

HUMET-R SYRUP

Roborating product for macro- and microelement supplementation;
its effect was confirmed by animal experiments

A paramedicinal pruduct

For a long time, it has been well-known in medicine that certain metals of the natural elements in the periodic table are essential for the living organism.

Intake of macro- and microelements, and their correct proportion in the body are inevitable for the healthy (optimal) function of the organism. In our age, nutrition is not always able to meet the complete macro- and microelement requirement of the organiym, so these substances should be supplemented. Up-to-date research has suggested that trace elements should be supplemented not in the form of monotherapy, but as complex treatment where interactions among elements are considered as well.

HUMET^{R} syrup, a product of Horizon-Multiplan Ltd. meets these requirements.

A specific feature of HUMET^{R} syrup is that essential elements (a total of 10 kinds of macro- and microelements) are bound to humic acids, organic carriers present in the organism as well. Humic acids in the product contain 16 kinds of amino acids whose presence can be verified by amino acid analysis.

National Institute of Pharmacy
1051 Budapest, Zrinyi u. 3.

Annex III. to Amending Decision
No. 9689/51/95

HUMET-R SYRUP

Roborating product for macro- and microelement supplementation; its effect was confirmed by animal experiments

A paramedicinal pruduct

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Intake of macro- and microelements, and their correct proportion in the body are inevitable for the healthy (optimal) function of the organism. In our age, nutrition is not always able to meet the complete macro- and microelement requirement of the organiym, so these substances should be supplemented. Up-to-date research has suggested that trace elements should be supplemented not in the form of monotherapy, but as complex treatment where interactions among elements are considered as well.

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A specific feature of HUMET^{R} syrup is that essential elements (a total of 10 kinds of macro- and microelements) are bound to humic acids, organic carriers present in the organism as well. Humic acids in the product contain 16 kinds of amino acids whose presence can be verified by amino acid analysis.

Role of the 10 kinds of macro- and microelements in HUMET^{R} syrup is as follows:
(On the base of MSD Medical Handbook - 1994 /The Merck Manual/):

Microelement	Role in the organism
Potassium	Muscular activity, neural transmission, intracellular acid-basis balance and water retention
Magnesium	Bone and tooth formation, stimulus conductance, muscular contraction, enzyme activation
Iron	Hemoglobin and myoglobin synthesis, enzyme component
Zinc	Enzyme and insulin component, maintenance of skin inteactness, wound healing, growth, immune system strengthening, nail and hair growth
Manganese	Enzyme component, bone formation, growth, maintenance of skin intactness, hair pigmentation, hair growth
Copper	Enzyme component, hemopoiesis, bone formation
Vanadium	Cholesterol synthesis, prevention of dental caries
Cobalt	Component of B12 molecule, increases hemoglobin concentration
Molybdenum	Component of redox catalizating enzymes, prevention of dental caries
Selenium	Antioxydant (protects from harmful effects of fre radicals), strengthens the immune system, supports heart function, protects from myocardial infarction

Active ingredients: The product contains 2.25 g humic acid, 1.10 g potassium, 450 mg magnesium, 420 mg iron, 300 mg zinc, 90 mg manganese, 15 mg vanadium, 6 mg cobalt, 5.2 mg molybdenum and 3.75 mg selenium in 300 ml flavored syrup.

Indications:
- for general roboration in convalescence periods and for the elderly,
- to help trace element defficiency conditions,
- to strengthen resistance of the organism and to prevent diseases in epidemic periods,
- to improve mental and physical performance
- to cease iron defficiency, to supplement iron-requirement in conditions with blood loss (e.g. in women's periods).

Counter-indications:
- the first third of pregnancy,
- renal diseases

Dosage: From well-shaken syrup, once daily, after a main meal, 10 ml is recommended for adults as dosed by the measauring device in the box, and one half of the adult dose is recommended for children below 40 kg.
Drink the syrup slowly, in draughts, as mixed with 100 to 200 ml water or fruit juice.
Medical consultation is essential when the product is given to children younger than 3 years of age.

Shelf life: use before the date indicated on the top of the box and the bottle.

Storage: store at 15 to 25 ° C.
Once opened, the bottle should be stored well-thight on a dark place, preferably in refrigerator. Broken product should be consumed within one month.

Warning:- If you are under medication, consultation with your physician about the use of HUMET^{R} is necessary.
- Other drugs or paramedicinal products used contomitantly with HUMET^{R} should be taken 3 hours before taking the product.
- HUMET^{R} is not recommended to take in combination with other micro- or macroelement products.
- In diabetes, consider that each dose of the product ontains 3.3 g carbohydrate.
- Feces might be discolored to dark brown in the period the product is consumed.

Registration No.: OGYI-430/1993

Manufactured by: Horizon-Multiplan Ltd.
1525 Budapest, P.O.Box 49.

HUMET-R SZIRUP

Makro- és mikroelemek pótlására szolgáló roboráló készítmény

Gyógyszernek nem minősülő, gyógyhatású készítmény

Nyilvántartási száma: OGYI–430/1993.

Az orvostudomány által régóta ismert, hogy a periódusos rendszer természetes elemei közül bizonyos fémek létfontosságúak az élő szervezetek számára.

A szervezet egészséges működéséhez nélkülözhetetlen a makro- és mikroelemek bevitele, illetve azok szervezeten belüli helyes aránya. A táplálkozás ma már nem minden esetben biztosítja a szervezet teljes makro- és mikroelem szükségletét, így pótlásáról gondoskodni kell. A modern kutatások eredményeként a *monoterápia helyett a komplex terápia alkalmazása* javasolt a nyomelempótlásnál, melynél figyelembe veszik az elemek közötti kölcsönhatásokat is.
Ezeknek a követelményeknek felel meg a Horizon-Multiplan Kft. készítménye a HUMET$_e$-R szirup.
A HUMET$_e$-R szirup különlegessége, hogy a létfontosságú elemek (10-féle makro- és mikroelem) huminsavakhoz kötődnek, ez a szerves hordozó a szervezetben is megtalálható. A készítményben felhasznált humintavak 16-féle aminosavat tartalmaznak, ezek jelenléte aminosav-analízissel igazolható.

A HUMET$_e$-R SZIRUPBAN LÉVŐ 10-FÉLE MAKRO- ÉS MIKROELEM SZEREPE:

(MSD Orvosi Kézikönyv – 1994 [The MERCK MANUAL] anyagának felhasználásával)

Elemek	Szerepe a szervezetben
Kálium	Az izomaktivitás, idegi transzmisszió, intracelluláris sav-bázis egyensúly és vízvisszatartás.
Magnézium	Csont- és fogképződés, ingerületvezetés, izomkontrakció, enzimaktiválás.
Vas	Hemoglobin- és mioglobin-szintézis, enzimek alkotórésze.
Cink	Enzimek és inzulin alkotórésze, a bőr épségének fenntartása, sebgyógyulás, növekedés, immunrendszer, köröm- és hajnövekedés.
Mangán	Enzimek alkotórésze, csontképződés, növekedés, a bőr épségének fenntartása, hajpigmentáció, hajnövekedés.
Réz	Enzimek alkotórésze, vérképzés, csontképzés.
Vanádium	Koleszterin-szintézis, fogszuvasodás-gátlás.
Kobalt	B12 molekula alkotórésze, emeli a hemoglobin-koncentrációt
Molibdén	Redox reakciót katalizáló enzimek alkotórésze, fogszuvasodás-gátlás.
Szelén	Antioxidáns hatású (véd a szabad gyökök sejtkárosító hatásától), immunrendszer erősítő, támogatja a szívműködést, véd az infarktus ellen.

