Technical Information

November 2012

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WF-No. 121245

Novata® Grades

® = Registered trademark of BASF in many countries.

Hard Fat for suppository masses

BASF
We create chemistry

PRD-No., Article-No. and CAS.-No.

	PRD-No.	Article-No.	CAS.-No.
Novata® B PH	30531224	50209107	67701-26-2
Novata® BC PH	30531225	50209108	67701-26-2
Novata® BCF PH	30531226	50209109	67701-26-2
Novata® BD PH	30531227	50209110	67701-26-2

Specifications

See separate documents: “Standard Specification” (not for regulatory purposes) available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

Regulatory Status

All Novata® PH Grades are complying to the Monograph “Hard fat” Ph. Eur.

Product characteristics

All Novata® PH grades are white to slightly yellowish, brittle pellets which are used for the production of suppositories. On account of its mean hydroxyl value range and the melting point, the product can be used as universal suppository mass, also in the chemists shop.

Typical Properties

Novata®	B PH	BC PH	BCF PH	BD PH
Acid value	≤0.5	≤0.5	≤0.5	≤0.5
Iodine value	≤3.0	≤3.0	≤3.0	≤3.0
Peroxide value	≤3.0	≤3.0	≤3.0	≤3.0
Alcaline impurities (mL)	≤0.15	≤0.15	≤0.15	≤0.15
Total ash (%)	≤0.05	≤0.05	≤0.05	≤0.05
Unsaponifialble (%)	≤0.6	≤0.6	≤0.6	≤0.6
Hydroxyl value	20 – 30	30 – 40	20 – 30	5 – 15
Saponification value	225 – 240	225 – 240	225 – 240	230 – 245
Mellting point (°C)	33.5 – 35.5	33.0 – 34.5	35 – 37	33.5 – 35.5
Heavy metals as sum Pb (ppm)	≤10.0	≤10.0	≤10.0	≤10.0

Application

The main application of the Novata® PH Grades are suppositories. Suppository is a drug delivery system that is inserted into the rectum (rectal suppository), vagina (vaginal suppository) or urethra (urethral suppository), where it dissolves or melts.

Suppositories may be used for patients (e.g. children) in case it may be easier to administer than tablets or syrups.

Suppositories may also be used when a patient has a vomiting tendency, as oral medication can be vomited out.

Another benefit of suppositories is, that drugs which often cause stomach upset during oral intake, for example diclofenac sodium are better tolerated in suppository form.

Suppositories are made from a greasy or waxy base, containing different Novata® PH grades in which the active ingredient and the other excipients are dissolved.

The main important point in formulating a suppository, is adjust the melting temperature of the complete formulation to the body temperature.

Apart from suppository manufacturing, solid triglycerides (hard fats) are used as carriers in capsule fillings, inlets, ointments and creams and in dental products. In topical formulation they can act as a sensory enhancer, because of their low melting point.

Raw material origin

All Novata® grades are based on vegetable origin. The raw material origin is coconut or palm kernel oil.

Toxicology

The toxicological abstracts are available on request.
Individual reports can be shared under secrecy agreement.

Stability and storage

In the original sealed containers all Novata® grades can be stored for at least 18 month, protected from moisture at below 30 °C.

Handling and Disposal

Please refer to the individual Material Safety Data Sheet (MSDS) for instructions of safe and proper handling and disposal.

Formulations

1. Pain Relief Suppository with Novata® B PH

Ingredient	Name	Amount (g)
I Kollisolv MCT 70	Medium Chain Triglycerides	0.200
Phenacetin		0.300
Codeinphosphate		0.010
Acetyl Salicylic Acid		0.500
Soya Lecithin		0.010
II Novalgin®		0.200
III Novata® B PH	Hard Fat	ad. 2.000

Remark
Tube rise melting point: 34.5 °C.

Preparation
Phase I is suspended and triturated with Phase II. Phase III is melted on a water bath at 50 °C after cooling to 38 °C is mixed to a pasty consistency with the additive trituration. Subsequent to even distribution of all additives, the compound is cast into moulds at 33 °C.

2. Suppository with Novata® BC PH against Hemorrhoids

Ingredient	Name	Amount (g)
Zink Oxide		0.100
Perugen		0.040
Novata® BC PH	Hard fat	ad. 2.000
Witch hazel extract, dest.		0.200
Bismuth Gallate, basic		0.100

Remark
Tube rise melting point: 34 °C.

Preparation
Phase I is melted 45 °C, it is suspended with Phase II at 45 °C. Phase III is triturated, added at 40 °C to the melt and cast into moulds at 38 °C.

3. Pain relief suppository

Ingredient	Name	Amount (g)
Isopropyl Phenazone		0.300
Novata® BD PH	Hard Fat	ad. 2.000
Coffein		0.050

Remark
Tube rise melting point: 34.4°C

Preparation
Melt Phase I at 50 °C on a water bath. At a temperature of 38 °C cast the compound into slightly cooled moulds.

Note

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