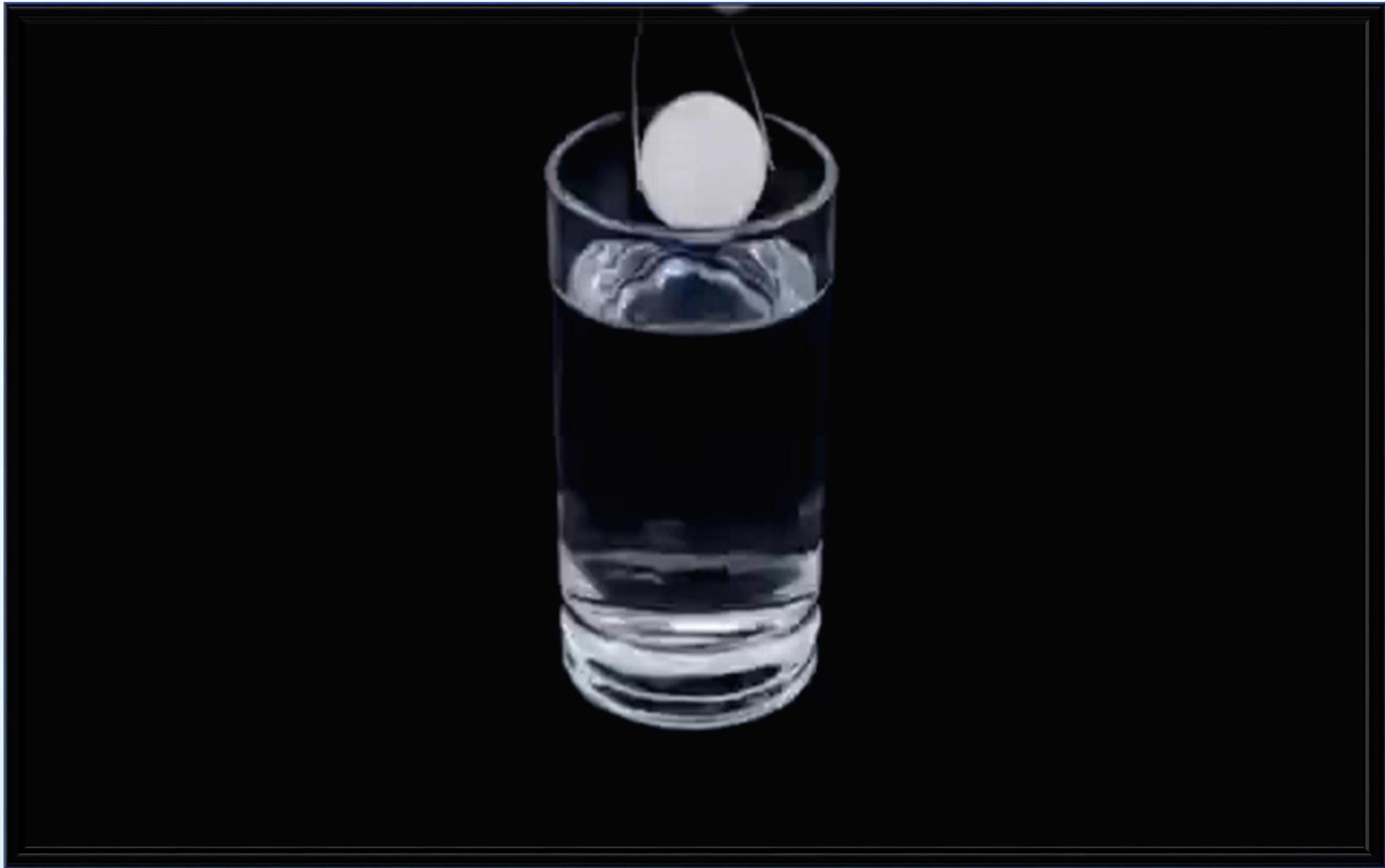


Effervescent Formulations

- A Lesser Explored NDDS/NDS

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Why Effervescent?

- Enhanced bioavailable form than conventional Solid Orals
- Quicker onset of action
- Improved taste for unpalatable actives
- Incorporation of large actives like Strontium ranelate 4 gm, Metformin 1500 mg etc.
- Ideal dosage form for geriatric & pediatrics
- With innovation better acceptability for all ages
- Lesser gastric side effects due to buffer solution intake

OUTLOOK

- Effervescent YTT
- Why less explored?
- Indian scenario of NDS
- Suggestions for further exploration
- Questions & Answers

Effervescent YTT

EFFERVESCENT YESTERDAY:

- Known since 18th century
- In compendia referred as “Compound Effervescent”
- Commercially called as “Seidlitz Powders”- used as saline cathartics.
- In 1932, Evolution of First Effervescent Tablet - “Alka Seltzer”
- Development continued to a great extent for supplements rather than pharmaceuticals