SAMPLES OF ACTIVE INGREDIENTS

HORIZON-MULTIPLAN LTD.

ANNEX 7.

TECHNICAL QUALITY CERTIFICATE

HORIZON-MULTIPLAN LTD.

HORIZON-MULTIPLAN Rt.

HUMET Trading and Development Company
1121 Budapest, Konkoly Thege u. 29-33.
114. P.O.Box 49.
1525

TECHNICAL QUALITY CERTIFICATE

Name of the product:	**HUMET - R Syrup**
Registration number:	OGYI – 430/1993
Manufacturer:	HUMET Co. (HORIZON-MULTIPLAN LTD.) Budapest 1121 Konkoly Thege u. 29-33. 114. P.O.Box 49. 1525
Batch number:	5241098
Production date: Expiry date:	16-th Oct. 1998. 16-th Oct. 2000.
Packaging unit:	Cardboard box of 20 dark bottles of 300 ml
Storage condition	15-25 C

1121 Budapest, Konkoly Thege út 29-33. Tel.: 395-9016, 395-9228, 1949. Fax: 395-9057, 395-9102. E-mail: [illegible]

Type of study	Requirement	Results
1. Properties		
1.1 Characteristics	A brown suspension with typical odour and taste. The suspension can be mixed with water in any proportion, its colour remains dark, brownish even after a tenfold dilution	Accepted
2.1. Mechanical impurities	The suspension should not contain any macroscopically detectable extraneous particles.	Accepted
2.2. Particle size	None of the linear dimensions of the suspended particles in the suspension should exeed 200 micrometer.	Accepted
2.3. Homogeneity, redispergability	The particles sedimented during storage shouls be homogeneously redispergated by shakeing.	Accepted
2.4. pH value	2.5 - 3.5 at 25 °C	2.98
3. Assays		
3.1. Identification tests		
3.1.1. Carbohydrate	According to Ph.Hg.VII.	Accepted
3.1.2. Humic acid metal chelate	According to manufacturer standard	Accepted
3.2. Purity		
3.2.1. Microbiological purity	Max 1000 microorganisms/ml Among them max 100 fungi/ml Not allowed: Enterobacteriaceae *Pseudomonas aeruginosa* Staphylococcus aureus	Accepted
3.2.2. Lead content	Max. 5 ppm	Accepted
3.3. Metal composition assay. Atomic absortion or ICP analisys after wet decomposition Content (mg) K 1100 Mg 450 Fe 420 Zn 300 Mn 90 Cu 60 V 15 Co 6 Mo 5,25	Accepted values mg 1100 - 1500 427 - 517 357 - 441 255 - 315 76,5 - 94,5 51 - 63 12,7 - 15,7 5,1 - 6,3 4,5 - 5,5	Resdults of ICP mg 1490 503 430 312 90 62 14,7 5,5 5,5	Accepted
Date: Budapest 26-th Sept. 1998.	Chief Pharmacist Head of Quality Assurance ..... Á. Király Pharm.D.	Certification of the product: Accepted

HUMET ©
Kereskedelmi, Kutatási és Fejlesztési
2 Részvénytársaság
Minőségbiztosítás

Fluka

Fluka Chemie AG Tel. 081 755 25 11
Industriestrasse 25 Telex 855282
CH-9470 Buchs Telefax 081 7565445

SALES-SPECIFICATIONS

Product-No: 60355 Page 1 21.10.1994
SEKR. ANALYTIK

di-Potassium hydrogen phosphate
Quality: purum p.a. > 98% (T)
powder

Synonyms: [sec.-Potassium phosphate] [Potassium biphosphate]

Extended formula: K2HPO4 Empirical formula: HK2O4P
Mr: 174.18
CAS No: 7758-11-4 EINECS No: 2318345
Product line: Chemika
Acceptable appearance: white powder

pH: 8.5 - 9.5 (5% in water, 25°C)
Anions:
Chloride (Cl) < 0.005% Sulfate (SO(4)) < 0.01%
Cations:

Ca <0.005%	Cd <0.005%	Co <0.005%	Cu <0.005%
Fe <0.005%	Na <1.5%	Ni <0.005%	Pb <0.005%
Zn <0.005%			

Last version: 02.08.1994

(Indications on tolerance, quality levels, symbols and abbreviations are to be found in the Fluka catalogue.)

Disclaimer:
Fluka warrants that this product will conform to the above information which is applicable at this time. When ordered, a lot specific certificate of analysis is available on demand. It does not relieve the purchaser from examining the product upon delivery and gives no assurance of suitability of the product for purposes other than laboratory use. See Fluka catalogue for additional terms and conditions of sale.

Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs

Tel. 081 755 25 11
Telex 855 282
Telefax 081 756 54 49

SALES-SPECIFICATIONS

Product-No: 61245 Page 1 02.05.1995
SEKR. ANALYTIK

Cupric sulfate Pentahydrate
Quality: purum p.a. > 99.0% (RT)
Special quality: USP
crystallized

Extended formula: CuSO4.5H2O Empirical formula: Cu04S.5H2O
Mr: 249.68
CAS No: 7758-99-8 EINECS No: 2318476
Product line: Chemika
Acceptable appearance: light blue crystals

pH: 3.5 - 4.5 (5% in water, 25°C)
Anions:
Chloride (Cl) < 0.01%
Cations:

Ca <0.005%	Cd <0.005%	Co <0.005%	Fe <0.01%
K <0.01%	Na <0.01%	Ni <0.01%	Pb <0.005%
Zn <0.005%			

Merck-Index: 11, 2659
Fieser-Index: 10, 107

Last version: 03.01.1995

(Indications on tolerance, quality levels, symbols and abbreviations are to be found in the Fluka catalogue.)

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Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs
Tel. 081 755 25 11
Telex 855 282
Telefax 081 756 54 49

SALES-SPECIFICATIONS

Product-No: 96501 Page 1 04.05.1995
SEKR. ANALYTIK

Zinc sulfate Heptahydrate
Quality: purum p.a. > 99.0% (KT)

Extended formula: ZnSO4.7H2O Empirical formula: O4SZn.7H2O
Mr: 287.54
CAS No: 7446-20-0 EINECS No: 2317933
Product line: Chemika
Acceptable appearance: colorless crystals

Anions:
Chloride (Cl) < 0.005%
Cations:

Ca <0.01%	Cd <0.005%	Co <0.005%	Cu <0.005%
Fe <0.005%	K <0.01%	Na <0.01%	Ni <0.005%
Pb <0.005%			

Merck-Index: 11, 10064

Last version: 03.01.1995

(Indications on tolerance, quality levels, symbols and abbreviations are to be found in the Fluka catalogue.)

