

## Replace “Fumed Silica + Talc” with Sylysia 350/770 FCP

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Impurities in pharmaceuticals are unwanted chemicals that remain with Active Pharmaceutical Ingredients (APIs) or develop during formulation or upon aging of both API and formulation. The presence of these unwanted chemicals even in trace amounts may influence the efficacy and safety of pharmaceutical product. The control of impurities is currently a critical issue for the pharmaceutical industry. International Conference on Harmonisation (ICH) formulates guidelines



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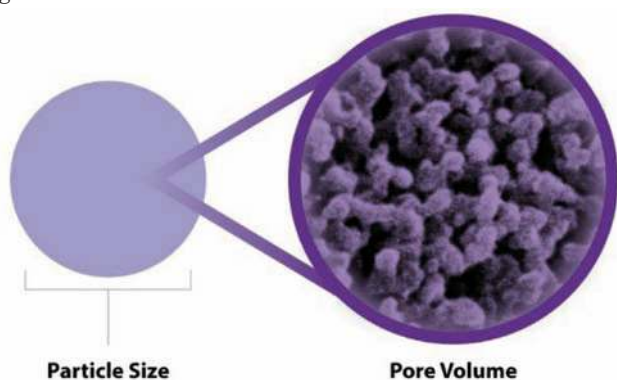
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and reduces API loss

- ◆ Facilitates wetting to aid in disintegration and dispersion
- ◆ Improves dissolution
- ◆ Improves mouthfeel of medicated chewing gums

(Mg<sub>3</sub>Si<sub>4</sub>O<sub>10</sub>(OH)<sub>2</sub>, Talc), generates many impurities as it contains Mg, Si. Due to porous structure of silicon dioxide, the formulation and a fine glidant, many impurities can be avoided and the formulation can be more thermostable and better stability.

It is possible to remove impu-



### < Tableting Test Results >

	Hardness (N)	Tensile Strength (Mpa)	Disintegration Time (S)
SYLYSIA 350 FCP	36.2 ± 2.94	0.99 ± 0.05	293.0 ± 9.5
SYLYSIA 770 FCP	30.9 ± 0.57	0.84 ± 0.02	292.2 ± 7.0
Aerosil 200	34.1 ± 2.73	0.92 ± 0.07	318.8 ± 12.5

regarding the control of impurities.

There are many APIs, plant extracts and oil-based tablets that tend to be hygroscopic in nature. They can absorb moisture from the environment, cake together or adhere to equipment depending on RH. Sylysia is a highly porous, micronised silica powder. When added to a formulation, the high porosity of Sylysia 350/770 is capable of adsorbing a considerable amount of moisture and oil, keeping the active ingredient dry and improving stability.

It can be replaced with Sylysia 350/770 for (Fumed Silica+Talc), As to highlight talc, it has many impurities and nitrosamine profile enough to destabilise the product. So, Sylysia can be used instead of (Fumed Silica+Talc) in any formulation for many benefits:

SYLYSIA 350/770\*FCP shows better tensile strength and disintegration time than Aerosil 200.

As a result of ICP analysis, both grades are high SiO<sub>2</sub> purity,

more than 99.7 per cent talc has lower density and poor performance than Sylysia. Talc density is normally 0.2 gm/cc and Sylysia 350 FCP is 0.06. In Japan, talc is not majorly used for Pharma excipients and lubricants due to impurities, magnesium and a crystal component. If there is too much magnesium, the taste of the tablets will be bitter.

### Many more benefits:

- ◆ Less dust, reduces the potential for cross contamination
- ◆ Improves flavour retention and oxidative stability
- ◆ Less bulky, easier to handle and store
- ◆ Reduces downtime from static build-up
- ◆ Eliminates or reduces need for sieving before
- ◆ Work as glidant and improve homogeneity
- ◆ Increases tablet hardness at a lower compression force
- ◆ Decreases friability, capping and lamination
- ◆ Improves flow for standard and challenging formulations
- ◆ Acts as an anti-static agent

rities with options to replace them with Sylysia 350/770. Similarly, many formulations can be discussed to derive solutions.

### Bibliography:

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4. Shelar J. *Report on 'toxic' talc worries India. The Hindu. https://www.thehindu.com/news/national/canada-report-on-toxic-talc-worries-india/article25699760.ece. Published December 8, 2018. Accessed December 4, 2020.*
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### < Tableting Condition >

Tableting machine	Tab A II (OKADA SEIKO CO. LTD.)
Compression Pressure	100 MPa
Compression Speed	10 RPM
Beetle	Flat beetle (Diameter 8mm)
Tablet Weight	180 mg

### < Tableting Formulation >

Composition	Formula (%)
Ginkgo biloba extract (Nippon F. Yakuin C.L.)	27
Fast Flo 316 (Foremost Farms)	65
Croscarmellose Sodium (JRS PHARMA)	3
Carboxymethyl Starch Sodium (JRS PHARMA)	3
Silica (SYLYSIA 350 / 770 FCP, Aerosil 200)	1
Magnesium Stearate (Mallinckrodt)	1
Total	100