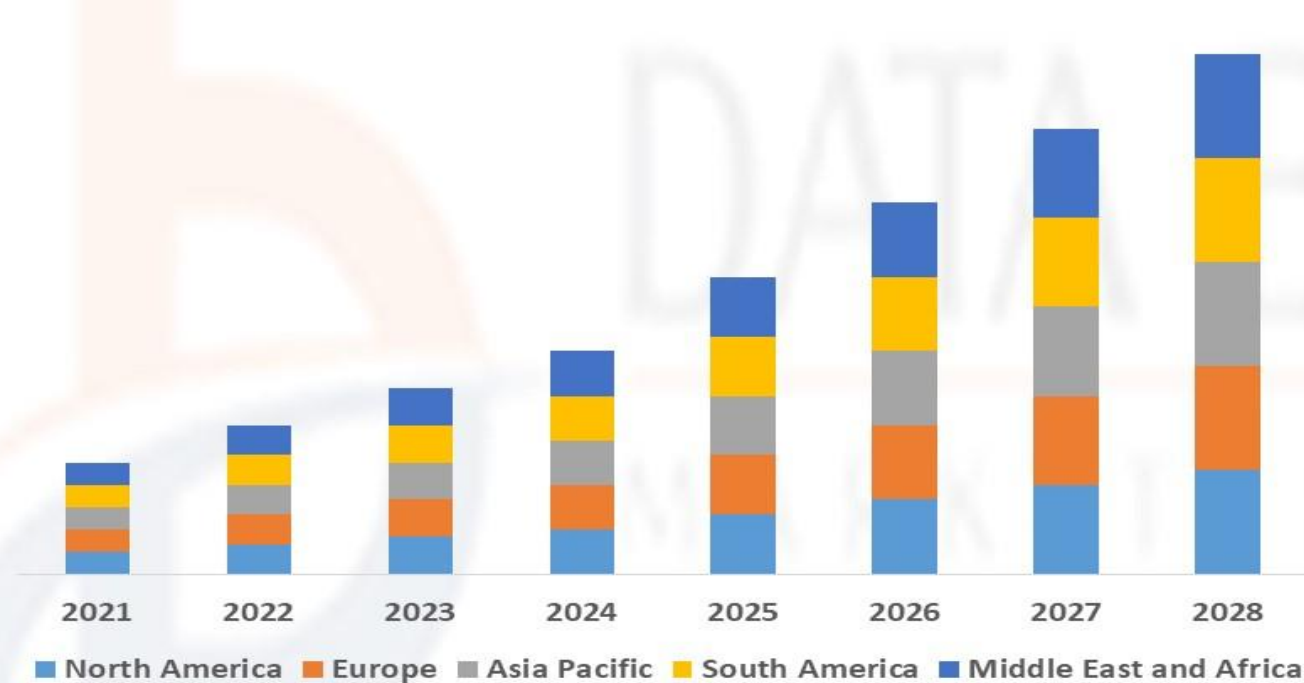


International Scenario₁

- No major developments in pharma effervescent till 1990s
- After 1990s, there was renewed interest in effervescent technology & several patents were granted for effervescent products
- Major development & commercialization in Europe than US & Japan

International Scenario₂

Global Effervescent Tablet Market is Expected to Account for USD 14,378.08 Million by 2028



Global Effervescent Tablet Market, By Regions, 2021 to 2028



DATA BRIDGE MARKET RESEARCH



International Scenario₃

- Total estimated global current market- US \$7.4 billion with CAGR 9%
- Major markets- North America, Europe, Japan, MENA
- Developing markets: India, South Africa, Nigeria, Vietnam, Korea, Thailand, Philippines
- Major manufactures- Bayer, GSK, RB, Amerilabs, Hermes, E-Pharma
- Estimated Worldwide Manufacturing units: 115 to 120

Current application as NDDS/NDS for

- Nutraceutical
- Pharmaceuticals
- Cosmetics/Household/Surgicals
- Animal Healthcare
- Agricultures
- Other like engineering , lubricants etc.

Effervescent ---Tomorrow

- Renewed interest as “Super generics”
- e.g. Fosamax to Binosto: Second RX product approved by US FDA
- Enhanced bioavailability desired for NSAIDS & specific drugs like Tranexamic acid
- Ease of ingestion due to higher demand in geriatric pediatric patients
- New developments like OD-EFFTABS[®] (Orally dissolving Effervescent Tablets)
- Use of Nanotechnology for Nano-effervescence
- Incompatibility avoidance bi-layer EffTabs

Effervescent in India YTT₁

Indian effervescent scenario yesterday

- Only known product ENO available since 1960
- No new development in pharmaceuticals after Disprin (1975)
- Regulatory authorities considers effervescent technology- non essential

e.g. USP -5 effervescent products

BP/EP-6 effervescent products

IP- Nil

Effervescent in India YTT₂

Indian effervescent scenario today

- Approved FDC list of drugs & supplements does not include any effervescent product
- ENO – Worldwide allopathic, in India as Ayurvedic (?)
- Only 4 GMP compliant dedicated manufacturers
- All others (6 to 8) concentrating on nutraceuticals than other categories
- Discouragement at regulatory levels for effervescent products & innovations of “1st in the world products”

Effervescent: Why Unexplored ?

- Lack of regulatory clarity, support for innovations.
- Amended FDC list of CDSCO including nutraceutical FDC 's missing/ignoring effervescent products.
- Limited manufacturers in the world & lesser product development since 2000; resulting in limited demand.
- After 2000, even with renewed interest, lesser product development & commercialization.
- Cost of development, manufacturing & evaluation are higher than oral dosage forms.

Indian Effervescent Scenario- Tomorrow

- Considering the high international demand in regulated markets with high growth potential- Big opportunity for Indian manufacturers
- Even with higher energy cost & CAPEX for plant set up lower manufacturing cost with innovative technologies
- High export potential in categories like herbal, nano-effervescentals, enzyme complex, agricultural, animal healthcare, cosmetics etc.
- World wide export possible with regulatory clarity & support

Indian Effervescent Scenario- Tomorrow

- Lets explore better effervescent technologies for super generics & other applications.

THANK YOU

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