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Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs

Tel. 081 755 25 11
Telex 855282
Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	61245
PRODUCT	KUPFER(II)-SULFAT PENTAHYDRAT, USP. KRISTALLISIERT CUPRIC SULFATE PENTAHYDRATE, USP. CRYSTALLIZED
PURITY	PURUM PA
FORMULA	CUO4S.5H2O
MOLECULAR MASS	249.68
REDOX TITRATION REDOX TITRATION	99.9 % (RT)
ASPEKT APPEARANCE	LIGHT BLUE FINE CRYSTALS WITH LUMPS
LOESLICHKEIT SOLUBILITY	LIGHT BLUE, CLEAR
LOESLICHKEIT (METHODE) SOLUBILITY-METHOD	0.5 G IN 10 ML H2O
PH-WERT PH	4.0
TROCKENVERLUST LOSS ON DRYING	35.8 %
PHARMAKOPOEA PRUEFUNG PHARMACOPOEA TESTS	CORRESPONDS TO USP XXII
SPURENANALYSE TRACE ANALYSIS	PASSED
CHARGE/LOT	326633/1

3.05.95

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs/Schweiz
Tel. 081 755 25 11
E-mail: bucmain@mail.sial.com
Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	63555
PRODUCT	MANGAN(II)-SULFAT MONOHYDRAT MANGANESE(II) SULFATE MONOHYDRATE
PURITY	PURUM PA
FORMULA	MNO4S.H2O
MOLECULAR MASS	169.00
CHARGE/LOT	369806/1
TITRATION (KT) EDTA 0.1M TITRATION (KT) EDTA 0.1M	99.1% % GEW.
ASPEKT APPEARANCE	VERY FAINTLY RED POWDER
LOESLICHKEIT (FARBE) SOLUBILITY (COLOUR)	ALMOST COLOURLESS
LOESLICHKEIT (TRUEBUNG) SOLUBILITY (TURBIDITY)	CLEAR (<3.5 TE(F))
LOESLICHKEIT (METHODE) SOLUBILITY (METHOD)	1 G IN 10 ML H2O HOT
SPURENANALYSE TRACE ANALYSIS	CORRESPONDS

FOR FURTHER INQUIRIES, PLEASE CONTACT OUR TECHNICAL SERVICE.

10.11.1997

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka

Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs
Tel. 081 755 25 11
Telex 855282
Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	96501
PRODUCT	ZINKSULFAT HEPTAHYDRAT ZINC SULFATE HEPTAHYDRATE
PURITY	PURUM PA
FORMULA	O4SZN.7 H2O
MOLECULAR MASS	287.54
KOMPLEXOM. TITRATION KOMPLEXOM. TITRATION	99.3 % (KT)
ASPEKT APPEARANCE	COLOURLESS FINE CRYSTALS WITH LUMPS
LOESLICHKEIT SOLUBILITY LOESLICHKEIT (METHODE) SOLUBILITY-METHOD	COLOURLESS, CLEAR 0.5 G IN 10 ML H2O
PH-WERT PH	4.5
SPURENANALYSE TRACE ANALYSIS	PASSED
CHARGE/LOT	347352/1 !

5.05.95

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka HORIZON

Fluka Chemie AG Tel. 081 755 25 11
Industriestrasse 25 Telex 855282
CH-9470 Buchs Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	60355
PRODUCT	DI-KALIUMHYDROGENPHOSPHAT PULV. DI-POTASSIUM HYDROGEN PHOSPHATE POWDER
PURITY	PURUM PA
FORMULA	HK2O4P
MOLECULAR MASS	174.18
TITRATION (NT) NON AQUEOUS TITRATION	99.5 % (NT)
ASPEKT APPEARANCE	WHITE POWDER
LOESLICHKEIT (METHODE) SOLUBILITY-METHOD	0.5 G IN 10 ML H2O
SPURENANALYSE TRACE ANALYSIS	PASSED
CHARGE/LOT	338354/1

24.10.94

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka

Fluka Chemie AG Tel. 081 755 25 11
Industriestrasse 25 Telex 855282
CH-9470 Buchs Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	72060
PRODUCT	NATRIUM(META)VANADAT SODIUM (META)VANADATE
PURITY	PURUM
FORMULA	NAO3V
MOLECULAR MASS	121.93
REDOX TITRATION REDOX TITRATION	98.3 % (RT)
ASPEKT APPEARANCE	FAINTLY YELLOW POWDER
TROCKENVERLUST (200 C) LOSS ON DRYING (200 C)	0.41 %
CHARGE/LOT	331933/1

8.11.94

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka Chemie AG
Industriestrasse 25
CH-9471 Buchs/Schweiz
Tel. 081 755 25 11
E-mail: bucmain@mmail.sial.com
Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	63142
PRODUCT	MAGNESIUMSULFAT HEPTAHYDRAT, PH EUR MAGNESIUM SULFATE HEPTAHYDRATE, PH EUR
PURITY	PURUM PA
FORMULA	MGO4S.7H2O
MOLECULAR MASS	246.48
CHARGE/LOT	367743/1
KOMPLEXOM. TITRATION KOMPLEXOM. TITRATION	99.9 % (KT)
ASPEKT APPEARANCE	WHITE CRYSTALS
LOESLICHKEIT SOLUBILITY	COLOURLESS, CLEAR
LOESLICHKEIT (METHODE) SOLUBILITY (METHOD)	0.5 G IN 10 ML H2O
PH-WERT PH	7.2
PHARMAKOPOEA PRUEFUNG PHARMACOPOEA TESTS	CORRESPONDS TO PH.EUR.II
SPURENANALYSE TRACE ANALYSIS	PASSED

FOR FURTHER INQUIRIES, PLEASE CONTACT OUR TECHNICAL SERVICE.

10.11.1997

Fluka Chemie AG
Quality Control

Dr. G. van Look

MOLAR CHEMICALS LTD
1147 Budapest Telepes u. 53

HUNGARY
tel/fax: (361)-183-6321

CA134

Minőségi specifikáció

Termék név:	NÁTRIUM-SZELENIT		
	Na_2SeO_3	M : 172,94	CAS[10102-18-8]
Lot. No.:	M9407014		
Mennyiség	5 x 1000 g		
Minőségi	tiszta		

Tartalom	99,7 %
Oldódás	megfelel
Klorid	0,01 %
Szulfát, szelenát	megfelel
Nitrát	0,06 %

Budapest, 1994 július 15.

MOLAR CHEMICALS KFT
1147 Bp., Telepes u. 53
Tel./Fax: 183-6321
Adószám: 10060723-2-01

Nagy Balázs
ügyvezető igazgató

Hegeciüsné
HM-331/95
1995-05-05

MOLAR CHEMICALS LTD
1147 Budapest Telepes u. 53

HUNGARY
tel/fax: (361)-183-0321

CA133

Minőségi specifikáció

Termék név:	KOBALT(II)- SZULFÁT 7 H_2O
	$CoSO_4$ 7 H_2O M : 281,10 CAS[10026-24-1]
Lot. No.:	M9407012
Mennyiség	12 x 2 kg
Minősítés	puriss, MSz n.t.

Tartalom:	> 99,0 %
Vízben oldhatatlan	< 0,01 %
Klorid	< 0,005 %
Szulfát:	< 0,002 %
Vas (Fe):	< 0,002 %
Nehézfém (Pb):	< 0,002 %
Össznitrogén	< 0,01 %
Alkáli és földfémek	< 0,2 %
Réz (Cu)	< 0,005 %
Mangán (Mn)	< 0,005 %
Nikkel (Ni)	< 0,05 %
Cink (Zn)	< 0,01 %

Budapest, 1994 július 15.

