



NPTAB[®]

UNIFORMITY VECTOR FOR LOW DOSAGE TABLETS

OBTAINED BY DIRECT COMPRESSION

Product data sheet

NPPharm proposes an innovative formulation with the patented excipient, NPTAB[®] :
The formulation with NPTAB[®] combines the pellet coating technology with the direct compression.

Content uniformity of solid low-dosage forms is a real challenge in pharmaceutical industry. This is due to the arrival on the market of increasingly potent therapeutic molecules which are not devoid of toxicity and need to be diluted with a large quantity of excipients.

Low dosage formulation with NPTAB[®] involves :

- at first, the coating of NPTAB[®] with a solution containing the dilute active, using traditional coating equipments,
- and then direct compression of the coated NPTAB.

Textural analysis results indicated that the mastered spraying of a drug solution onto the spherical and monodispersed carrier, led to a homogeneous layered NPTAB[®] particles population. And the excellent mechanical properties (flowability and compressibility) of NPTAB[®] secure weight and content uniformity of tablets.

Definition

- ✧ “NPTAB[®] contain not more than 92 per cent of sucrose, calculated on the dried basis. The remainder consists of maize starch”. *European Pharmacopoeia*
- ✧ Compliance with Eur. Ph., USP/NF and JP.
- ✧ Produced in accordance with the cGMP.
- ✧ Available particle size :

- NPTAB 190 (180-212 µm)	}	<i>Non exhaustive list</i>
- NPTAB 220 (212-250 µm)		
- NPTAB 270 (250-300 µm)		
- NPTAB 320 (300-355 µm)		

Chemical specifications

- | | |
|---------------------|--------------|
| ✧ Loss on drying | ≤ 4.00 % |
| ✧ Sulphated ash | ≤ 0.20 % |
| ✧ Heavy metals | ≤ 5 ppm |
| ✧ Sucrose content | ≤ 92.0 % |
| ✧ Specific rotation | +41° to +61° |
| ✧ O.V.I. | Absent |

Microbiological specifications

- | | |
|--------------------------------|-----------|
| ✧ Total aerobic bacteria count | ≤ 100/g |
| ✧ Salmonella | Absent /g |
| ✧ <i>Escherichia coli</i> | Absent /g |
| ✧ Moulds | ≤ 100/g |



NPTAB[®]

Physical properties

- ✧ Minimum of 80 % (w/w) of NPTAB[®] are between the lower and the upper limits of the size stated on the label.
- ✧ True density* 1.550 – 1.590 g/cm³ * vary with particle size
- ✧ Surface area (BET)* 0.15 – 0.20 m²/g
- ✧ Carr index < 10 %
- ✧ Flow time < 10 s for 100 g ⇒ EXCELLENT FLOWABILITY

Mechanical properties

- ✧ Lubricant < 0.25 % (Eur. Ph. recommendation < 1%)
 - ✧ Pressure transmission > 90 %
 - ✧ Residual strength < 15 daN
 - ✧ Ejection strength < 50 daN
- } Good and constant compression parameters
- ✧ Good tablet cohesion is obtained with moderate compression pressures.

Application

- ✧ Used as cores to be coated in the manufacture of tablets.
- ✧ Suitable for very low dosage forms and for drugs with a low therapeutic margin.
- ✧ Divisible and printable tablets.
- ✧ Many other applications as :
 - Placebo tablets,
 - Tableting process validation,
 - Clinical batch production...

Using NPTAB[®] product is interesting into a transfer strategy of capsules with pellets to tablets.

NPTAB[®] IS SUPPORTED BY A GLOBAL ORGANIZATION WHICH KNOWS ABOUT YOUR BUSINESS.

A KNOWLEDGE STAFF CAN ASSIST YOU IN ALL MATTERS CONCERNING QC/QA,

APPLICATION KNOW HOW AND COMMERCIAL ASPECTS.

FOR FULL INFORMATION ON FUNCTIONAL PROPERTIES AND CHEMICAL ANALYSIS, PLEASE CONTACT US.

General information

- ✧ Packaging : 50 kg cardboard drums, tightly closed, with polyethylene liner.
- ✧ Storage conditions : in original sealed drums, protected from humidity, at a temperature between 15°C and 30°C.
- ✧ Shelf life : 3 years guaranteed.
- ✧ Samples kept for 5 years and records available for 6 years.
- ✧ Certificate of Analysis and Material Safety Data Sheet attached to each delivery.

For further information, please contact

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