Nagy Balázs
ügyvezető igazgató

MOLAR CHEMICALS KFT
1147 Bp., Telepes u. 53.
Tel./Fax: 183-0321
Adószám: 10404713-2-01

MOLAR CHEMICALS LTD
1147 Budapest Telepes u. 53

HUNGARY
tel/fax: (361)-183-8321

Certificate of Analysis

Product name : **AMMONIUM MOLYBDATE 4 HYDRATE**
Lot No. : **MK008/94**
Quantity : **20 x 1000 g**

Assay	101,0 %
Chloride	< 0,0005 %
Heavy metals (Pb)	< 0,001 %
Nitrate	< 0,0025 %
Phosphate	0,0005 %
Sulphate	< 0,02 %
Insoluble (in water)	< 0,01 %

The parameters of this material fit the requirements of MSz 25765-70 a.h.
The material suitable for analytical purposes.

Budapest, 1994 03. 23

Nagy [illegible]
managing director

MOLAR CHEMICALS KFT
1147 Bp., Telepes u. 53.
Tel./Fax: 183-8321
MNH: 218-98141-536-03177-3
Adószám: 10886713-2-01

Fluka HORIZON 1/2

Fluka Chemie AG Tel 081 7552511
Industriestrasse 25 Telex 855282
CH-9470 Buchs Telefax 081 756 54 49

CERTIFICATE OF ANALYSIS

PRODUCT-NO.	44980
PRODUCT	EISEN(II)-SULFAT HEPTAHYDRAT, PH EUR, USP FERROUS SULFATE HEPTAHYDRATE, PH EUR, USP
PURITY	PURUM PA
FORMULA	FEO4S.7H2O
MOLECULAR MASS	278.02
TITRATION TITRATION	99.8 %
ASPEKT APPEARANCE	LIGHT BLUE-GREEN CRYSTALS
PHARMAKOPOEA PRUEFUNG PHARMACOPOEA TESTS	CORRESPONDS TO PH.EUR.II
SPURENANALYSE TRACE ANALYSIS	PASSED
CHARGE/LOT	334279/1

21.10.94

Fluka Chemie AG
Quality Control

Dr. G. van Look

Fluka

2/2

Fluka Chemie AG Tel. 081 755 25 11
Industriestrasse 25 Telex 855282
CH-9470 Buchs Telefax 081 756 54 49

SALES-SPECIFICATIONS

Product-No: 44980 Page 1 21.10.1994
SEKR. ANALYTIK

Ferrous sulfate Heptahydrate
Quality: purum p.a. > 99.0% (RT)
Special quality: Ph Eur, USP

Extended formula: FeSO4.7H2O Empirical formula: FeO4S.7H2O
Mr: 278.02
CAS No: 7782-63-0 EINECS No: 2317536
Product line: Chemika
Acceptable appearance: light green crystals

Anions:
Chloride (Cl) < 0.005%
Cations:

Ca <0.005%	Cd <0.005%	Co <0.005%	Cu <0.005%
Fe(3)(+)	<0.2%	K <0.01%	Na <0.01%
Ni <0.005%	Pb <0.005%	Zn <0.005%	

Merck-Index: 11, 4006

Last version: 01.09.1992

(Indications on tolerance, quality levels, symbols and abbreviations are to be found in the Fluka catalogue.)

Disclaimer:
Fluka warrants that this product will conform to the above information which is applicable at this time. When ordered, a lot specific certificate of analysis is available on demand. It does not relieve the purchaser from examining the product upon delivery and gives no assurance of suitability of the product for purposes other than laboratory use. See Fluka catalogue for additional terms and conditions of sale.

BORMIOLI ROCCO E FIGLIO S.p.A.
DIVISIONE PLASTICA

Castelguelfo, 02/04/1999

Messieurs

HUMET RT

HUNGARY

REFERENCE: Conformity of materials utilised in the production of the following articles delivered to you:

FI8061M14: 380 ML PET AMBER BOTTLE SUITABLE FOR PFP28 NECK – DRAWING A3385/B - PET AMBER

In compliance with the regulations prescribed by the ministerial decree 21.3.73 and with the later updating (circular 84 by the Ministry of Health dated 28.12.77) we state that:

a) The basic resins indicated here below with the terminology specified in the enclosure II, section 1, part A of the mentioned ministerial decree are utilised for the production of the a.m. articles supplied to you:

- POLYETHYLENETEREPHTHALATE + AMBER DYE IN %

b) For the preparation of the a.m. articles we utilise exclusively resins, additives and dyes of which we are given a certificate of compliance in accordance with the ministerial decree 21.3.73 and further updating;

c) We submit the finished articles to the dye migration control following the procedures layed down by the section 7 of the enclosure IV and verify the total migration in accordance with the tests foreseen in the section 1 of the enclosure IV of the ministerial decree 21.3.73 and in the circular 84 of the Ministry of Health dated 28.12.77;

d) We guarantee, on the basis of the norms of good techniques, the readiness of the formulations and of the technological procedure utilised for the manufacturing of the articles.

Physical Property Data Sheet

Kodapak PET Copolyester 9921W (Clear)

PROPERTY,[a] UNITS	TYPICAL VALUE	TEST METHOD
Intrinsic Viscosity	0.80	ECC-A-AC-G-V-1
Molecular Weight, Number Average ($\overline{M}_n$)	26,000	—
Weight Average ($\overline{M}_w$)	52,000	
Crystalline Density, g/cm³	1.4	ASTM D 1505
Bulk Density, kg/m³ (lb/ft³) Poured	817 (51)	ASTM D 1895
Vibrated	881 (55)	
Melt Density, @ 285°C, g/cm³	1.2	ASTM D 1238-82 (Note A, Table 2)
Acetaldehyde, ppm	<1	TEPP-A-PO-G-GC-1
Crystalline Peak Melting Point, °C	249	ASTM D 3418
Heat of Fusion, kJ/kg	59	ASTM E 793
Thermal Conductivity, W/m•K	0.25	ASTM C 177
Specific Heat, kJ/kg•K @ 23°C	1.13	DSC
80°C	1.42	
100°C	1.51	
200°C	1.88	
250°C	2.05	
Fines, wt %, maximum	0.1	TEPP-A-PO-G-GA-4
Pellet Size, mm (in.)—Shape	2.5 (0.1)—Cubical	—

[a] Unless noted otherwise, all tests are run @ 23°C (73°F) and 50% relative humidity.

Comments:

Kodapak PET thermoplastic polyesters are condensation polymers produced by a continuous melt-phase polymerization process followed by a solid-state polymerization process. Typical packaging end uses include carbonated beverages, cosmetics, food, and water.

Properties reported here are typical of average lots. Eastman makes no representation that the material in any particular shipment will conform exactly to the values given.

EASTMAN

BORMIOLI ROCCO E FIGLIO SPA

DIVISIONE PLASTICA

9143 8015

IMBOCCATURA BAGUE FINISH MÜNDUNG PFP 24

ml	CODICE					
100 ml	9143	112	15	PFP 24	92,5	47
200 ml	8015	228	21	PFP 24	130,0	55

8062 8061 8037 8048 8043

IMBOCCATURA BAGUE FINISH MÜNDUNG PFP 28

ml	CODICE					
250 ml	8032	262	23,0	PFP 28	125,7	61,7
250 ml	8062	296	18,5	PFP 28	130,7	63,2
300 ml	8061	330	28,5	PFP 28	142,8	65,6
500 ml	8048	525	37,0	PFP 28	166,4	74,0
1000 ml	8043	1061	44,0	PFP 28	217,7	88,0
200 ml	8037	214	22,2	PFP 28	140,5	58,5x37,7

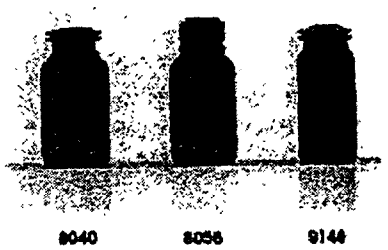
BORMIOLI ROCCO E FIGLIO S.p.A.
DIVISIONE PLASTICA

We confirm therefore that the a.m. artic.es are supplied in accordance with the ministerial decree 21.3.73 and later updating

We remind you, though, that the article 6 of the ministerial decree 21.3.73 prescribes that the transfer tests on the finished artic.es must be carried out by the utilised in relation with the real utilisation conditions to make sure that there are no unfavourable modifications of the organoleptic properties of the contained product.

Quality Assurance Manager

Paolo Zucchi



8040 8056 9144

INBOCCATURA A FASCETTA · BAGUE A SERTIR · RING FINISH · KRIMPMÜNDUNG 20

ml	CODICE					
10 ml	9149	13	4,6	20	48,9	21,5
15 ml	8040	17	4,4	20	49,0	24,5

INBOCCATURA · BAGUE · FINISH · MÜNDUNG PFP 17,8

ml	CODICE					
15 ml	8056	17,2	4,6	17,8	52,3	24,5

8028 8027 8028

INBOCCATURA · BAGUE · FINISH · MÜNDUNG SC 40

ml	CODICE					
150 ml	8028	166	20	SC 40	85,6	53,5
240 ml	8027	254	27	SC 40	94,3	64,0
300 ml	8028	322	31	SC 40	117,0	64,0

TUTTI I FLACONI SONO DECORABILI - TOUS LES FLACONS PEUVENT ÊTRE DÉCORÉS
ALL BOTTLES CAN BE DECORATED - ALLE FLASCHEN SIND DEKORIERBAR

BORMIOLI ROCCO E FIGLIO S.p.A.
DIVISIONE PLASTICA
Strada Nazionale Emilia, 58 • 43010 Castelguelfo - Parma
Tel (0521) 613411 • Fax (0521) 618077

Tel (0521) 613411 • Fax (0521) 618077

HORIZON-MULTIPLAN RT.	MINŐSÉGI ELŐIRAT	Kiadás dátuma: 99.08.31.
	Humet PET flakon/300 ml	Változat : 1. Lapszám : 1./2.

Kémiai megnevezés:

Móltömeg :
Szinonim nevek : Bormioli PET flakon/300 ml
PET AMBER bottle/300 ml

Jellemzők : 300 ml-es barna szín/ PET flakon PFP 28-as
csavarmenet A3355/B
1.sz.melléklet: üveg minőségi jellemzői
flako súlya: 28,5 g

Összetétel / :
analitikai érték

Egyéb jellemzők :

Tisztaság : csira szegény Katalógus :

Szállító : Bormioli Rocco Parma Gyártó : Bormioli Rocco Parma

Csomagolási mód : zsugorfóliázva Kiszerelés [kg]: Tárolási mód : Fedett, raklapon Tárolási kód : 24FT 24 hónapig Fedett h. Móregkezelés I/N: N Tűzveszélyesség : D Funkció : kiszerelőanyag	Megjegyzés :

HORIZON-MULTIPLAN RT.	MINŐSÉGI ELŐIRAT	Kiadás dátuma: 99.08.31.
	Humet PET flakon/300 ml	Változat : 1. Lapszám : 2./2.

Ellenőrzés/vizsgálat jellege (Ell.)		
1. kód:	2. kód:	3. kód:
* - minden tételen	H - Horizon-M. vizsgálat	1 - Mintaszám/tétel
3 - 3 tételen	m - műbizonylat alapján	* - minden egység
n - nem vizsgált		

No	Vizsgálati paraméter	Ell.	Követelmény Minimum	Maximum	Vizsgálati előírás
1	Összehasonlítás az etalonhoz	*H*	megfelel		
2	Minőségibizonyítvány összehasolítása	*H*	megfelel		
3	Mikrobiológiai vizsgálat	*m*	megfelet		

Készitette : Minőségellenőrzés laborvezető	Jóváhagyta : Min.bizt. vezető

ANNEX 8.

MANUFACTURERS AUTHORISATIONS

HORIZON-MULTIPLAN LTD.

HORIZON-MULTIPLAN Rt.

TO WHOM IT MAY CONCERN

We, HUMET Development and Trading Co, legal succesor of HORIZON-MULTIPLAN Ltd. manufacturer of the curative preparation

HUMET - R syrup 300 ml,

approved in HUNGARY under registration No: OGYI-430/1993, hereby declare that the manufacture of our product is being carried out in our plant according to GMP standards.

In this respect we are holding the certificate of the National Institute of Pharmacy, Budapest, Hungary 28-th February 1994 under reference No 8575/50/93.
Budapest, 29-th October 1998.

Dr. Á. Király

Head of Quality Assurance

HUMET ⊖
Kereskedelmi, Kutatási és Fejlesztési
Részvénytársaság
Minőségbiztosítás

1121 Budapest, Konkoly Thege út 29-33. Tel.: 395-9036, 395-9220/1949, Fax: 395-9057, 395-9102, E-mail: humet@mail.horizon.hu

No. of Certificate 9a54 /38/1998

Exporting (certifying) country: HUNGARY

Importing (requesting) country: YEMEN REPUBLIC

Certificate of a Paramedicinal Product[1]

Proprietary name (if applicable) and dosage form: HUMET-R syrup 120 ml

Active ingredient(s)[2] and amount(s) per unit dose:[3] See Appendix

1. Is this product licensed to be placed on the market for use in the exporting country[4]? If yes complete box A; if no, complete box B

A Import Co.

Product licence holder: HORIZON-MULTIPLAN Ltd.

Status of licence holder[5]: a. ☒ b. ☐ c. ☐ d. ☐

Number of product licence[6] and date of issue: OGYI-430 /1993

Is an approved technical summary appended?[7] yes ☒ no ☐

Is the attached product information complete and consonant with the licence?

yes ☒ no ☐ not privided ☐

Application for certificate if different from the licence holder[8]:

B

Applicant for certificate :

Status of applicant[5] a. ☐ b. ☐ c. ☐ d. ☐

Why is authorisation lacking? not required ☐ not requested ☐ under consideration ☐ refused ☐

Remarks[9]

2. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes ☒ no ☐ If No, proceed to question).

Periodicity of routine inspections(years): 2 years.

Has the manufacture of this type of dosage form been inspected? yes ☒ no ☐

Do the facilities and operations conform to GMP? yes ☒ no ☐

3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party[10]?

yes ☐ no ☐ If No, explain:

Address of certifying authority: National Institute of Pharmacy
Budapest, V. POB 450 H- 1372

Name of authorized person: dr. Tamás Paál General Director

Signature:

Stamp and date: 08.07.1998., Budapest

Telephone/fax numbers:

ANNEX 9.

RECORD OF REGISTRATION RESOLUTION

HORIZON-MULTIPLAN LTD.

List of countries
where registration process has been started

(name of the country, date of application, in the case of registration refusal-reasons)

Name of the country	Date of submission	Status	Reason of refusal
Canada	1998	Pending	
Lithuania	1998	Pending (accepted)	
Jemen Republic	1998	Pending	

List of countries
where the pharmaceutical agent has been registered

(name of the country, number of registration certificate, date of registration, validity period of registration certificate)

Name of the country	Registration date	Gegistration number	Validity
Hungary	20. 09.1993.	OGYI -430/1993	3 year period
Slovak Republik	16.10.1995.	Z-9775/95	31.12.2000
Belarus	25.06.1997	B-2-LS No 2809/97	5 years
Russia	14.10.1997	TX/RX NO 3849 PO1	5 years
Ukraine	20. 01.1997	2042	30.01.2002

ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET
1051 Budapest V., Zrínyi u. 3
Levélcím: 1373 Postafiók 450.
Telefon: 117-1488
Telefax: 118-1167

Budapest, 19. 93. okt. 18.

Szám: 8575/So/93
Előadó: Vné dr. Bogdán Mária
Melléklet: 5 db
Tárgy: Nyilvántartásba vételi határozat

A 10/1987.(VIII.19.) EÜ.M. számú rendelet alapján Intézetünk a

HORIZON - MULTIPLAN Produkciós KKT

előállító/forgalmazó által benyújtott és szakmailag értékelt bizonylatok alapján a

HUMET-R szirup

elnevezésű terméket

OGYI-.43o/1993..... szám alatt

a gyógyterméket hatósági nyilvántartásába felvette, és a fenti EÜ.M. sz. rendelet I. sz. mellékletében szereplő ...II.... kategóriába sorolta.

A termék kizárólag ezen okirat mellékletében feltüntetett feltételek szerint és a forgalomba hozatali engedély birtokában forgalmazható.

Ezen nyilvántartás visszavonásig, illetve legfeljebb a kibocsátástól számított 5 évig érvényes. Meghosszabbítása a lejárat előtt 3 hónappal kérhető.

Dr. Paál Tamás
főigazgató

TRANSLATION

NATIONAL INSTITUTE OF PHARMACY
H-1051 Budapest, Zrinyi u. 3.
Phone: 117 1488
Fax: 118 1167

Budapest, 1993. okt. 18.
Ref. No: 8575/50/93
Ref.country: Vné dr.Bogdán M.

Subject: Record of registration resolution

On the basis of decree no. 10/1987. (VIII. 19.) Eü.M. our Institute - based on the professional expert evaluations submitted by the manufacturer/distributor of the requested product, HORIZON-MULTIPLAN Ltd. - has taken up the product named

HUMET-R syrup

under registration No. OGYI-430/1993.

into the official records of the curative preparations, and has listed same into category II. figuring in Annex I. of the above decree no. 10/1987. (VIII. 19.) Eü.M.

The product is subject to the conditions of the present certificate and can be distributed only in possession of the distribution permit.

This registration is valid until its withdrawal, or for 5 years from the date of issue. Extension of said registration should be requested 3 months prior to expiry.

(director general)

Міністерство охорони здоров'я України

Бюро реєстрації лікарських засобів

Реєстраційне посвідчення

№ 2042

Посвідчення видане фірмі
"Хорізон-Мультиплан", Угорщина

що відповідно до порядку, встановленого Міністерством охорони здоров'я України, препарат під назвою
ГУМЕТ-Р

зареєстрований в Україні у вигляді лікарської форми:
сироп у флаконах по 120 мл № 1

Посвідчення не є зобов'язанням щодо закупівлі цього препарату.

Посвідчення видане "30" січня 1997 р.
Посвідчення дійсне до "30" січня 2002 р.

Голова Бюро реєстрації лікарських засобів А.М. Сердюк

1997-02-13

Ministry of Health of Ukraine

Bureau for Pharmaceuticals Registration

Registration Certificate

2042

This certificate is issued to the firm
"Horizon-Multiplan", Hungary

ascertaining that in compliance with a regulation, set by Ministry of Public Health of Ukraine, the preparation called
HUMET-R

is registered in Ukraine as a therapeutic form
syrup in bottles 120 ml N 1

The certificate is not a commitment for purchasing this preparation.

The certificate is issued on: "30" January 1997
The certificate is valid until: "30" January 2002

Chairman
Bureau for Pharmaceuticals Registration Andriy M. Serdiuk

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

ФАРМАКОЛОГИЧЕСКИЙ ГОСУДАРСТВЕННЫЙ КОМИТЕТ

123128 Москва, ул. Щукинская, 6

от 17.12.1997г. № 211-8886-25

Представительство фирмы

'98 03/13 13:16 TX/RX NO. 3849 P01

на № _____ от _____

"АО Гедеон-Рихтер"
/Венгрия/

УВАЖАЕМЫЕ ГОСПОДА!

Сообщаем Вам, что Фармакологический государственный комитет на заседании от 1 ноября 1997г. (протокол № 12) рассмотрел материалы на препарат ГУМЛТ-Р

в лекарственной форме сироп во флаконах по 120 и 300 мл

и принял решение:

- РАЗРЕШИТЬ МЕДИЦИНСКОЕ ПРИМЕНЕНИЕ указанного препарата.

С уважением,

Председатель В.Шашенко

Зам. Ученый секретарь ФГК, профессор В.М. [illegible]

МІНІСТЭРСТВА
АХОВЫ ЗДАРОЎЯ
РЭСПУБЛІКІ БЕЛАРУСЬ

MINISTRY
OF HEALTH OF THE
REPUBLIC OF BELARUS

РЭГІСТРАЦЫЙНАЕ ПАСВЕДЧАННЕ
REGISTRATION CERTIFICATE

Б-2-ЛС № 2809/97

Сапраўднае пасведчанне выдадзена фірме
This certificate has been given to

"HORIZON-MULTIPLAN LTD", Венгрыя
(назва фірмы, краіна / manufacturer, country)

і з'яўляецца падцверджаннем таго, што Міністэрства аховы здароўя Рэспублікі Беларусь зарэгістравала лекавы сродак
it is hereby certified that the Ministry of Health of the Republic of Belarus has registered the drug

HUMET-R
(назва лекавага сродка, міжнародная непатэнтаваная назва / name of drug, international nonproprietary name)

ў лекавай форме(ах)
in medical form(s)

сіроп у флаконах па 120мл і 300мл
(стандартная упакоўка / standard package)

Рэгістрацыйнае пасведчанне выдадзена на 5 гадоў і ні ў якім разе не гарантуе закупку названага лекавага сродка.
This certificate is valid for 5 years and does not guarantee this drugs purchase under any conditions.

Дата рэгістрацыі 25.06.97г. [illegible] № 6
Date of registration

Намеснік міністра
Deputy Minister

А.С. Курчанкоў

Š T Á T N Y Z D R A V O T N Ý Ú S T A V
Pracovisko zdravotnej kontroly dovážaných poživatín v SR
820 09 Bratislava 29,PP 26,Ružinovská 8

Číslo jednacie: 1664/lab. *Bratislava,dňa:*14. 7.1995
Číslo rozboru: 5649/M-CH

V Ý S L E D O K R O Z B O R U

Vzorka:
č.5649 Humet-E výž. doplnok 300ml

Výrobca v zahraničí: HORIZON MULTIPLAN KFT.,H-1525 Budapest,Pf.49., Maďarská republika

Dovozca v tuzemsku: Lupus spol. s r.o., Bratislavská 25, Veľký Biel

Odobral: MUDr. Liška, CSc.
Balenie: orig.
Dátum odberu: 22.6.95

Mikrobiologický nález:

Počet mikróbov v 1g

Číslo vzorky	CPZ /celkov.poč. mikróbov/	koliformných baktérií	plesní	kvasiniek
5649	0	0	neg.	neg.

neg.=menej ako 10/g

Bežne sledované patogénne a podmienene patogénne mikróby sa vo vzorke nezistili.Vyšetrenie na prítomnosť salmonel v 25g bolo negatívne.

Záver:
Vzorka č.5649 v rozsahu vykonaných mikrobiologických vyšetrení nejavila známky zdravotnej závadnosti.

Štátny zdravotný ústav
hl. mesta SR Bratislavy
Ružinovská ul. č. 8
820 09 Bratislava 29, P.O. Box 58

MUDr. Jana Hrabárová
vedúca oddelenia

MINISTERSTVO ZDRAVOTNÍCTVA
Hlavný hygienik
SLOVENSKEJ REPUBLIKY
833 43 Bratislava, Limbová 2

Bratislava, 16.10.1995
Číslo: I-9445/95-SHE/SZÚ

R O Z H O D N U T I E

Ministerstvo zdravotníctva - Hlavný hygienik Slovenskej republiky ako príslušný orgán podľa ust. § 18 ods. 2 zák.č. 272/1994 Z.z. o ochrane zdravia ľudí preskúmal žiadosť spol. s r.o. Lupus, Veľký Biel zo dňa 9.5.1995 a podľa ust. § 19 písm. n/ zák.č. 272/1994 Z.z. vydáva tento

p o s u d o k :

žiadosti spol. s r.o. Lupus, Veľký Biel zo dňa 9.5.1995 sa vyhovuje a s dovozom a distribúciou prípravku HUMET-R SZIRUP à 300 ml fy Horizon Multiplan Kft., Budapest, Maďarsko

sa s ú h l a s í do 31.12.2000.

Zároveň sa ukladá povinnosť
1. na dodacích listoch uvádzať číslo a dátum tohoto rozhodnutia,
2. ku každému spotrebiteľskému baleniu tohoto prípravku zabezpečiť príbalový letáčik s návodom na jeho použitie v slovenskom jazyku.

O d ô v o d n e n i e:

Spol. s r.o. Lupus, Veľký Biel podaním zo dňa 9.5.1995, doplneným dňa 4.10.1995 požiadala v zmysle ust. § 27 ods. 2 písm. j/ zákona č. 272/1994 Z.z.o ochrane zdravia ľudí o vydanie posudku k dovozu, hore uvedeného prípravku. Podľa predložených výsledkov laboratórneho vyšetrenia, odborného vyjadrenia Výskumného ústavu výživy v Bratislave zo dňa 30.5.1995 a odborného vyjadrenia Štátneho ústavu pre kontrolu liečiv v Bratislave č. 1381/95 zo dňa 8.5.1995 prípravok spĺňa podmienky určené predpismi na ochranu zdravia. Z dôvodov primárnej ochrany zdravia bol súhlas časovo obmedzený a uložená povinnosť na dodacích listoch uvádzať číslo a dátum tohoto rozhodnutia a ku každému spotrebiteľskému baleniu prípravku zabezpečiť príbalový letáčik s návodom na jeho použitie.

Na základe uvedeného bolo rozhodnuté tak, ako je to uvedené vo výroku tohoto rozhodnutia.

p o u č e n i e:

Proti tomuto rozhodnutiu je možné podať do 15 dní odo dňa jeho doručenia rozklad podľa § 61 odst. 1 zákona č. 71/1967 Zb. o správnom konaní na Ministerstvo zdravotníctva Slovenskej republiky.

MUDr. Ivan R. O. n ý
Hlavný hygienik SR

Doslane: LUPUS
spol. s r.o.
Bratislavská 25
900 24 Veľký Biel

ŠTÁTNY ZDRAVOTNÝ ÚSTAV HL.MESTA SR BRATISLAVY
Pracovisko zdravotnej kontroly dovážaných požívatín v SR
Ružinovská 8, 820 09 BRATISLAVA, P.O.BOX 26

Číslo jednacie: 1664/lab.
Číslo rozboru: 5649/CH
Žiadateľ: LUPUS spol.s r.o., Bratislavská 25, 900 24 Veľký Biel
Dátum prijatia: 7.7.1995
Dátum expedície: 27.7.1995
Dôvod vyšetrenia: Návrh na dovoz
Názov vzorky: HUMET-Ň SZIRUP 300 ml
Výživový doplnok s obsahom huminovej kyseliny a stopových prvkov
Výrobca: Horizon Multiplan Kft., Budapest, MR
Krajina pôvodu: Maďarsko
Balenie: originálne

V Ý S L E D O K R O Z B O R U

Organoleptické hodnotenie:
Obal papierová skladačka s potlačou, vo vnútri sklenená fľaška uzatvorená závitovým uzáverom, prelepená etiketou
Vzhľad tekutina nepriehľadná
Farba tmavohnedá
Vôňa a chuť typická, sladkokyslá
Bez cudzích pachov a príchutí.
Fyzikálno-chemické hodnotenie:

Obsah kadmia v mg/kg	ND
Obsah medi v mg/kg	100.9
Obsah olova v mg/kg	ND
Obsah zinku v mg/kg	504.4
Obsah arzénu v mg/kg	0.007
Obsah ortuti v mg/kg	0.05
Obsah vanádu v mg/kg	26.2
Obsah mangánu v mg/kg	155.9
Obsah železa v mg/kg	743.6
Obsah kobaltu v mg/kg	10.6
Obsah molybdenu v mg/kg	155.9
Obsah selénu v mg/kg	0.9
Obsah horčíka v mg/kg	571.7
Obsah draslíka v mg/kg	2318.4
Obsah kyseliny benzoovej v mg/kg	ND
Obsah kyseliny sorbovej v mg/kg	366.0

Obsah syntetických farbív: Vzorka nebola prifarbená syntetickým farbivom.

ND - nezistené použitou metódou

Štátny zdravotný ústav
hl. mesta SR Bratislavy
Ružinovská ul. č. 8
820 09 Bratislava 29, P.O. Box 26

Ing. Oľga Brodňanová
vedúca odboru hyg.lab.

Upozornenie:
Výsledok rozboru nenahradzuje rozhodnutie MZSR k dovozu podľa zákona NR SR 272/94 Z.z. o ochrane zdravia ľudí, k žiadosti o súhlas je však nevyhnutným podkladom.

MINISTRY OF HEALTH AND SOCIAL AFFAIRS OF GEORGIA

DRUG AND PHARMACY DEPARTMENT

REGISTRATION CERTIFICATE

№ MP - 0 0 3 4 9 1

The certificate has been issued to the firm

HUMET Co (HUNGARY)

as a confirmation of the established rules of the Ministry of Health and Social Affairs of Georgia that the

HUMET-R
(trade name)

humet-r
(international nonproprietary name INN)

has been registered in Georgia as a

syrup 120ml , 300ml in glass vial

The certificate is issued *"14"September 2000*

This certificate is valid for 5 years

A. Tomadze
Head of Department

FULCRUM HEALTH LIMITED
Raebarn House, 100 Northolt Road,
South Harrow, Middlesex HA2 0DY
Telephone: 020-8422-6951
Facsimile: 020-8422-6952

9th December 1999

Dr. Gabor Sekoszy,
HUMET Trade, Research & Development Co.
Konkoly Thege ut 29-33
H-1121 BUDAPEST

Dear Sir,

Humet®-R

Fulcrum Health Limited is the licence holder and distributor of Humet®-R in the United Kingdom of Great Britain. We have been importing Humet®-R for sale since 1996.

We have to date sold in excess of 15,000 bottles Humet®-R and we are entirely satisfied with the product. We have not received any unfavourable reports on its use, or of any adverse side effects.

We consider Humet®-R to be a quite outstanding mineral supplement.

Yours faithfully,
for Fulcrum Health Limited

David C. J. Ward
Director

ANNEX 10.

DECREE OF DISTRIBUTION

HORIZON-MULTIPLAN LTD.

TRANSLATION

NATIONAL INSTITUTE OF PHARMACY
H-1051 Budapest, Zrinyi u. 3.
Phone: 117 1488
Fax: 118 1167

Budapest, 1994. júl. 6.
Ref. No: 6808/51/94
Ref.country: Vné dr.Bogdán M.

Subject: Decree of Distribution

The product named HUMET-R syrup 300 ml manufactured by HORIZON-MULTIPLAN LTD. under our Institute's registration No. OGYI-430/1993. as "curative preparation not regarded as medicine" (health adjuvant) with reference to decree No. 10/1987.(VIII.19.) Eü.M. I declare herewith the following authorization:

I authorize the distribution of the above mentioned product by HORIZON-MULTIPLAN LTD. - on the basis of the original registration Decree No. 8575/50/93. and of the Modification of said registration number 6245/51/94. and of the conditions stipulated in its valid Appendices - in pharmacies and special herbal shops.

Concerning the distribution the existing legal requirements must be taken into account in all other respects.

Justification

The registration application and supporting documentation concerning the "curative preparation not regarded as medicine" submitted by the manufacturer complies with the requirements of such preparations based on the control tests and evaluations carried out.

We have found the submitted final sample acceptable.

(director general)

1051 Budapest V., Zrínyi u. 1
Levélcím: 1372 Pf.: 450.
Telefax: 117-1498
Telefon: 118-4167

Budapest, 1994. július 6.

Szám: 6808/51/94

Ügyintéző: Vné dr. Bogdán Mária

Melléklet:

Tárgy: Forgalomba hozatali határozat

Az HORIZON - MULTIPLAN Kft.
által előállított, Intézetünkben OGYI-AJo../1993. számon nyilvántartásba vett

HUMET - R szirup, 300 ml

elnevezésű, gyógyszernek nem minősülő gyógyhatású készítménnyel kapcsolatban a 10/1987.(VIII.19.) ÉÜ.M. számú rendeletben kapott felhatalmazás alapján meghozom az alábbi

határozatot.

A fent megjelölt készítmény forgalomba hozatalát az eredetileg ...8575/50/93..szám alatt kiadott, 6245/51/94... szám alatt módosított nyilvántartásba-vételi határozatban és annak hatályos mellékleteiben rögzített feltételek mellett .

HORIZON-MULTIPLAN Kft

forgalmazónak engedélyezem gyógyszertárhálózatban, gyógynövényszaküzletekben, [illegible].

A forgalomba hozatalt illetően egyéb tekintetben a hatályos jogszabály követelményeit kell figyelembe venni.

Indoklás

Az előállító által gyógyszernek nem minősülő gyógyhatású készítmény nyilvántartása iránt benyújtott kérelem és érvanyag a lefolytatott ellenőrző vizsgálatok és értékelés alapján megfelel a készítményekkel szemben támasztott követelményeknek.

A benyújtott végleges mintát megfelelőnek találtuk.

Dr. [illegible] Tamás
főigazgató

Translation

NATIONAL INSTITUTE OF PHARMACY*
H-1051 Budapest, Zrinyi u. 3.
6101/51/98Phone 3171488, fax: 3181167 Telex: 224656 ogyi h
HUNGARY

Budapest 15-th Jun July. 1998.
Ref. No
Our clerk::Vné dr. Bogdán Mária
Subject:Modification of registration

MODIFICATION OF THE MARKETING AUTHORIZATION

Authorized by the Order No 10/1987 (VIII. 19.)/Eü.Min. issued by the Ministry of Health , herewith I make the following

decision:

Decision on Registration' of the paramedicinal product below, originally issued No. 8575/50/93, amended under Nos 6245/51/94, 10008/51/94, 7419/51/95 9689/51/95, 9026/51/96 is modified as follows:

Name of the paramedicinal product: **HUMET®-R syrup**

Registration number: OGYI-430/1993

No of the Distribution Licence: 6808/51/94

The amended registration data of the paramedicinal product apply to the shelf life of the product.
The amended data see below:

Shelf life : 24 month.

Reasoning : Onthe base of documentation submitted to the Institute, the above modification professionally wee-grounded.

Appeals against the above decision may be executed within 15 days as from the delivery, as addressed to the Ministry Social Affair and Health, but submitted to us.

Stamp, Signature
Prof. Tamás Pail Ph.D.
General Director

ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET
1051 Budapest V., Zrínyi utca 3.
Levélcím: 1372 Postafiók 450.
Telefon: 117-1488
Telefax: 118-1187

Budapest, 19 98. június 15.
Szám: 61ol/51/98
Előadó: Vné dr. Bogdán Mária
Melléklet:
Tárgy:

NYILVÁNTARTÁSI ADATOK MÓDOSITÁSA

A 1o/1987.(VIII.19.) EÜ.Min. rendeletben kapott felhatalmazás alapján meghozom a következő

h a t á r o z a t o t .

Az alábbi gyógyszernek nem minősülő gyógyhatású készitmény (gyógytermék) eredetileg 8575/5o/93 számon kiadott és 6245/51/94, 1oo08/51/94, 7419/51/95, 9609/51/95, 9o26/51/96 számon módositott "nyilvántartásba vételi határozatot" az alábbiak szerint

m ó d o s i t o m .

Gyógytermék neve: Humet-R szirup

Nyilvántartási száma: OGYI-43o/1993

Forgalombahozatali engedély száma: 68o8/51/94

A gyógytermék módositott nyilvántartási adatai a készitmény

lejárati idejére

vonatkozik.

A módositott adatokat lásd alább:

lejárati idő: 24 hónap

Indoklás: Az Intézethez beérkezett dokumentáció alapján a fenti változás szakmailag megalapozott.

A jelen határozat ellen kézhezvételtől számitott 15 napon belül, a Népjóléti Minisztériumnak címezve, de hozzánk benyújtva fellebbezéssel élhet.

Dr. Paál Tamás
főigazgató